

NORPLANT

New questions about the "dream" contraceptive

The FDA claims it's reliable and easy to use. But is it safe?

BY SARAH HENRY

When Paula Gorman heard about Norplant—a contraceptive that was introduced in 1991—she thought it seemed like the perfect method of birth control. Since Norplant is a hormone-releasing device that's implanted under the skin, a woman doesn't have to bother with taking pills every day. "Norplant sounded so much simpler than oral contraceptives," says Gorman, a 40-year-old day-care provider who lives in Cranston, R.I. "And an IUD wasn't an option for me because I'd had one that had caused an infection. My doctor told me not to use an IUD again."

Gorman's gynecologist inserted Norplant—six matchstick-size capsules made of Silastic, a form of silicone—in a fanlike pattern beneath the skin of her

upper arm. The doctor explained that the capsules would release a low, continuous dose of the hormone progestin for five years.

For Gorman, Norplant didn't turn out to be as trouble-free as she had expected. Soon after it was inserted, she started having prolonged menstrual bleeding—a common side effect that usually diminishes over time, said her doctor.

In her case, though, it persisted. Gorman decided to have the Norplant capsules removed after three years—two years before the end of their five-year life span.

But having the contraceptive taken out wasn't that simple either. "I had been told by my doctor that the capsules would be easy to remove," she says. "The first session took about three to three-and-a-half hours. The capsules were so embedded in scar tissue that the nurse practitioner who performed the procedure was able to get only two of them out," Gorman remembers.

Gorman returned a week later for another three-hour procedure, to have the four remaining capsules removed. There are now three "pretty noticeable" scars on her arm.

Gorman is not the only one who believes she was harmed by Norplant. Of the 1 million women in the United States who have chosen to use the contraceptive, thousands have turned to attorneys charging that they have had serious problems, according to Chris Parks, of Parker,

Parks & Rosenthal in Port Arthur, Tex., who is representing hundreds of women in a class-action lawsuit against Norplant's U.S. distributor, Wyeth-Ayerst Laboratories of St. Davids, Pa. (Gorman herself has joined a class-action suit originally filed in 1993 in Illinois.) The complaints allege not only removal difficulties but also infections at the insertion site and debilitating side effects during Norplant use—including severe menstrual bleeding, migraine headaches, depression, uncontrollable weight gain and hormonal imbalances. There have also been rare reports of autoimmune diseases, strokes and heart attacks among women using Norplant.

In February, Parks filed a complaint in Beaumont, Tex., that consolidated more than 20 class-action cases from across the country into one master class-action suit. The suit alleges that Wyeth "understate[d] and underplay[ed]" the severity of side effects, removal difficulties and subsequent scarring.

But the question is: Are these allegations justified? There's little scientific evidence to support some of the more serious claims, says Francine Sinofsky, M.D., an associate professor of clinical obstetrics and gynecology at the Robert Wood Johnson Medical School in New Brunswick, N.J., where Norplant has been available since trials of the contraceptive began there in 1983. In more than ten years of prescribing Norplant,

For Paula Gorman, having Norplant removed proved to be an ordeal.



Sinofsky has seen very few serious side effects. "We haven't had any major problems," she reports.

A revolutionary new method of birth control

When Norplant first hit the market, it was hailed as a dream contraceptive. Once it was implanted, a woman could virtually forget about it. And while it isn't cheap (the cost is usually about \$700, including insertion and removal), it's less expensive than five years' worth of birth-control pills.

Norplant is considered to be ideal for women who want to postpone child-bearing for at least five years or who are considering sterilization but aren't ready to make a final decision. Wyeth said Norplant is "the first truly innovative method of contraception available for American women in more than 30 years."

From the start, Wyeth has acknowledged that Norplant is not without its drawbacks. Indeed, in the patient booklet and labeling information, Wyeth lists numerous possible side effects, including

irregular menstrual bleeding, headache, nausea, dizziness, nervousness, breast tenderness, enlargement of the ovaries and/or fallopian tubes, weight gain and acne. The patient booklet also mentions that problems can occur during Norplant removal: "the...procedure usually takes 15 to 20 minutes but may take longer. If some of the capsules are difficult to remove, an additional visit and incision may be required."

While the Food and Drug Administration (FDA) has received about 8,000 reports of adverse reactions from Norplant users, most of them have been related to irregular bleeding.

Experts aren't ready to write off the possibility of more serious side effects, though. In an article published in the April 1995 issue of *Obstetrics & Gynecology*, researchers at the FDA reviewed the serious reactions to Norplant (including strokes) reported between February 1991 and December 1993.

Although the incidence of these reactions did not exceed the rates expected in the general population, side effects are often underreported, the article noted. The researchers concluded that Norplant may be linked to strokes, pseudotumor cerebri (an increase in pressure on the brain causing headaches, nausea and vomiting) and a rare blood disease (thrombotic thrombocytopenia purpura), and that physicians "should inform patients of the possibility of these occurrences." Wyeth revised the drug's labeling to include reports of these conditions.

Still, cause and effect have not been proven. Wyeth spokesperson Audrey Ashby says: "While these events occurred, a causal relationship to the Norplant System is unknown. These conditions also occur in women who don't have Norplant."

According to a prepared statement, the company "will continue to contest class actions and other law-



Mary Conway, a health-care professional, was very satisfied with Norplant.

playing it smart

Before you decide to use Norplant, talk to your physician about the contraceptive's possible side effects in light of your own health status. Tell your doctor if you have a history of menstrual irregularities, such as unexplained vaginal bleeding, or any other medical problems. (Norplant should not be used by women with certain conditions, such as breast cancer and liver disease.) If you decide to use Norplant, to reduce your risk of side effects, infections or removal difficulties, make sure your physician has attended training seminars on its insertion and removal. (To find a trained physician, contact Wyeth-Ayerst Laboratories, Norplant's distributor, at 800-934-5556.)

suits." Ashby labeled the class-action claims "inappropriate" because each woman's experience with the contraceptive is "individual." In fact, Ashby charges that Norplant—used by 2.5 million women worldwide and tested for more than 20 years on 55,000-plus women in 55 countries—has been unfairly targeted by product-liability lawyers and sensational news accounts.

There are lingering questions about safety

Many critics, on the other hand, are glad the word is finally getting out about Norplant's possible risks. The Texas suit, for example, accused the company of failing to warn that "the silicone used in the capsules could cause other serious health risks." (Wyeth points out that the form of silicone in Norplant has been used for decades worldwide in medical products such as heart valves.) It also alleges that Wyeth failed to conduct adequate testing of the contraceptive, postmarketing follow-up of Norplant users, and training for providers on the insertion and removal of Norplant.

While most of the women who are suing say their side effects disappeared af-

ter Norplant was removed, a few maintain their problems have continued after removal, according to attorney Jewel Klein, who filed the Illinois suit. In fact, one of her clients, Lorri Bishop, claims that she developed new ailments after she had the device taken out.

Bishop, a 31-year-old mother of two who lives in Toney, Ala., says that she's experienced mood swings, painful breasts and weight gain as a result of an estrogen deficiency that she blames on Norplant, since the drug temporarily changes the body's hormonal balance.

Whether Norplant can cause postremoval hormonal imbalances is unknown, but it's well established that women can have complications when the device is removed. Some Norplant providers blame these difficulties on poor insertion of the device. "We know that in some cases Norplant is difficult to get out and that it can travel from its original position, although this is a very rare occurrence," notes Anita Nelson, M.D., who has trained hundreds of doctors to insert and remove Norplant. "These problems often occur because the device has been placed too deeply under the skin. I ▶

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urge women to go to an experienced Norplant inserter," says Nelson, medical director of the Women's Health Care Clinic at the Harbor UCLA Medical Center in Torrance, Calif.

Indeed, Norplant's prescribing information for physicians states: "Health-care professionals are strongly advised to be instructed in the procedures before they attempt them."

However, Pearson's group pressed for surveillance of these women lasting 15 years or more, and for follow-up studies of women who had participated in earlier clinical trials outside the United States.

Is the criticism deserved?

Some health-care professionals say Norplant is being unjustly accused. "I don't think Norplant is for everyone—there is no per-

even less likely to experience them, because Norplant doesn't contain the hormone estrogen.

"The trouble is that everyone who has a side effect while using Norplant blames the device, even though it could have been a coincidence—they could have gotten that symptom whether they were using Norplant or not," says Sinofsky. She calls the frequently reported complaint of menstrual irregularities "a big nuisance, not a big risk."

When asked whether it's possible for the contraceptive to trigger a prolonged imbalance of hormones, Nelson says, "Absolutely not." The active ingredient in Norplant, progestin, is quickly cleared from the blood, she explains, and "routinely there is a rapid return to fertility."

From the feedback she's received from her patients, Nelson believes Norplant "works extremely well... and should continue to be on the menu of methods of contraception available to women" but that women do need to be thoroughly counseled about side effects.

Some women's health organizations feel the same way. "I simply pray that Norplant will continue to be available," says Jane

selecting Norplant—and could have a chilling effect on the development of other methods of contraception. The demand for Norplant, which was growing steadily, has recently tapered off, Johnson says. "There's no question about it—with all of the attention, more women are coming in wanting Norplant taken out," she says, echoing the experience of others in the health-care field. "It's easy to terrify women about their health."

There are many Norplant users who are satisfied; Mary Conway is one. A physician assistant (physician assistants are trained to perform many of the same tasks a physician does), Conway has implanted the device in dozens of patients. In 1991 she chose it for herself. "It was after the birth of my youngest child. I was in my mid-30s and wasn't ready to make a decision about whether I was going to have another baby," says the Blackwood, N.J., mother of a "blended" family of eight children. "I needed something very effective."

"I was extremely happy with it," says Conway, now 41, who used Norplant for two years before deciding to undergo sterilization. As for the removal, she says, "I can honestly tell you I've gotten worse scars from shaving my legs. I'm very frightened of seeing women's options limited by this litigation."

But women like Gorman and Bishop, who are suing, say they don't see themselves as restricting women's choices. It's their belief that they were given a product whose side effects were much worse than they had expected. And they're angry.

Their primary objective, they claim, is to protect other women. "I just want people to realize what can happen with Norplant," says Gorman. "I don't think any other woman should have to go through what I went through." ■

Lorri Bishop had some disturbing hormonal problems after the removal of Norplant.



The problem, says Cindy Pearson, program director of the National Women's Health Network, based in Washington, D.C., is that any medical practitioner can obtain Norplant and offer to do the procedure.

"The company could have restricted the product to trained providers," she says. Pearson's not surprised by the complaints that have surfaced with Norplant. At FDA hearings in 1989, a network representative argued it would be "premature" to introduce Norplant because of "the lack of data on long-term safety." In the '80s, Wyeth-Ayerst conducted five-year clinical trials in the United States involving about 1,000 women.

“Some argued that Norplant was put on the market prematurely.”

fect method of birth control," Sinofsky points out. "But I do think it's good. For a lot of patients it's the best choice because it's long-term and reversible, and doesn't require remembering to use something on a daily basis."

As for the risk of heart attacks or strokes, Sinofsky says that these are highly unlikely. "Women on birth-control pills are at low risk for such problems, but women on Norplant are

Johnson, executive vice president of the Planned Parenthood Federation of America in New York City. She notes a high degree of satisfaction among Planned Parenthood clients who choose Norplant, which she attributes to careful client screening, counseling and the competency of clinicians in inserting and removing Norplant.

Johnson fears that the pending legal action will discourage women from