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# A Hidden Side of Norplant

by

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On December 6, 1990 *USA Today* proclaimed the soon to be licensed NORPLANT contraceptive implant, "As perfect a method as you can have."<sup>1</sup> Three years later the *Chicago Tribune* headline read, "No panacea: Norplant suit charges failure to educate patients."<sup>2</sup> What happened during this time to dampen the initial enthusiasm for Norplant?

## What is Norplant?

The "NORPLANT SYSTEM" is a birth control method involving the surgical insertion of six flexible match stick size rods of Silastic into the inner upper arm of women. The rods (implants) contain levonorgestrel, a progesterone type drug, which is released slowly to prevent pregnancy for up to five years.<sup>3</sup>

Levonorgestrel and its chemical relative norgestrel have been components of oral contraceptives ("birth control pills") for several years.<sup>4</sup> Since Norplant does not contain estrogen, which is associated with blood clotting and cardiovascular disorders<sup>5,6</sup>, the manufacturer promotes Norplant ". . . as a particularly good option for a woman who . . . wants a form of hormonal contraception but does not wish to use estrogen-containing contraceptives."<sup>7</sup>

## How Is Norplant Inserted?

After the woman lies on the doctor's examining table, and her upper inside arm prepared with antiseptic, she receives six injections of local anesthetic "to mimic the fanlike position of the implanted capsules." Next, a scalpel is used to cut a 2mm shallow incision in the woman's arm. Through this incision is inserted a large-bore needle, and the six implants placed through this needle under the skin in a fan shape. "Correct and carefully performed subdermal insertion of the six capsules" is important because "failure to do so may result in deep placement . . . and could make removal more difficult." After three days, keeping the wound clean and dry, she may resume normal activities. A typical insertion procedure takes about fifteen minutes.<sup>3</sup>

## What Are the Side Effects of Norplant?

Nearly all women on Norplant experience changes in menstrual patterns, ranging from excessive bleeding, spotting, or total absence of periods. Women are warned that this irregular bleeding could "mask symptoms of cervical or endometrial cancer." Common adverse reactions during the first year include: headache, nervousness, nausea, dizziness, dermatitis (skin inflammation), acne, change of appetite, mastalgia (painful breasts), weight gain, hirsutism (excessive hair growth), hypertrichosis (facial hair), and scalp hair loss.

Other Possible adverse reactions include breast discharge, cervicitis (inflammation of the cervix), musculoskeletal pain, abdominal discomfort, leukorrhea (white vaginal discharge), and vaginitis (vaginal inflammation). "Warnings" and "Precautions" include the following: delayed follicular atresia (ovarian follicles do not reduce in size after ovulation; may require surgical correction); ectopic pregnancy (risk may increase the longer Norplant is used); caution if breastfeeding; foreign body carcinogenesis (cancer); thromboembolic (blood clotting) disorders; caution in smokers; possibility of elevated blood pressure; myocardial infarction (heart attack); carcinoma (cancer of the breast, uterus, ovaries, or cervix); hepatic (liver) tumors; ocular (eye) lesions; gallbladder disease; possible changes in carbohydrate metabolism (may complicate diabetes); hyperlipidemia (high blood fat concentration); liver function (jaundice may develop); fluid retention; emotional disorders; visual changes with contact lenses.<sup>3</sup>

Although several or none of the above adverse effects may occur in any particular woman, drug company lawyers use similar lists in the manufacturer's "Package Insert" as a defense when these companies are sued by recipients of drugs or vaccines.<sup>8, and others.</sup>

To stem the high incidence of Norplant side effects<sup>9-11</sup>, it was suggested to give estrodiol (an estrogen-type drug;<sup>12,13</sup>) or oral contraceptives<sup>14</sup> to reduce the duration of excessive bleeding caused by Norplant. It is ironic that Norplant is advertised as containing no estrogen, but that estrogen-containing products are recommended to remedy Norplant's side effects.

### How Effective Is Norplant?

Norplant's effectiveness in preventing pregnancy is in the same range as male or female sterilization.<sup>3</sup> However, this high efficacy (0.2 pregnancies per 100 women for five years of Norplant use) *only applies to women who weigh less than 110 pounds*. For women weighing 110-130 pounds, the five year pregnancy rate rises to 3.4 (per 100 women using the method for five years), and to 5.0 for women weighing between 131-153 pounds. For larger women (weighing more than 154 pounds) the five-year cumulative pregnancy rate rises to 8.5 (per 100 women). Based on these rates the manufacturer is careful to state that Norplant provides "up to" five years of contraception.<sup>3</sup>

### How Does Norplant Prevent Pregnancy?

Norplant uses several mechanisms to prevent pregnancy. First, the hormone in

Norplant inhibits ovulation in about half of cycles, with a trend toward less ovulation in the first year of Norplant use, and more in the later life of the implant (cycles inhibited: 20 to 75%<sup>15</sup>; 59%<sup>16</sup>; 40 to 86%<sup>17</sup>; 67%<sup>18</sup>). In cycles where ovulation occurs, less progesterone is produced after ovulation in Norplant users<sup>15,16,18</sup> resulting in luteal phase defects, this phase being important for implantation of a fertilized ovum, and for the early pregnancy to be maintained.

Norplant also changes the quality of cervical mucus, making it thick and hostile to sperm migration, thereby reducing the possibility that sperm and ovum will unite.<sup>16,19</sup>

Lastly, Norplant causes growth of the endometrium (inner lining of the uterus) to be suppressed, resulting in its inability to support implantation of a fertilized ovum, the new human life.<sup>20</sup> Although this latter researcher states, "The actual role of these endometrial alterations in the overall contraceptive effect of Norplant . . . is difficult to assess . . .," others deny that this abortifacient action plays any role in the overall mechanism of Norplant. However they acknowledge that an early pregnancy would be easy to miss due to the irregular bleeding patterns of Norplant users<sup>18</sup>, or the lack of sensitivity of the blood test used to detect hCG during the first five days after fertilization<sup>21</sup> (hCG=human chorionic gonadotropin; produced by the fertilized ovum in early stages of pregnancy).

Since pregnancy occurs in a small number of women on Norplant<sup>18,21</sup>, it is obvious that these back-up contraceptive mechanisms are not always operative.

### **Norplant Use In Teens**

Despite the lack of pre-license testing of Norplant in those under 18 years of age to determine safety and efficacy in this age group<sup>22</sup>, teen use of Norplant has been advocated.<sup>14,23</sup> Planned Parenthood clinics require no parental consent before Norplant insertion<sup>24</sup>, their attorneys determining that when implants are inserted through the large-bore needle poked directly through the skin, bypassing the small incision, "the procedure is not legally . . . surgery . . . and nullifies requirements for parental consent".<sup>23</sup>

In January 1993 a Baltimore public school for pregnant girls, or girls already with babies, began to perform Norplant insertions at its health clinic, with more schools expected to follow.<sup>25,26</sup> Except for rare dissent based on moral or racial objections<sup>27,28</sup>, the press has basically supported the policy, with concerns expressed only about Norplant's failure to protect users from sexually transmitted diseases (STD), including AIDS.<sup>29-31</sup> These concerns are valid, based on the high rate of gonorrhea infection in teen-age girls as compared to older women.<sup>32</sup>

### **Cost of Norplant**

Norplant can cost up to \$700, which includes purchase price of the implant and physician charges for insertion and removal. Medicaid pays the cost of Norplant in all fifty states for women on welfare.<sup>33</sup> For those not eligible for Medicaid, i.e., "working poor," Maryland budgeted \$1 million for Norplant and Depo-Provera (a 3-month injectable birth control drug), with an unexpected high demand for these products during the first three months of the state's program.<sup>34</sup>

For indigent women living in other states, Norplant's manufacturer established

The Norplant Foundation, described as "a charitable, non-profit foundation committed to improving voluntary access to Norplant for American women." Eligibility is based on annual income, lack of insurance coverage for contraception, and a physician willing to waive the insertion and removal fees.<sup>35,36</sup>

Although the initial cost of Norplant to U.S. women approaches \$700, the annualized (per year) costs of Norplant may be significantly higher in some women. With a first year removal rate in the range of 20%, many women do not achieve the five years of contraception promoted to them by Wyeth. With the costs of difficult surgical removal of the implant, or administration of additional drugs, e.g., estrogens or combination oral contraceptives, to remedy Norplant side effects<sup>12-14</sup>, the yearly cost of Norplant may actually surpass that of oral contraceptives. These hidden costs are not factored into Wyeth's idealized cost estimates for Norplant use.<sup>33</sup>

### **Coercive and Deceptive Use of Norplant**

Less than one month after Norplant's U.S. licensing a California judge sentenced a 27-year-old pregnant mother of four children to have the birth control rods implanted as part of a criminal sentence for beating two of her children.<sup>37</sup> Three months after the sentence this judge, who prided himself on "creative sentencing"<sup>38</sup>, removed himself from the case due to the nationwide attention, including an American Civil Liberties Union supported appeal.<sup>39-46</sup>

Later that year a Texas judge ordered a 23-year-old woman to use Norplant after her baby was born with methadone in his blood.<sup>47</sup>

This sort of "creative sentencing" prompted several state legislatures to discuss financial incentives for women on welfare to use Norplant, or make welfare contingent on Norplant use.<sup>48-53</sup> A bill was even introduced in Ohio which would have required Norplant or tubal ligation for women, or vasectomy for men, if the family had a child and received welfare benefits for their support. Parents would have faced jail for refusing sterilization or Norplant.<sup>54</sup>

The American Medical Association decried this government pressure, stating, "Court-ordered use of long-acting contraceptives . . . raises serious questions about a person's fundamental right to refuse medical treatment, to be free of cruel and unusual punishment, and to procreate." The AMA also asserted, "Government benefits should not be made contingent on the acceptance of a health risk."<sup>55</sup>

This U.S. coercion reflects several foreign pre-licensing studies, where women were not properly warned of Norplant-associated risks, or were refused removal of the rods when requested.<sup>56-59</sup>

Concerns were also expressed that Indonesian medical authorities do not know the identities of women with Norplant who are due for its removal. The chance of ectopic pregnancy is reported to increase if the rods are not removed after five years, resulting in possible Fallopian tube rupture with potential fatal internal hemorrhage. These women are called "walking time bombs," because many live in remote areas lacking medical care.<sup>60</sup>

## Difficulty in Norplant Removal and Class Action Lawsuit

As expected, based on experience with other contraceptives,<sup>61</sup> a class action lawsuit was filed September 13, 1993 in Illinois on behalf of women severely or permanently injured by Norplant. The amended complaint, filed on November 5, 1993, alleges that the manufacturer failed to warn "about the difficulty of (NORPLANT) removal," and as a result, women "... were damaged... and... will require continuing medical care due... to the difficulty with removal of Norplant."<sup>62</sup>

The complaint details the unfavorable experiences of four women with Norplant. One woman suffered "interrupted and/or heavy and continual menstrual flow, nausea, weight gain (20 pounds), and severe headaches." Sixteen months after Norplant insertion, the physician, who unsuccessfully attempted to remove the rods, closed the incision and told her to return again. Three months later, and after two additional failed attempts to remove the rods, she was forced "to undergo surgery, under a general anesthetic... to remove the Norplant implants," and now "has severe scarring..."

A second woman gained eighteen pounds, developed menstrual irregularities, excessive hair growth, acne, and emotional side effects (irritability) during her thirteen-month use of Norplant. The more than two-hour implant removal surgery required two separate incisions. Her arm was "bruised and sore," and "... left with two ugly scars." She continues to consult a dermatologist for the acne.

During a third woman's seventeen months on Norplant she "experienced abnormally long menstrual cycles," which progressed to lack of menstrual cycles," which progressed to lack of menstrual cycles, "... hot flashes, headaches, and a numbness and pain in her left arm" so severe that "she could not pick things up with her left hand..." Although she sought removal of the Norplant rods fifteen months after insertion, doctors were unsuccessful in removing them, even after nearly 1½ hours of surgery. Two months later two more surgeons finally removed the implants through two separate incisions. She now has "severe scarring" after the two painful removal surgeries.

A fourth woman's Norplant experience included "excessive bleeding for two weeks" (after insertion), with "nausea, dizziness, weight gain, ... migraine headaches, diminished sex drive, (and) ... irritability" for the thirteen months the Norplant rods were in her body. Four months after insertion she complained to her doctor about the side effects, and was told twice to wait for two months (an additional four months). She finally demanded removal of the Norplant rods ten months after they were inserted.

Dependent on public assistance she was told that the clinic lacked government funds for Norplant removal, and to wait three more months until the next fiscal year. During these three months she failed to find a physician who would remove the implants. When government funds became available, she returned to the clinic and underwent 1½ hours of surgery to remove only two of the six implants. The next month she endured three more surgeries, one lasting 3½ hours with eight injections of anesthetic, yielding removal of only one implant. Another surgical attempt failed to remove any of the three remaining implants. She was

referred to a specialist who recommended surgery under general anesthesia. Nearly five months after asking for Norplant removal, the fourth surgery removed the remaining three implants. She now has "severe scarring" and arm pain.

The suit accuses Norplant's manufacturer, Wyeth-Ayerst, of nine charges, including "negligence" and "consumer fraud," asks that Wyeth improve its warnings to women, and devise a "sufficient training program" for those who insert Norplant. The plaintiffs ask that a compensation fund be established for these and other women (similar to the funds established several years ago for women damaged by intrauterine devices<sup>63-66</sup> and recently proposed for women damaged by silicone gel breast implants<sup>67</sup>).

Considering that the approximately 800,000 U.S. women who currently use Norplant will ultimately seek removal of the implants, it is unknown how many other women will experience problems similar to those in the lawsuit. One could reasonably expect that the longer the implants are in place, the more difficult they might be to remove due to adhesions and scar tissue formation. In fact, it has been recommended that when the implants can not be felt in the woman's arm, or they migrate to deeper tissues, x-ray or ultrasound be employed to help locate the Norplant rods.<sup>68</sup>

At a 1993 contraception conference a Planned Parenthood physician reported that insertion of Norplant rods is usually uncomplicated, but some health care providers have expressed difficulty in removing them. An obstetrics and gynecology professor recommended use of a curved hemostat to "vigorously break up" adhesions.<sup>69</sup>

### Conclusion

Three years of use in the United States has uncovered the hidden side of Norplant. Nearly all Norplant users will experience side effects, forcing early implant removal in about one-fifth of them during the first year alone. Implant removal is difficult in some women, possibly involving multiple prolonged surgical attempts, including surgery under general anesthesia, leaving unsightly scars. In addition, Norplant has not proven to be the solution to the moral and social problem of teenage out-of-wedlock pregnancy, as was predicted, nor does it protect against STD's. For many women Norplant has been a disappointment, if not an abject failure.

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