The Linacre Quarterly

Volume 60 | Number 1 Article 7

February 1993

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Contraceptive implant technology dates back to the mid 1960s. Subdermal implants have been available in Finland since late 1983 and in at least 14 other countries at the present time. They provide a slow-release carrier of various progestins—hormones that have progesterone-like activity. The prototype in this field is Norplant, which is a set of silicone rubber (silastic) rods packed with crystalline levonorgestrel. It was developed under the auspices of the Population Council's Center for Biomedical Research and approved by the FDA December 10, 1990.

Norplant has been heralded as the first major contraceptive advance in over thirty years. Its development has been controversial with most of the testing being done on Third World women amid charges of "gross violations of medical ethics."[1] It has been alleged that women were not told that the drug was experimental nor were they told of the possible dangers of Norplant. Indeed it has been reported that monetary incentives were paid to women for accepting the birth control method, that reporting of complications was discouraged by clinic staff, and that proper health care was withheld from women who experienced side effects. Funding for this project has come from the United States Agency for International Development, the Canadian Government, the United Nations Population Fund and private donors.

The Norplant system is made up of six small, thin, flexible rods (2.4 mm in diameter and 34 mm long) made up of soft silastic tubing filled with a synthetic hormone called levonorgestrel (see Figure 1). Each rod contains 36 mg. of the hormone levonorgestrel. They are inserted, in a fan-like pattern, just under the skin of the upper arm in a minor, in-office surgical procedure costing approximately $350.[2] The silastic rods are non-biodegradable and must be removed after 5 years (3 years for Norplant 2).

Small amounts of levonorgestrel diffuse continuously through the walls of the silastic capsules to maintain blood levels. It is said that "contraception" is provided within 24 hours of the insertion of the rods if they are inserted within the first

seven days of the menstrual cycle. It is promoted as a continuous contraceptive lasting as long as five years in duration.

Levonorgestrel is a progestin which has progesterone-like properties. It is important to emphasize that it is *not* progesterone but rather a progestin which is synthetic and foreign to the body. This artificial hormone releases slowly over the five years in which the system is used. Blood levels of the levonorgestrel are much higher in the first 9 months (85 mcg/day) than they are over the remaining 51 months (30 mcg/day). As a result, one can anticipate that the mechanism by which Norplant works would differ somewhat during the first year of use versus the latter years of use.

As with other progestin-only "contraceptives", Norplant is thought to have three modes of action:

1. It acts on the hypothalamus and the pituitary gland to suppress the LH surge which is responsible for ovulation.
2. The cervical mucus should become viscous and scant making it less permeable to sperm.
3. The endometrium shows signs of suppression.

The suppression of ovulation by Norplant is highly irregular. During the first year of use, 11.1 percent of menstrual cycles have been found to be ovulatory. But, after the first year of use, the incidence of ovulatory cycles increases as the amount of hormone diffusion decreases averaging 46.3 percent in years 2 through 5 and 66.8 percent thereafter.[3] When levonorgestrel suppresses ovulation it works as a contraceptive agent. When it adequately interferes with the cervical mucus to prevent the sperm from penetrating the cervix, it is also acting contraceptively. However, there is very little data to show the significance of this latter mechanism.[4]

The third mechanism of action, that action associated with its effects on the endometrium, are dramatic. In nearly 90 percent of endometrial samples, the endometrium is disturbed.[5] This mechanism of action renders Norplant an *abortifacient.* The exact incidence of its abortifacient properties is not yet known, however, it is clear that this mechanism exists and undoubtedly occurs.[6]

The "contraceptive" effectiveness of Norplant is listed in Table 2. The effectiveness varies rather considerably with the weight of the individual woman. The highest effectiveness ratings of 99.8 percent are in women who weigh less than 110 pounds. If the woman weighs over 154 pounds that effectiveness decreases to only 91.5 percent.

The discontinuation rates are also very high over the years in which Norplant is used. In the first year the discontinuation rate is about 19 percent. However, by the third year that increases to 50.4 percent and by the fifth year, 70.5 percent (see Table 3).

The most significant side effect to Norplant is abnormal bleeding. The type of bleeding pattern a woman will have cannot be predicted. In addition, women may experience headache, nervousness, nausea, dizziness, enlargement of the ovaries with ovarian cyst (10 percent), dermatitis, acne, changes in appetite, weight changes, mastalgia (breast tenderness), hirsutism (excessive hair growth), hair loss and hyperpigmentation over the implant site.

The surgical scar under the arm and the silastic tubules which are seen underneath the skin, identify women as users of Norplant. It is possible that this may cause women who use Norplant to be respected less and to be more susceptible to being used as a sexual object. The scar may be conspicuous in certain types of dress.

Norplant also will not protect against sexually transmitted diseases such as Chlamydia and Gonorrhea. Because the fear of pregnancy is greatly reduced in unmarried teenagers using Norplant, increased sexual activity will put these women at risk for permanent infertility, Herpes Simplex Type II and Acquired Immune Deficiency Syndrome (AIDS).

One of the promoted advantages of the Norplant system is its capability of being used by women who would be otherwise non-compliant to other systems of birth control. This also provides it with one of its more controversial concerns.

Hearings have been held in the Kansas Legislature on a bill that would pay welfare mothers $500 to get the implant. It would also pay for the Norplant, plus an annual check up and a $50 check per year.

It has been promoted as the best contraceptive choice for teenagers because of its one-time only insertion capability.[8]

Judge Howard Broadman of Tulare County Superior Court in Visalia, California ordered a convicted female child abuser to use Norplant as a condition placed upon the woman's probation.

And recently, an editorial in the *Philadelphia Inquirer* suggested that a good way to fight poverty would be to pay black welfare recipients to use Norplant.[9]

The odd thing about all of the above issues is that organizations like the American Civil Liberties Union (ACLU) and advocates of abortion such as syndicated columnist, Ellen Goodman, have cast the argument that the government has no right to dictate birth control use. Unfortunately, the Catholic Church has been relatively silent on these issues.

A good summary of the Norplant debate from a Catholic perspective has been written by Sr. Renee Mirkes, a consultant to the Pope John Center.[10] She writes:

> The Catholic Church enters the Norplant debate with an antithetical set of premises and conclusions. The practice of contraception, using Norplant or any other artificial contraceptive, apart from any regrettable circumstances associated with its use, is primarily morally objectionable because the act of contraception, in and of itself, is evil. This is so because contraceptive intercourse deliberately acts against the basic human good of procreation, a good that, by God's arrangement, is meant to be fostered or respected in every engagement in or abstention from marital intercourse. Furthermore, in the case of a birth control drug which is also an abortifacient, the destruction of the basic good of human life is risked as well. Although further evil uses — such as threats to a woman's health — may compound the evil of contraception, the moral status of contraception does not originate primarily from these.
>
> In other words, it is not as if the morality of using Norplant depends on whether it results in additional evils such as a threat to a woman's health, deprivation of user-control, discrimination against women by making them solely responsible for family planning, etc.; contraception is a moral evil by virtue of its very nature. It destroys human goods which, when respected or actively embraced, contributes to a basic dimension of personal fulfillment. God has designed marriage and human love within marriage in such a way as to provide a husband and wife, in the context of the most intimate expression

of their reciprocal self-gifting, to imitate Him and His divine manner of loving, i.e., to engage in a love that is faithful, total, selfless and fruitful.

It should come as no surprise to a reflective person that failure to exercise a marital love that is at once life-giving and love-giving might result in all sorts of undesirable consequences or auxiliary evils. But even if none of these were ever associated as direct results of contraception or even if they never occurred, the act of contraception would still take its silent toll on the human goal of all married love; the ever-expanding growth and personal, familial and societal fulfillment and well-being.[10]

FIGURE 1: Diagramatic sketch of Norplant implants placed in the inner aspects of the left upper arm.

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TABLE 1

FREQUENCY OF OVULATION[1]

FIRST SEVEN YEARS

NORPLANT USERS[2]

	OVULATORY		ANOVULATORY		UNCERTAIN	
YEAR	N	%	N	%	N	%
1	3	11.1	22	81.5	2	7.4
2	13	61.9	6	28.6	2	9.5
3	10	27.8	23	63.9	3	8.3
4	10	43.5	12	52.2	1	4.3
5	25	52.1	22	45.8	1	2.1
6	14	73.7	5	26.3	0	0.0
7	9	60.0	5	33.3	1	6.7
1 thru 7	84	44.4	95	50.3	10	5.3

1. Based on luteal phase plasma progesterone levels.
2. From: Croxatto, H.B., Diaz, S., Pavez, M., et al: Plasma Progesterone Levels During Long Term Treatment with Levonorgestrel Silastic Implants. Acta Endocrin. 101:307-311, 1982.

TABLE 2

EFFECTIVENESS OF NORPLANT

CUMULATIVE PREGNANCY RATES PER 100 USERS[1]

BY WEIGHT CLASS

	5 YEAR CUMULATIVE	
WEIGHT CLASS	PG. RATE	CONTRACEPTIVE EFFECTIVENESS
< 110 LBS.	0.2	99.8
110 - 130 LBS.	3.4	96.6
131-153 LBS.	5.0	95.0
≥ 154 LBS.	8.5	91.5

1. From: Woutersz, T.B.: The Norplant System of Contraception. *Int. J. Fertility*, Supp (3): 51-56, 1991.

TABLE 3

DISCONTINUATION AND CONTINUATION RATES (PER 100 USERS), NORPLANT

	CUMULATIVE RATE BY YEAR				
STATUS	**1**	**2**	**3**	**4**	**5**
D/C for Menstrual Irregularities	9.1	17.0	21.9	25.2	28.1
D/C for Medical Reasons	6.0	11.6	15.7	19.7	24.8
D/C for Personal Reasons	4.6	7.7	24.0	34.7	46.4
Continuation Rates	81.0	62.7	49.6	38.0	29.5

1. from: Woutersz, T.B., The Norplant System of Contraception. *Int. J. Fertility,* Supp (3): 51-66, 1991.

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9. *Wisconsin State Journal.* Will Sterilization of Welfare Mothers Come Next? January 2, 1991.

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