CHAPTER 6

NORPLANT:

Access to Contraceptives

The Norplant system is a subdermal form of reversible contraceptive that can prevent pregnancy for up to five years with an efficacy rate of over 99.9%. The implant system consists of six Silastic capsules that are inserted into a woman's upper arm and release the synthetic progestin levonorgestrel on a continual basis. The administration of Norplant requires a medical provider, specialized equipment, and 10 to 20 minutes for the insertion procedure. A medical provider is also necessary for Norplant removal, a procedure that can be conducted any time after insertion.

The Population Council, a New York–based nonprofit organization, began developing Norplant in the 1960s. The idea behind the development of an implant contraceptive was that its long-acting effectiveness and limited maintenance were ideal for women who lacked regular access to health services. Norplant fit this profile. It resembles the pill in that it inhibits ovulation but differs in its long-acting effectiveness. The implant contraceptive is also similar to the intrauterine device (IUD) in that it is long acting, reversible, and highly efficacious, but unlike the IUD, Norplant does not require a gynecological procedure. Norplant was approved by the U.S. FDA in 1990, offering women a new choice for long-term contraception that generated excitement around the world.

This case study begins with the story of Norplant development and then examines the product introduction activities of the Population Council and its partners in the 1980s. The chapter then assesses efforts at scaling up global access to Norplant from the early 1990s to today. The Norplant story involves several key players: the Population Council, product developer and global coordinator of product introduction in developing countries; the U.S.-based company Wyeth-Ayerst Laboratories (now Wyeth Pharmaceuticals), provider of Norplant to the private sector in both developed and developing countries; the Finland-based manufacturer Leiras Oy (now Bayer Schering Pharma AG), provider of the Norplant system to the public sector in developing countries; as well as government and non-governmental organizations' family planning programs, health providers, and women who use the implants. The chapter pays particular attention to the Population Council's efforts to construct effective architecture for Norplant at the global and national levels.

The Norplant case study examines a technology that was repeatedly shown to have high safety, efficacy, and effectiveness in clinical trials and postmarketing surveillance but still encountered numerous access problems within countries. Some access barriers are related to the technical characteristics of Norplant that created problems of end-user adoption. These characteristics also affected availability,

because as a provider-dependent technology, Norplant required trained health professionals for insertion and removal. Other barriers, such as cost, are less specific to Norplant and relate to broader issues of affordability in providing access to health technologies in poor countries. The lessons learned by the Population Council and its partners in promoting access to Norplant worldwide serve as a cautionary tale to access planners for other new health technologies.

Product Development of Norplant (Phase 1)

In the mid-1960s, Sheldon J. Segal, director of the Biomedical Division at the Population Council, and postgraduate fellow Horacio Croxatto proposed that subdermal capsules of polydimethylsiloxane (also known by Dow Corning's trade name Silastic) could be used for long-term, reversible, steroidal contraception. Silastic, a medical-grade plastic, is the polymerized form of a silicone-based compound. At the time Segal and Croxatto became interested in the compound, it had already been in medical use for over 15 years and was used, among other applications, as tubing to drain fluid building up around the brain into the abdominal cavity for children born with hydrocephalus. Silastic's most important property was its biocompatibility; it can be used in the human body without causing a reaction or an allergic response.[1]

According to Segal, the concept of a subdermal implant contraceptive was a "logical extension" of work at Children's Hospital in Boston. Judah Folkman, a pediatric surgeon, and his colleague David Long were using Silastic in experimental surgery and discovered that oil-soluble dyes slowly diffuse out of Silastic.[2] As Segal recalled after hearing about Folkman's findings, "I immediately thought, if oil-soluble dyes, why not oil-soluble hormones? Putting this together with biocompatibility, I could envisage a system placed subdermally, like the hydrocephalus shunts, that would slowly release a steroid hormone and serve as a long-acting contraceptive."[3] Segal envisaged a new contraceptive method that "would enable a woman to substitute one clinic visit for thousands of days of pill taking."[4]

To make this new concept a reality, Segal and his team at the Population Council needed to identify a suitable contraceptive compound, potent enough so that a small amount released each day could act as a contraceptive. They also needed to decide on the most appropriate form of Silastic implant to provide the desired safety and effectiveness for human use. Moving forward on these two activities required first securing the appropriate intellectual property rights on Silastic. Folkman's patent on the principle of steroid diffusion through Silastic had been assigned to the Dow-Corning Company of Midland, Michigan. Folkman

agreed to waive royalty rights for any product that might come out of the Population Council's work, but this needed approval by Ira Hutchinson, an executive at Dow-Corning. Hutchinson agreed to the waiver after several visits to the Population Council, which assured him that the Council was not planning to use the patent for commercial purposes.[5] The issue of intellectual property rights, however, would have to be revisited once Segal and his team identified a suitable contraceptive compound since all the compounds under consideration belonged to different companies.

To move forward on the biochemical and clinical studies, Segal decided to work through a cooperative research group. As he states in his memoir, "Instead of hiring a large clinical research group, as was customary for product development efforts in pharmaceutical companies, I decided to form a team of talented people who would stay in their home academic positions and work with us on contraceptive development projects."[6] This cooperative research group became known as the International Committee for Contraceptive Research (ICCR).[7] The structure of this group resembles the model of a "virtual research organization" employed by some of today's public-private partnerships for product development, such as the Drugs for Neglected Diseases Initiative.

ICCR's search for the optimal contraceptive hormone to use with the implant confronted a series of challenges. The team first studied a progestin called megestrol acetate, owned by the British Drug House of the United Kingdom. After "considerable progress" with the compound, the research group faced a "discouraging setback" when the British Drug House withdrew the chemical because of adverse findings in beagle dogs.[8] The group then decided to test all progestins used in oral contraceptives or for other gynecological purposes. A major scientific advance proved vital to the research team's work—the discovery of a synthesis process to produce the progestin called norgestrel. This compound has a high potency per unit weight compared to other progestins and showed good diffusion characteristics from Silastic.

In 1974, ICCR began human studies of a six-capsule contraceptive drug delivery system comparing several different synthetic hormones. The research team finally chose norgestrel, belonging to Wyeth-Ayerst Laboratories of Radnor, Pennsylvania,[9] after conducting a randomized clinical trial in 1975 comparing norgestrel with a super-progesterone named R2010 from the Roussell-UCLAF Company of Paris. The study was conducted in six countries (Brazil, Chile, Denmark, Finland, the Dominican Republic, and Jamaica), and found that norgestrel had a higher level of contraceptive efficacy, although R2010 limited the amount

of vaginal bleeding. While Segal wanted to pursue both hormones to give women more choice, budgetary constraints required ICCR to select only one compound, and norgestrel made the final cut based on efficacy, clinical acceptability, and safety.[10] Norgestrel's safety was further supported by animal studies and large-scale human studies conducted by Wyeth-Ayerst, which already produced oral contraceptives containing norgestrel.[11]

Intellectual property rights again emerged as an issue when the Population Council asked Wyeth-Ayerst to use their compound for the contraceptive implant. As Segal explains,

Ordinarily, companies are reluctant to release compounds that are used in their successful commercial products for other uses. An unexpected finding could be extremely damaging. By this time, Wyeth's line of oral contraceptives was the high-riding leader of the pack in the U.S., so there was a lot at stake. Once again, the credit belongs to an in-house executive who believed in the importance of the Population Council's work. At Wyeth, it was Dr. Richard Bogash, a chemist with a worldly view, who had risen to become a vice president of the company. He persuaded his company to enter into an "agreement to agree" with the Population Council so that we could proceed with our implant studies with assurance that, if successful, a product would be made available to women around the world.[12]

The Norplant system that resulted from the product development process consisted of six flexible, silicone-based capsules made of Silastic, each containing 36 milligrams of levonorgestrel (a more potent version of norgestrel). Each capsule was 34 millimeters long with a diameter of 2.4 millimeters. The wall thickness of Silastic controlled the rate of diffusion and was custom made for Norplant. The implants, inserted into a woman's upper arm in a "fan" pattern under local anesthesia, released levonorgestrel into a woman's circulation at a relatively constant rate over five years.

Product development for Norplant was not an easy road, as often happens with many health technologies. As Segal states, "It sounds so straightforward in retrospect, but we hit brick walls along the way. On at least two occasions I can recall, we came close to dropping the idea."[13] During the development process, ICCR scientists assessed as many safety problems as they could hypothesize (see Table 6.1 for a list of studies). With these studies completed and results satisfactory, Norplant was ready in the early 1980s for introduction in developed and developing countries.

Table 6.1 | Trials undertaken in development of Norplant

Clinical Trials in 15 Countries:	
1975-1979	Phase III multinational trials in Brazil, Chile, Denmark, Dominican Republic, Finland, Jamaica (PC/ICCR)
1980-1982	Trials begin in Colombia, Ecuador, Egypt, India, Indonesia, Thailand (PC)
1981	Phase II/III studies begin in the United States. Another multinational Phase III clinical trial begins in Chile. Dominican Republic, Finland, Sweden, and the United States (PC/ICCR)
1990-1995	Phase III clinical trials of soft tubing Norplant capsules and reformulated Norplant with two rods in Chile, Dominican Republic, Egypt, Finland, Singapore, Thailand, United States
Preintroduction Studies in 30 Countries (start dates):	
1984	Bangladesh, Brazil, Chile, China, Dominican Republic, Haiti, Kenya, Nepal, Nigeria
1985	Philippines, Singapore, Sri Lanka, Zambia
1988	Colombia, El Salvador, Ghana, Malaysia, Mexico, Pakistan, Peru, Senegal, South Korea, Tunisia, Venezuela, Zambia
1989	Bahamas, Rwanda, Zaire (now Democratic Republic of Congo)
1990	Bolivia, Madagascar
Private-Sector Training in 7 Countries (Leiras Oy):	
1988	Belgium, Bulgaria, former Soviet Union, France, Israel, West Germany, Taiwan
Postmarketing Surveillance in 8 Countries (WHO/HRP, PC, FHI)	
1988-1997	Bangladesh, Chile, China, Columbia, Egypt, Indonesia, Sri Lanka, Thailand
Training Curriculum Testing:	
	Nigeria, Rwanda, Kenya
International Training Centers:	
	Dominican Republic, Egypt, Indonesia
Regional Training Center	
	Kenya
Over 70 Acceptability Studies in 20 Countries (FHI, PC, PATH, clinics, health ministries):	
1987 (start date)	Bangladesh, Brazil, China, Colombia, Dominican Republic, Ecuador, Egypt, Haiti, Indonesia, Kenya, Mexico, Nepal, Nigeria, Peru, Philippines, Rwanda, Sri Lanka, Thailand, United States, Zambia

Note. FHI = Family Health International, ICCR = International Committee for Contraception Research, PATH = Program for Appropriate Technologies in Health, PC = Population Council. From *Contraceptive Research, Introduction, and Use: Lessons from Norplant* by Polly F. Harrison and Allan Rosenfield, eds., 1998, New York: National Academy Press, p. 109. Copyright 1998 by the National Academy of Sciences. Adapted with permission.

Introducing Norplant in Developing Countries (Phase 2)

In 1980, the Population Council turned its attention toward access for Norplant in developing countries. Staff members in the organization recognized that some of Norplant's characteristics would present challenges to access. For example, in many women Norplant can cause menstrual changes, including frequent, prolonged, or absent bleeding. Council staff knew that these changes would create inconvenience to some users. In addition, they knew that the product depended on quality health services. Norplant requires trained health staff for counseling, insertion, removal, and clinical management. As Spicehandler notes, "From the outset of the introduction program, it became clear that Norplant would be both a training-intensive and service-intensive method."[14]

The Population Council decided to undertake systematic planning for the introduction and scaling up of Norplant in developing countries. This effort marked the first time that a public-sector organization managed contraceptive introduction in this way.[15] As Spicehandler reports, the decision emerged from three concerns that Council staff had about worldwide access to Norplant.[16] The first concern related to lessons learned in earlier attempts to introduce the intrauterine device (IUD) into family planning programs. The IUD had been seen as a revolution in the contraceptive field because of its high efficacy in clinical trials. But once women began to use the technology, many reported problems with inadequate preinsertion checks and insufficient management of side effects. These difficulties, combined with growing rumors of IUD problems, led to high discontinuation rates and a drop-off in insertions. In her analysis of the IUD experience in India, Soni points out, "The [IUD] programme had, quite simply, been rushed through without organizational preparedness to cope with the known side effects, which in any case were higher than anticipated among a population containing many malnourished and anaemic women."[17] In his annual address in 1966, Population Council President Bernard Berelson commented that too much attention had been given to scaling up quickly and too little to communicating with women about difficulties they might experience with the IUD.[18]

The Council's second concern was the importance of addressing the perceived needs of contraceptive users in relation to a new technology. The Council understood that access to Norplant depended on the adoption of this technology by family planning organizations and by women interested in contraception. The organization's final concern related to misinformation about contraceptives. The Council knew that misinformation creates controversy, which can then limit contraceptive choice. The Council was acutely aware of the negative publicity over

the faulty Dalkon Shield (an IUD associated with pelvic inflammatory disease and septic spontaneous abortion, leading to its market withdrawal in 1975) and of how the American public mistakenly linked that IUD with all others.

With an awareness of these three issues and a desire to ensure widespread access to Norplant, the Population Council began to design a comprehensive plan and architecture for Norplant. In its broader work, the Council focused on the goal of promoting increased use of family planning services instead of advocating for a specific contraceptive method. This meant that the organization would have to take a "nonpromotional approach to Norplant introduction."[19] The challenge for the Population Council was to introduce the new technology into family planning services without promoting the new method alone, so that women would have a full choice of contraceptive options.

The Population Council based its access plan in 1982 on six main strategies.[20] The first strategy was to ensure widespread availability of Norplant to the public sector at the lowest possible price. This required locating a company to produce, register, and distribute Norplant. Leiras Oy, an international pharmaceutical firm based in Turku, Finland, had collaborated with the Council during the last stages of product development. Together the two organizations worked out a licensing agreement for worldwide distribution of the product at a low price for public-sector family planning programs in developing countries. In 1984, Finland (the country of manufacture) became the first country to approve Norplant. Leiras Oy then began registration and distribution of Norplant in other countries. Meanwhile, the Population Council negotiated a licensing agreement with Wyeth-Ayerst allowing the company to manufacture and distribute Norplant in the private sector in the U.S. and other countries. The Population Council submitted the New Drug Application for Norplant to the U.S. FDA in 1988 and received approval in December 1990.

The Council's second strategy was to provide training to health providers through international training centers. Three centers (in the Dominican Republic, Chile, and Indonesia) were chosen, all of which had experience with the ICCR clinical trials. The centers offered a large caseload of both insertions and removals for training purposes and had knowledgeable staff familiar with the counseling needs specific to Norplant.[21]

The third strategy sought to promote adoption in specific countries by carrying out preintroduction trials. These trials would provide firsthand experience with the method and assessments of the effectiveness, safety, and acceptability of the method under local conditions. Undertaken during the product development

phase, these studies represented an innovation in technology introduction.[22] They were important for several reasons. Sivin et al. point out that the studies helped national programs and health providers assess the method in their own settings and also provided local training.[23] In addition, in some countries regulatory approval required data on local experience with Norplant. The preintroduction studies provided these data. The studies also gave the Population Council and national governments a basis for assessment of end-user and health service needs in varying cultural and socioeconomic situations. Finally, the studies afforded the opportunity to fine-tune local management strategies for responsible introduction of the method into family planning programs and to distribute informational materials. In all, the Council and its partners conducted more than 30 preintroduction trials (as shown in Table 6.1).

The access plan's fourth strategy was to conduct end-user feedback research to assess women's satisfaction with the method. While the preintroduction studies focused on the clinic's experience with the method, the end-user research focused on the client's experiences and perceptions. This end-user research represented a critical component of the Council's Norplant access strategy.[24] The research studied whether and why women continued with Norplant despite menstrual irregularities and also the impact of these irregularities on daily life. Studies also looked at problems with access to removal on demand, sufficiency of information about Norplant, and competence of counseling and support when choosing the method.[25] The Council and its partners conducted over 70 user-acceptability studies in 20 countries (see Table 6.1 for a list of these countries).

The Council's fifth and sixth strategies related to communication activities designed to reduce negative publicity about the contraceptive. One communication activity was to inform national and local groups about Norplant and its service delivery requirements. These groups included government officials, women's groups, the medical community, counselors, and end-users. The other activity was to develop prototype informational and training materials for family planning programs to adapt to their particular contexts.

Implementing these strategies required staffing changes at the Population Council.[26] A larger management team was needed than in past Council programs. The Council decided to hire a core team of three professionals in New York and three full-time medical professionals in regional offices. In addition, two multidisciplinary advisory bodies provided input to the program's development: one on policy, biomedical, and regulatory matters, the second on end-user and health service needs. The Council also created a global architecture for Norplant based

on partnerships with a number of non-governmental agencies (including Family Health International, the Program for Appropriate Technology in Health, and the Association for Voluntary Surgical Contraception). The groups had substantial expertise in training, clinical study, materials development, end-user acceptability research, and operations research.

During the introduction phase for Norplant, several global agencies began assessing the new contraceptive method. The World Health Organization (WHO) conducted a technical evaluation of Norplant in 1984 and stated that the contraceptive was "particularly advantageous to women who wish an extended period of contraceptive protection."[27] The United Nations Population Fund (UNFPA) also approved the method, and many professional organizations, including the American College of Obstetricians and Gynecologists and the American Society for Reproductive Medicine, reviewed safety and efficacy data and endorsed Norplant. These endorsements promoted both global and national adoption of the new technology.

Based on lessons learned from the introduction of the IUD and other contraceptives, the Population Council devised a comprehensive Norplant access plan for developing countries. As Council staff had anticipated, many of the access problems in countries were related to training and health service quality. However, other problems were unanticipated. The specific access barriers and facilitators that arose in the Norplant story are discussed below. We draw heavily on the experiences of the two countries with the most Norplant users in the mid-1990s: Indonesia, a developing country in which the government worked with the Population Council to provide Norplant to the public sector, and the United States, a developed country in which Wyeth-Ayerst provided the contraceptive to public and private clinics.

Scaling Up Global Access to Norplant (Phase 3)

In 1986, Indonesia became the first developing country to approve Norplant for national introduction. The National Family Planning Coordinating Board (known by its Indonesian acronym, BKKBN), with assistance from the Population Council and USAID, became the driving force for implementation of the Norplant system in Indonesia. The Indonesian government had a formal policy of emphasizing long-acting contraceptive methods. In introducing Norplant, the government sought to expand choice for women and offer a contraceptive alternative to sterilization, a procedure that is forbidden in Islam because it alters the body. Norplant promotion efforts were targeted to mothers aged 20–25 for birth

spacing, mothers older than 30 to limit future births, and rural women.[28] Preintroduction trials beginning in 1981 facilitated Norplant's entry into Indonesia. Following Norplant's approval in the country, BKKBN moved from working on introductory trials to promoting nationwide access. Norplant use expanded rapidly, with sharp increases in both the late 1980s and in 1994–95.[29] By 1994, Indonesia claimed the most Norplant users per country, with 1.8 million women adhering to this method, representing 9.5% of all contraceptive users.[30] A 1998 study of end-users found that most women who were using Norplant came from rural areas, had some primary education, and had two or more children.[31]

In the United States, the FDA approved Norplant in December 1990, and Wyeth-Ayerst launched the product nationwide soon thereafter, in February 1991. The product's introduction took place rapidly. Wyeth-Ayerst handled all aspects of training, marketing, and distribution of the product in the U.S. as the Population Council focused its efforts on developing countries. The American public was enthusiastic about the new contraceptive. Even prior to FDA approval, Norplant was acclaimed as a major contraceptive breakthrough. This enthusiasm arose from positive reports in the press that emphasized Norplant's efficacy, convenience, and reversibility.[32] Many American women had high expectations for Norplant, even before its launch. Wyeth-Ayerst estimated that 100,000 women received Norplant implants in 1991, and by mid-1993, 750,000 implant kits had been sold.[33] The demand for the product initially surpassed Wyeth-Ayerst's projections, leading to supply shortages and waiting lists in parts of the country.[34] The company calculated in late 1992 that of the implant kits distributed, 48% went to private physicians, 33% to clinic-based practitioners, and the remaining 19% to other providers.[35]

In addition to Indonesia and the United States, Norplant was approved and launched in many other developing and developed countries. To ensure the new product's safety and effectiveness, the WHO conducted the first large-scale, longer-term prospective drug surveillance project in developing countries, known as the Post-Marketing Surveillance Study of Norplant.[36] This five-year follow-up study was conducted in 32 family planning clinics in eight countries from 1988–1997 (as shown in Table 6.1). This WHO study, like the preintroduction Population Council studies, confirmed high effectiveness rates with failure rates of less than 1% per year, essentially equal to that provided by nonreversible methods. The main side effect of Norplant, menstrual pattern changes, tended to stabilize by the end of the first year to a level that became acceptable to most women. The researchers concluded that the contraceptive is safe, well tolerated, and highly

effective.[37] Despite these important findings, attempts to promote Norplant worldwide encountered three access barriers related to: (1) affordability, (2) end-user adoption, and (3) provider removal services. We show below that the relative importance of these barriers depended on the particular setting.

Affordability

As a result of licensing agreements between the Population Council and the two manufacturers of Norplant (Leiras Oy in Finland and Wyeth-Ayerst in the United States), a tiered pricing system determined the product's price in different markets. In the public sector in developed countries and the private sector worldwide, Wyeth-Ayerst provided Norplant at a relatively high price: $350 per implant kit in the United States and about half that in Europe. Leiras Oy offered the product at a much lower price, $23 per implant kit, for public-sector family planning programs in developing countries.

The price of the Norplant product and services to insert and remove it posed an access problem for end-users in the United States. Wyeth-Ayerst, the company that manufactured and marketed the product in the country, did not provide Norplant at a lower public-sector price, as it and other companies had done with oral contraceptives.[38] Though the price of a set of Norplant implants in the United States was $350, the total cost to users of the method, including the price of implants and clinic or physician fees, ranged between $500 and $1,000. Depending on the clinic or physician, there could also be an additional fee for removal. Many private insurance plans, however, did cover part or all of the costs of Norplant, as did Medicaid agencies in all 50 states. (Medicaid is the U.S. health program for low-income people.) But Medicaid did not guarantee coverage of Norplant removal if a woman became ineligible during the life of the contraceptive.[39] Although Medicaid paid for Norplant for the poor, and higher income women could either pay for it or their insurance covered it, low-income women ineligible for Medicaid were left without coverage for Norplant. For potential end-users in this latter group, Norplant access was limited because of a lack of product affordability. This affordability problem also influenced provider adoption. An Alan Guttmacher Institute nationwide survey of family planning agencies in 1992 found that some agencies did not promote Norplant because of its high cost.[40]

To address these problems with affordability in the United States, Wyeth-Ayerst established the Norplant Foundation to provide Norplant at no cost to women without insurance or Medicaid coverage. But the Foundation could not keep up with demand.[41] The Foundation also required that clinics order each kit

separately, making it impossible for clinics to stockpile a small supply.[42] In addition, the Foundation limited providers to 10 kits a year and required that clinicians perform Norplant insertion without reimbursement.[43] Several years later, in December 1995, Wyeth-Ayerst decided to sell Norplant implants to public-sector providers at a reduced price, something that family planning advocates had been requesting since 1991.[44]

End-user Adoption

Following the launch of Norplant, concerns were raised in a number of countries about whether end-users were adopting the new contraceptive based on free choice. In Indonesia, some providers reportedly steered women in the direction of long-acting methods such as Norplant because government policy favored these methods. Choices about contraception thus occurred in the context of a hierarchical provider-client interaction and government focus on demographic objectives.[45] Hardee et al. recount how a women's group in Bangladesh raised questions about whether Norplant trials (which began in 1985) targeted poor, uneducated women because they could be intimidated.[46] While a study by an international research team found that illiterate rural women were not targeted by the clinical trials, political controversy surrounding allegations of Norplant coercion continued in Bangladesh in the mid-1990s.

In the United States, Norplant's launch generated enthusiasm, positive media reports, and high expectations. But there was also public discussion early on about the potential for coercive uses of the method. While many family planning advocates and policy makers believed that Norplant could reduce high rates of unintended pregnancy (particularly among young people and low-income women), others worried that the method might be forced on women who were not willing or fully informed (including women of color, young people, and low-income women).[47] Some potential end-users and family planning advocates, for example, were suspicious of the motivations for Medicaid funding for Norplant, feeling that this public funding might pressure women of color and low-income women into using the method.[48] Two days after the FDA approved Norplant, the *Philadelphia Inquirer* published an editorial called "Can Contraception Reduce the Underclass?" This began media commentary and public debate nationwide about using Norplant in the fight against black poverty.[49] After this editorial and ensuing public debate, many Americans began to view Norplant as a method of social control.[50] Beginning in 1991, legislators in 13 states proposed two dozen bills that made welfare payments conditional on Norplant use or offered financial

incentives to welfare recipients who use the implant.[51] In addition, courts ordered at least four women convicted of child abuse to have Norplant inserted as a condition of probation. These actions singled out poor, single mothers, frequently black or Hispanic.[52]

In the end, none of the bills linking Norplant to welfare payments passed into law.[53] Furthermore, a study of 2,000 low-income women in the U.S. found no evidence of coercion in the use of Norplant in private interactions between women and their health care providers.[54] These researchers concluded that the public debate about Norplant was a "double-edged sword." On the one hand, it may have reduced the magnitude of coercion through increased vigilance; on the other hand, the debate stigmatized the method in the United States. The case illustrates the importance of having end-users make informed and free decisions about selecting and using technologies—for ethical reasons and also to protect the reputation of the technology and promote its proper use.

In the late 1990s, studies of Norplant end-users around the world showed a high level of satisfaction with the contraceptive.[55] Studies of Norplant continuation generally found high rates through the first two years of use, except in the United States, where discontinuation was associated with negative media coverage. In general, after five years of using Norplant (the approved term of use), approximately half of the women who originally chose the method were continuing use, with a significant proportion of discontinuation due to the desire to start a pregnancy. Findings from clinic-based studies also showed that most women who continued using Norplant were satisfied with the method, although they had not found it easy to get used to. A large majority of these end-users would recommend it to others. Satisfaction levels were slightly below levels for oral contraceptives and the injectable contraceptive known as Depoprovera. Importantly, women who decided to discontinue the method were much less positive, and only a few said they were "very satisfied." Many women in this group did not like Norplant because they experienced menstrual irregularities after insertion. Both groups of women pointed to convenience and effectiveness as Norplant's best features.

Studies also found that end-users were more satisfied with Norplant and more likely to continue using the contraceptive if they received sufficient information about the technology and potential side effects.[56] The three principal areas of limited awareness among end-users were Norplant's five-year efficacy, the right to early removal, and the common side effects. When unaware of Norplant's five-year efficacy, users would not seek removal and could become pregnant because of decreased effectiveness. The lack of communication about the right to early

removal may have encouraged women to use the product longer than they would otherwise have done, which in turn decreased levels of satisfaction. In one study, less than one third of users could not name one common side effect associated with Norplant use.[57] Those who were not educated about potential side effects, particularly menstrual irregularities, became concerned about these changes and tended to request early removal. These end-users were likely to communicate their less than positive experiences with Norplant to other potential users in their social networks. As Widyantoro explains, "It has been found in Indonesia that clients who experience side effects without being forewarned are more likely to discontinue and will share their disappointment with others. In a society where personal recommendations from friends and family are important, the lack of full information can have a negative effect."[58] In response to these problems, the Indonesian government worked to improve the information given to Norplant users and, with the Population Council, created materials and held refresher training for providers.[59]

Provider Removal Services

After Norplant insertion, the contraceptive implant remains efficacious for five years; a provider must remove the implant within the five-year period. If a woman wishes to continue using Norplant, the provider can at the time of removal insert a new implant system. For several reasons, removal problems became major barriers to Norplant access in some countries, with negative implications for the product's reputation, appropriate use, and customer satisfaction. End-users encountered difficulties in obtaining removal services and also experienced problems with the quality of removal services.

The high price of the product reportedly made some providers reluctant to remove Norplant before the full five years of efficacy. Tuldahar et al. report that some Indonesian providers refused early removal and justified their position by stating that removal before five years for reasons other than a desire to conceive was trivial and a waste of government resources.[60] Women dealt with this problem by lying about their motivation for removal (saying they wanted to conceive even when this was not their reason for early removal), going to unqualified practitioners, or even removing Norplant themselves. In Bangladesh, Hardee et al. state that removal problems occurred in a handful of centers due to a few providers who felt that Norplant was costly and should not be removed at will.[61] This resistance by providers meant that some women could not have the implant removed on demand.

Problems also arose with provider training on the technical aspects of insertion and removal, and on the management of side effects and medical problems. Harrison and Rosenfield point out that the speed of Norplant's scale up exacerbated the problems of training:

Introduction of any new medical technology typically requires new learning and education in its use. Although many new medical devices and surgical techniques are introduced gradually, often through academic medical centers, that was not so with Norplant. The implant system was introduced countrywide and its initial market penetration grew so rapidly that the base of deliverers, although broad, was not deep; this was true in the United States and in the very large Indonesian program. The combination of speed and lack of depth became especially problematic when removals became an issue.[62]

Despite attempts to train providers by the Population Council and national governments in developing countries, and by companies in developed countries (such as Wyeth-Ayerst in the U.S.), the result was often uneven. AGI's survey of family planning agencies across the United States in 1992 found the lack of a trained clinician often explained why the agency did not promote Norplant to its clients.[63] In Indonesia, only a few practitioners had been trained in removal at the time Norplant was introduced nationally since the initial training program had focused only on insertion techniques.[64] Provider culture and attitudes contributed to the training problems as well. Physicians in many countries felt that this new technology did not require special training and resisted spending time on training.[65] In addition, successful Norplant training required that practitioners prove competency in both insertions and removals, something that the training programs did not always require.

In the United States, intense public controversy arose around the quality of removal services for Norplant. A class action lawsuit was filed in mid-1994 against Wyeth-Ayerst on behalf of 400 women who contended that they suffered severe pain and scarring when their doctors removed the implants. The suit was then extended to include a number of side effects about which the women claimed they were not adequately informed. It also included accusations that Wyeth-Ayerst withheld information from users that the implant's capsules or rods are made of Silastic, a material that some women claimed prompted immune-system problems.[66] The suit alleged that Wyeth-Ayerst failed to adequately warn women and their physicians of dangerous side effects of Norplant. The plaintiffs collectively argued that

they experienced almost a thousand different side effects since the method went on the U.S. market in 1991.[67] Side effects included memory loss, muscle pain, depression, autoimmune disorders, infections, seizures, blindness, cancer, and heart attacks. By 1995, 50,000 women had joined Norplant lawsuits. The lawsuits against Norplant were brought by many of the same lawyers who previously sued the makers of silicone breast implants (and won a $4 billion settlement).[68]

With the lawsuits, the tone of media coverage in the United States shifted from enthusiasm to negativity. In May 1994, a TV report on *Eye to Eye with Connie Chung* presented the first broad public airing of Norplant problems, focusing on women who had experienced difficult implant removals. That year, requests for Norplant insertions began to drop, and discontinuation rates rose dramatically. In 1995, Norplant sales in the United States dropped from 800 to 60 units per day.[69]

In August 1999, Wyeth-Ayerst agreed to pay a $1,500 settlement to any American woman who had filed suit before March 1 of that year. Over the next three years, about 32,000 plaintiffs accepted the offer, and another 2,960 either rejected it or failed to respond.[70] In August 2002, a federal judge in Texas dismissed the claims of most of the remaining women, stating that they had "not produced a shred of evidence or expert testimony that supports an association between Norplant and any of the exotic conditions."[71] Meanwhile, Wyeth-Ayerst spent more than $40 million defending itself against Norplant claims. In July 2002, the company decided to discontinue marketing Norplant in the United States, although the company stated that its decision was due to the short supply of certain components of the product and not the litigation. Harrison and Rosenfield point out that problems with implant removal combined with rumors about serious side effects and complications created a critical mass of opinion and events, leading to decreased Norplant use in the U.S.[72] The story of Norplant in the United States demonstrates how litigation and the media can shape public perceptions about a technology in ways that a company finds difficult to control, leading to stigma, declining use, and ultimately withdrawal from the market.

Norplant's Legacy

Given the withdrawal of Norplant in the United States in 2002, many view the product's experience as a "disaster."[73] Yet millions of women around the world became Norplant users. By the end of 1992, 24 countries had granted regulatory approval to Norplant; by mid-1997, that number reached 58. By the end of 1996, over 5 million implants had been distributed worldwide, with about 3.6 million

of those in Indonesia and close to a million in the United States.[74] As of 2002, an estimated 10.5 million units had been distributed worldwide.[75] In 2003, an estimated 6 million women were using the contraceptive.[76] Norplant also paved the way for a new generation of long-acting contraceptive implants. Two new implant products have U.S. FDA approval (Jadelle and Implanon), a third product (Nestorone) has approval in Brazil, and one other is in development (Uniplant). In 2003, Norplant, Jadelle, and Implanon were approved in 60 countries and were being used by an estimated 11 million women around the world.

The new implants differ from Norplant in having a smaller number of rods or capsules, which makes insertion and removal easier for providers. The primary advantage of the new implants over other contraceptives remains their high degree and long duration of efficacy. Like Norplant, however, the new implant products require a surgical procedure for insertion and removal, calling for trained providers. Also, in some contexts the implants remain costly. In addition, the new implant products are like Norplant (and other progestogen-only contraceptives like the injectable Depoprovera) in that end-users can experience menstrual problems. Oral contraceptive pills use a combination of a progestin and estrogen, so women do not have the same type of menstrual irregularities. Scientists have turned to basic research to try to understand the mechanisms underlying normal endometrial bleeding in order to improve progestogen-only contraceptives.[77]

Norplant also changed the way that international family planning agencies work with developing countries to provide access to contraceptives. Beginning in 1991, the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development, and Research Training in Human Reproduction (HRP) developed a new process—based on lessons learned in the Norplant experience—for considering whether new contraceptive methods should be added into service settings.[78] The HRP process has three main premises: (1) contraceptive introduction must focus on the needs of actual and potential users; (2) policy and operational decisions should concentrate on the institutional capacity to provide contraceptive methods with attention to service quality; and (3) decisions about contraceptive introduction must be placed in the context of all potentially relevant contraceptive methods, instead of focusing on only one method.

The government of Vietnam and WHO used the HRP process in 1994 to assess government plans to introduce Norplant and Depoprovera. Research found that the health system in Vietnam lacked adequate capacity to support Norplant use. These research findings fed directly into government policy, leading to a reversal of the decision to introduce Norplant at that time. As Ruth Simmons and

Peter Fajans, two of the creators of the HRP approach, state, "Decisions not to introduce or to reverse introductory plans are just as important outcomes as is the decision to introduce new methods. Previous technologically and demographically focused approaches to introduction would not have reached such a conclusion."[79] In sum, Norplant's legacy is both a wider array of implant contraceptives available to women and a strategic rethinking about how to introduce (and not introduce) new contraceptive products worldwide.

Conclusions

In 1988, at the 12th World Congress of the Federation for International Gynecology and Obstetrics, the then-director of the HRP said of Norplant, "Probably no other contraceptive on the market has been developed by research done on such a large scale and reported step-by-step to the scientific community."[80] By 1988, more than 50,000 women in 44 countries took part in Norplant trials, and more than 400 articles were published in peer-reviewed scientific journals. Yet the Norplant story demonstrates that having a large research record and a highly safe and efficacious technology is not enough to ensure successful access and appropriate use by providers and clients. (Table 6.2 presents a summary of barriers to Norplant access.) A key lesson is that a technology's problems can be extrinsic to its safety and efficacy.[81] The perception of a technology by end-users and providers can shape its ultimate fate in access. In addition, the end-user's ability to obtain quality services on demand is also an important access factor. The Norplant case also shows how affordability problems can create barriers for public providers and end-users in settings where the product is not offered at a lower public-sector price. For Norplant, these availability, affordability, and adoption issues played major roles in the contraceptive's lack of sustained success in many developed and developing countries.

The Population Council became the product champion for Norplant worldwide and created a largely effective architecture for access. The organization managed the 25-year product development phase and then promoted the adoption, availability and affordability of Norplant in developing countries. Wyeth-Ayerst and Leiras Oy also played core roles in Norplant's access architecture. Total expenditures on product development and access activities by these three actors exceeded $110 million.[82] The Population Council's costs on research ($23.5 million) and access activities ($16 million) came from public-sector funding from the U.S. government and from some private foundations. Leiras Oy spent $23 million to

develop manufacturing procedures, while Wyeth-Ayerst spent $50 million to introduce the contraceptive into the private market and also donated levonorgestrel to the Population Council for development of the Norplant system.

The Population Council coordinated both product development and access activities, allowing the development team to work closely with the access team to ensure full understanding of the technical aspects of the product. But some analysts have suggested that problems arose because the Council acted as Norplant's champion. In Indonesia, some researchers argue, the Population Council and other international experts underestimated problems with counseling and implant removal.[83] These researchers maintain that the issues could have been addressed more effectively if the Council and its partners had collected and analyzed more research from different perspectives. The Council's deep commitment to Norplant may have blinded the organization to anticipating and addressing some of the difficulties encountered in adoption and availability for both providers and end-users.

A key feature of the Norplant experience was the creation of an introduction phase for the new technology. The Population Council conceived of this phase as a bridge from research, development, and clinical trials to Norplant's entry into national family planning programs in developing countries. The activities included introductory trials, acceptability studies, and service delivery research, with the goal of identifying management and technical issues affecting method delivery. The concept was to move beyond a focus on the technology itself as the solution and place the technology within the broader context of health service quality and user perspectives. Although the methodologies used in Norplant introduction provided extensive empirical knowledge about the method, they did not always adequately prepare the national service system for widespread access.[84] The introduction phase in some countries did not provide a systematic link between research and policy, and service delivery research did not inform the planning of large-scale access.[85] As described in the previous section, the lessons learned from Norplant led the HRP to develop a new approach to contraceptive introduction that consists of a staged process of research and policy development.

The scaling-up phase of Norplant involved transitioning from the introductory bridging activities to making the technology widely available. This case study demonstrates that for provider-dependent methods such as Norplant, which require proper training and service quality, the pace of scaling up needs to be coordinated with the strengthening of system capacity. The experiences in Indonesia and the United States demonstrate that rapid scaling up may increase the

availability of a technology but can also result in poor service quality, which can negatively influence user satisfaction, long-term use, and product reputation—and thereby undermine access.

The price of Norplant and related services in the United States affected affordability in negative ways, especially the inability of some end-users to pay for insertion and removal. In many settings, product cost also affected provider practices. In the United States, many potential users and family planning experts questioned the product's tiered pricing structure, particularly in terms of the implant's high price in the private sector, when much of the product development costs were borne by the American public sector and private foundations. Family planning experts raised these questions even while recognizing that the profit requirements of industry and their exposure to risk need to be reflected in the price of the product to the consumer.[86]

End-user adoption of Norplant was influenced by many factors, depending on the particular sociocultural and historical context. Islamic women in Indonesia viewed Norplant as an acceptable alternative to sterilization, which was forbidden by Islam. In the United States, the introduction of Norplant to low-income women led to concerns about social coercion based on previous experiences with sterilization. The Norplant story emphasizes the need to understand—for ethical, practical, and reputational reasons—the social and historical context within which decisions about technology access are being made.[87] The case study also demonstrates the challenges of learning from past experiences. The Population Council, for example, identified several critical lessons from previous efforts at contraceptive introduction (such as the IUD) but was unable to effectively implement all those lessons in its promotion of access to Norplant.

The Norplant story provides important lessons about access for other contraceptives and technologies. A major finding is that assuring safety and efficacy for a product is not sufficient to create access. Critical determinants of access also include affordability for both governments and end-users. Important availability barriers involve provider training and competency on insertion and removal as well as assuring adequate health system capability to deliver quality services—especially for technologies (like Norplant) that depend on health system performance. The technology must also respond to the perceived needs of end-users. Finally, the Norplant story demonstrates the role of end-user adoption factors, particularly the importance of providing end-users with information about the new technology and potential side effects, and also the role of the media and litigation in influencing a product's reputation and fate.

Table 6.2 | Norplant access

	BARRIER	STRATEGY	SPECIFIC ACTION
ARCHITECTURE	Need for a global champion for Norplant	Identify effective leadership and design partnerships for the technology	The Population Council assumed the role as product champion and coordinator for the development, introduction, and scaling up of Norplant in developing countries
ADOPTION	Problems with end-user adoption and continuation due to side effects, poor information about the technology and its side effects, stigma, and negative media coverage	Produce acceptance of the technology at the global and national levels, while creating demand among providers and end-users	The Population Council and its national partners improved training courses for providers and information for end-users in developing countries; these actions addressed adoption barriers in some contexts
			Wyeth-Ayerst decided to settle lawsuits filed in the U.S. by women claiming damages due to side effects from Norplant; the company later withdrew the product from the market
AFFORDABILITY	Limited government funds to purchase Norplant in some developing countries	Assure affordable price for government purchasing agencies	Tiered pricing arrangement for developing country markets
	High price of Norplant for end-users in developed countries	Assure affordable price for individual end-users	Wyeth-Ayerst established the Norplant Foundation in the U.S. but was unable to keep up with demand; the company later decided on a reduced price for public-sector providers
AVAILABILITY	The challenge of dividing different markets to provide access in developing countries while meeting private company interests in the U.S.	Assure adequate quality and quantity of production for different markets	The Population Council assumed responsibility for all activities in developing countries, with a manufacturer in Finland, while Wyeth-Ayerst assumed responsibility for the U.S. market
	Problems in obtaining quality removal services, due to product service and cost, and inadequate provider training	Manage provider activities and provision of removal services to end-users	The Population Council and Wyeth-Ayerst upgraded its training courses for providers and its information for end-users which improved removal services in some settings; in other contexts, removal services remained poor quality

Endnotes

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[4] Segal, *Under the Banyan Tree*, 159.

[5] Segal, *Under the Banyan Tree*.

[6] Segal, *Under the Banyan Tree*, 91.

[7] ICCR has since been responsible for developing a wide range of products in contraceptive and reproductive health. Staff at the Future's Group calculated that in the year 2000, products developed by the ICCR since its inception in 1971 accounted for 50.9% of reversible contraceptive methods used in developing countries. More than 120 million women in the developing world were using products developed through the research group. See: Segal, *Under the Banyan Tree*.

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