

GAO

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Report to the Chairman, Subcommittee  
on Regulation, Business Opportunities  
and Technology, Committee on Small  
Business, House of Representatives

October 1994

# FAMILY PLANNING CLINICS

## Strain of Norplant's High Up-Front Costs Has Subsided



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**Health, Education, and  
Human Services Division**

B-258533

October 7, 1994

The Honorable Ron Wyden  
Chairman, Subcommittee on Regulation,  
Business Opportunities and Technology  
Committee on Small Business  
House of Representatives

Dear Mr. Chairman:

The Food and Drug Administration's (FDA) approval of Norplant, in 1990, made available the first new contraceptive in the United States in 30 years. This new contraceptive—a surgically implanted device—was expected to provide women a simple way to prevent pregnancy for a 5-year period. Questions remain, however, about why U.S. Norplant prices are higher than those in other countries and whether such pricing restricts access by women who must pay for Norplant out of pocket because they are uninsured or underinsured. Therefore, as agreed with your office, we focused our efforts on determining how (1) Norplant's U.S. price compares with its price in Canada and other countries, (2) the price affects the budgets of Title X family planning clinics, and (3) the U.S. price has affected the demand for and acceptability of Norplant.

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**Background**

Norplant, a contraceptive implant, comprises six match-sized capsules that contain the hormone used in oral contraceptives. The capsules, inserted under the skin of a woman's upper arm, slowly release the hormone over a 5-year period, after which they must be removed. Since FDA approved Norplant in December 1990, about 900,000 implants have been inserted in women nationwide, according to American Home Products—Wyeth-Ayerst's parent company.

The Population Council, a nonprofit organization that conducts and sponsors research on international population activities and human reproductive biomedicine, developed and owns the license for the Norplant contraceptive system. Norplant combines the active hormone levonorgestrel with a tubular drug delivery system—silastic. Wyeth-Ayerst developed and owns the rights to levonorgestrel; Dow Corning developed silastic.

Under an agreement with the Population Council, Wyeth-Ayerst has the right of first refusal to manufacture and market any products the

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Population Council develops using levonorgestrel. Wyeth-Ayerst refused the right to manufacture Norplant but is currently Norplant's licensed distributor in the United States and Canada. The Population Council and Wyeth-Ayerst licensed Leiras Oy to manufacture and distribute Norplant in foreign markets. Leiras sells Norplant directly to Sweden and Finland, as well as to international family planning organizations that, in turn, distribute Norplant in many developing countries. Roussel Uclaf distributes the implant in Great Britain.

In fiscal year 1994, the Congress appropriated \$180.9 million for family planning under Title X of the U.S. Public Health Service Act. Under the act, Title X clinics provide a broad range of family planning methods, including Norplant, that are approved by FDA as medically effective.<sup>1</sup> Over 4,000 Title X-funded clinics serve about 4.5 million women, including low-income families, adolescents, and people to whom other sources of family planning services are inaccessible.<sup>2</sup> About 10 to 20 percent of the women who receive Title X clinic services are Medicaid eligible and can obtain Norplant free of charge.<sup>3</sup> Clinics subsidize services to the rest of the clientele, including the uninsured and underinsured, by charging for services on a sliding scale based on income.

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## Results in Brief

When Norplant was first introduced in the United States in 1990, its high up-front cost made it difficult for Title X clinics to provide Norplant to all clients requesting it. Because the demand for Norplant has since leveled off and in some cases declined, however, Norplant's U.S. price is no longer a major budgetary issue for Title X clinics.

Comparing Norplant's U.S. price to its international prices is difficult because different pharmaceutical companies distribute the implant in the United States and other countries. Wyeth-Ayerst Laboratories, Norplant's U.S. and Canadian distributor, sells Norplant for \$365—about \$100 more than Roussel Uclaf sells it for in Great Britain. Also, the contents of the

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<sup>1</sup>Title X grantees receive funds from the Office of Population Affairs within the Department of Health and Human Services (HHS) to provide or contract for family planning services. Grantees include state and territorial health organizations, local government agencies, community organizations, and other organizations—such as Planned Parenthood—that sponsor family planning services.

<sup>2</sup>For purposes of this discussion, low-income families include families with incomes less than 250 percent of the federal poverty guidelines—ranging from about \$7,000 for a family of one to \$24,000 for a family of eight.

<sup>3</sup>Medicaid is a jointly funded federal and state health insurance program for low-income people. Eligible recipients include low-income people who are aged, blind, disabled, or the parent of a dependent child.

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Norplant package vary among distributors. While the U.S. and Canadian price covers a kit that contains a set of six Norplant capsules and the surgical implements clinicians need to insert and remove them, Norplant's price in Great Britain covers only the set of six capsules. However, Roussel Uclaf provides the surgical implements free of charge on request. In developing countries, another distributor—Leiras Oy—sells the set of six capsules for \$23 because its licensing agreement with the Population Council limits company profits on such sales.

To help meet the initial pent-up demand for the implant, HHS, the states, and Title X grantees took action soon after Norplant's introduction to lessen Norplant's budgetary burden on family planning clinics. The subsequent decline in demand for Norplant appears to be due to the fact that it lasts 5 years and is reported to have adverse side effects. Further, women have turned to another more recently introduced injectable contraceptive that does not involve surgery and costs \$30 plus physician fees for 3 months of contraceptive protection.

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## Scope and Methodology

To identify Norplant price differences in the United States, Canada, and Europe, we interviewed officials from Wyeth-Ayerst Laboratories and got pricing information from health departments in Sweden, Germany, Great Britain, France, and the Netherlands. Wyeth-Ayerst officials, however, would not give us detailed pricing information because the company considers this information proprietary. Price information was unavailable from France, Germany, and the Netherlands because Norplant has not been approved for sale in these countries.

To identify the effect of Norplant's price on the budgets of Title X family planning clinics and steps these offices have taken to provide access to Norplant, we interviewed officials from HHS' Office of Population Affairs headquarters and 10 regional offices. To determine the effect of Norplant's price on the family planning budget process, we interviewed state officials of Illinois, Michigan, and Oregon family planning agencies, as well as an official of six Chicago-area family planning clinics. We also reviewed federal guidance for the regions on providing Norplant and states' budgets devoted to Norplant.

To determine consumer demand for Norplant and the factors that affect the implant's acceptability, we reviewed research literature from the Alan Guttmacher Institute, Planned Parenthood Federation of America, Inc., and various medical journals. We also interviewed officials and obtained

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data from FDA, HHS' Office of Population Affairs, state family planning agencies, and Title X clinics on consumer demand for and acceptability of Norplant. Wyeth-Ayerst officials gave us information on the total number of Norplant kits sold but would not disclose sales by class of trade because they consider this information proprietary.

We conducted our study between February 1994 and September 1994 in accordance with generally accepted government auditing standards.

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## Principal Findings

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### Norplant's Price Varies by Country

Wyeth-Ayerst sells the Norplant kit for \$365 in the United States and Canada. The kit contains the six Norplant capsules and the surgical implements to insert and remove them. In addition to the kit, Wyeth-Ayerst also provides patient counseling materials and health practitioner training on properly inserting and removing Norplant.

Wyeth-Ayerst officials told us that Norplant's price was based on the prices of competing contraceptives, rather than the kit's contents.<sup>4</sup> According to Wyeth-Ayerst, when Norplant's \$365 price is amortized over the implant's 5-year life, its daily cost is within the range of competing contraceptives, such as birth control pills. However, most women do not use the implant for the full 5 years. The implant's label shows that during clinical trials, before FDA approval, about 80 percent of women discontinued use by the third year. Therefore, using 5 years as the basis for determining Norplant's daily cost may not be the best way to compare price with other contraceptives. When the implant's cost is amortized over a 3-year period, the cost increases from 20 cents to about 33 cents per day.

Roussel Uclaf sells the Norplant capsules to Great Britain's National Health Service for about \$100 less than Wyeth-Ayerst's U.S. price.<sup>5</sup> Roussel Uclaf packages the Norplant capsules separately from the surgical implements for insertion and removal. Roussel Uclaf will provide physicians the surgical implements free of charge on request.

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<sup>4</sup>Wyeth-Ayerst officials told us that they will begin to discount Norplant's price to the public sector by 1996 in accordance with their agreement with the Population Council. However, the agreement does not specifically state the amount of the discount.

<sup>5</sup>Norplant in Great Britain is about \$100 less than Wyeth-Ayerst's product when calculated using an exchange rate of \$1.50 to £1. Also, Great Britain does not have a private market for Norplant; as a prescription-only medication, the implant can only be obtained through the national health care delivery system.

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Under Leiras Oy's agreement with the Population Council, Leiras limits its profits to 12 percent for Norplant sales to developing countries. Accordingly, Leiras sells Norplant for \$23 to the U.S. Agency for International Development, the United Nations' family planning agency—the United Nations Population Fund—and to the International Planned Parenthood Federation.

Leiras Oy also sells Norplant for about \$51 in Sweden. The Swedish health care system subsidizes the cost of the implant so that the consumers' out-of-pocket cost is about \$30. Swedish officials reported that the product they receive from Leiras contains only the six Norplant capsules and not the counseling or training materials that Wyeth-Ayerst and Roussel Uclaf provide.

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### Norplant's High Up-Front Costs Required Some Family Planning Clinics to Adjust Their Budgets

Initially, Title X clinics had to limit availability of Norplant due to its high price and clinic budget constraints and to ensure that clients received a broad range of contraceptive options. To augment their supply of Norplant kits, some clinics earmarked money especially for Norplant purchases and sought additional funding from private sources. Despite the additional funding, some clinics could still not meet the initial demand for Norplant and had to ration it.

Office of Population Affairs instructions require Title X clinics to provide a broad range of acceptable, effective, and FDA-approved contraceptive options. Because Norplant is an approved contraceptive, clinics must provide it on a sliding fee schedule either on site or by referral. However, Norplant's high up-front cost made it difficult for Title X clinics to provide Norplant and charge for services based on income. For example, a teenager earning less than \$7,000 per year would not be charged for the implant, counseling, insertion, or follow-up visits. In this case, a Title X clinic would immediately bear the full cost of services, which could amount to \$500 or more (\$365 for the implant plus medical fees), rather than spread the implant's cost over a multiyear period.

To minimize Norplant's potential financial impact on Title X clinics without causing them to serve fewer clients, HHS allowed the clinics to limit Norplant services based on budget constraints and patient demand for other contraceptives. HHS also permitted Title X grantees to concentrate Norplant services in magnet or hub locations into which clinics could channel patients. For example, Planned Parenthood of Chicago has six clinic sites, but only the Austin Health Center provides

Norplant services. The other five clinics channel patients desiring Norplant to the Austin Health Center.

Grantees may also receive additional year-end funds from the Office of Population Affairs to augment their budgets. The Office of Population Affairs normally reserves a portion of the Title X appropriation to, in part, respond to special needs that arise during the fiscal year. The Office distributes unused funds from this reserve to the regions that, in turn, award the funds to their Title X grantees. In several regions, grantees earmarked these funds for Norplant purchases.

In addition, states recognized the financial burden that Norplant placed on Title X clinics and took a variety of steps to help grantees and clinics meet demand for the implant. For example, Wisconsin used privately donated funds in 1991 to purchase Norplant for low-income women not covered by Medicaid. California set aside \$5 million for Norplant in state fiscal years 1992, 1993, and 1994. In 1993 and 1994, the Michigan legislature allocated about \$500,000 for Norplant. Between January 1993 and April 1994, Illinois purchased more than 250 Norplant kits to distribute to its Title X clinics on demand.

Some Title X clinics also augmented their resources by having clinic-affiliated clinicians apply for Norplant Foundation kits.<sup>6</sup> Wyeth-Ayerst established the Norplant Foundation to provide up to 8,000 free kits yearly to low-income women without medical insurance.<sup>7</sup> The Foundation limits each clinician to 10 donated kits annually. Through July 1994, the Foundation provided about 16,500 kits to low-income women. However, we could not determine the extent to which Title X clinics augmented their resources using these donated kits because the Foundation does not keep data on the number of kits provided to Title X-affiliated clinicians.

State family planning and Title X clinic officials told us that relatively few women received the Norplant Foundation kits. The Foundation's requirement that clinicians insert and remove donated kits without reimbursement may be impractical for nonprofit family planning agencies, which must collect fees or third-party reimbursements to remain

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<sup>6</sup>Title X requires its family planning clinics to have a medical director on staff. Clinics may contract with local physicians for additional medical procedures, such as intrauterine devices, Norplant insertions, and sterilizations.

<sup>7</sup>To qualify, women must have no insurance coverage for reversible contraceptives, an annual income less than 185 percent of the federal poverty income guidelines, and clinician sponsorship.

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financially viable. According to the Alan Guttmacher Institute, local health departments and Planned Parenthood clinics' sliding scale fees ranged between \$35 and \$385 for inserting Norplant and between \$162 and \$250 for removing the implant. Title X clinic representatives believe that forgoing such fees can compromise their clinics' financial viability or reduce the number of clients served and services provided.

Title X clinics can also make the implant more accessible by allowing clients to pay for services in installments or with a credit card. According to the Alan Guttmacher Institute's November 1992 survey, more than 40 percent of the 616 responding family planning agencies offering Norplant reported accepting installment payments for the implant. Twenty-one percent of clinics reported allowing patients to use a credit card to pay for services.

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### Title X Clinic Demand for Norplant Has Declined

Eight of the 10 Office of Population Affairs regional offices reported that the initial demand for Norplant has subsided, decreasing clinic demand for the implant. Regional officials attributed the decreased demand to the implant's high up-front costs, long-term nature, and surgical insertion and removal procedures. An official in one region stated, however, that it is difficult to determine whether demand for Norplant has declined solely because of its cost or because of patient knowledge that clinics have limited supplies.

In June 1994, about 1,000 Norplant users joined a nationwide class action suit alleging that Wyeth-Ayerst did not adequately warn them of the lengthy surgery and scarring that may occur when the implant is removed. Moreover, some women found Norplant's side effects, such as irregular menstrual cycles and weight gain, intolerable.

Some women have chosen to use an alternative contraceptive called Depo-Provera that FDA approved in 1992. Each injection costs about \$30 plus physician fees and protects against pregnancy for 3 months. While Depo-Provera has many of the same side effects as Norplant, its lower cost, shorter duration, and quarterly injections are preferable to some women.

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As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, we will send copies to the Secretary of Health and



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Human Services, the Surgeon General, the Assistant Administrator of the Office of Population Affairs, and other interested parties. We will also make copies available to other interested parties on request.

Should you or your staff have any questions about this report, please contact John Hansen, Assistant Director, at (202) 512-7105 or Enchelle Bolden, Senior Evaluator, at (312) 220-7684. Other major contributors to this report include Shaunessye Curry and Janina Johnson.

Sincerely yours,

A handwritten signature in cursive script that reads "Leslie G. Aronovitz".

Leslie G. Aronovitz  
Associate Director,  
Health Financing Issues