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they get the more pressing become their medical needs; yet few of these older people are in position to pay large hospital and medical bills. Many people in these age groups are not insurable, or insurable only at very high rates. All of these problems will increase pressure for federal interest and federal aid in medical care.

Rapidly changing medical techniques, rising costs of medical care and the increasing demand that more medical care be made available to all segments of the public will undoubtedly promote further experimentation with forms of medical practice. The real threat to the physicians' independence is not prepaid service-type medicine. Rather, it is that private groups who are currently sponsoring such programs may yield to the temptation of thrusting the burden on government. To the layman the questions involved in such programs are essentially issues not of medical ethics, but of medical economics. Only by meeting these questions in terms of the real issues can organized medicine contribute to their solution. By assuming leadership in experiments with new and unproved systems of practice and payment organized medicine can best insure preservation of the profession's essential interests and independence.

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Progestational Steroids: Some Moral Problems

John J. Lynch, S.J.
Professor of Moral Theology
WESTON COLLEGE, WESTON, MASS.

EDITOR'S NOTE. Physicians now have at their disposal certain new drugs which apparently are proving effective in the correction of various gynecological disorders. But because these drugs can also inhibit ovulation and consequently produce a state of sterility until withdrawn, some of our doctors have raised the question of the licitness of prescribing them for their patients. Accordingly we have asked Father Lynch to comment on the drugs in question from the moralist's point of view.

SOME SIX years ago Dr. Benjamin Sieve claimed rather spectacular success with phosphorylated hesperidin as an oral contraceptive agent.1 Taken each day in tablet form and in specified quantities, this compound would allegedly after ten days produce a state of sterility which would then last as long as the medication was continued, and which could be reversed simply by discontinuing the drug. The sterilizing effect was reportedly achieved by creating a viscous barrier around the ovum, making it immune to the penetrating properties of spermatozoa. After experiments conducted on some three hundred couples, Dr. Sieve claimed 100% effectiveness for his oral contraceptive, and also maintained that two hundred and twenty of the wives involved conceived within three months after discontinuing the medication.

Whether or not the claims made by Dr. Sieve are scientifically sound, the method he proposed is at least in theory typical of one possible form of physiologic fertility control, viz., a medication whose one and only purpose would be to induce a temporary state of sterility for patently contraceptive reasons. With regard to this generic type of fertility control there can be no doubt in the moral order: since the one and only immediate effect of such medication would be temporary sterility, its use would necessarily be condemned as an illicit form of sterilization, in accordance with the teaching of the Church that direct sterilization of man or woman, whether perpetual or temporary, is forbidden by natural law. Furthermore, since the only conceivable reason for taking such medication would be to prevent conception by disrupting the natural post-coital processes, the practice would also assume the malice of onanism, and would consequently

be a violation not only of the Fifth Commandment but also of the Sixth. The same must be said of any form of physiologic fertility control whose one and only effect would be to induce sterility.²

MORE RECENT DEVELOPMENTS

In more recent years, however, attention has been focused on the progestational steroids which likewise are capable of inducing sterility by inhibiting ovulation. But as antifertility factors these compounds both medically and theologically distinct from the previous type insofar as they are of their nature calculated to produce not only the effect of temporary sterility but also other immediate effects which in themselves are the legitimate objects of direct intent, e.g., the correction of certain menstrual disorders. Consequently the moral question which immediately arises is this: would the use of these drugs in some circumstances admit of legitimate application of the principle of double effect?² In other words, are there practical medical situations in which their use for a legitimate purpose could be justified, even though temporary sterility would also be necessarily but unintentionally induced?

Before answering that question, a priori perhaps should be made specific to our understanding of the nature and function of the drugs in question, which already can be identified by various trade names according as one or another pharmaceutical house has produced its own version. Enovid, the product of G. D. Searle & Co., can best serve as an example, since authoritative reports on the use of this compound appear to be the most abundant of any.

Enovid is a synthesized steroid which exercises progestational activity within the reproductive system. One gathers, in other words, that these synthetic hormones produce artificially many of the effects which would be caused naturally by the hormonal balance which is characteristic of the period of pregnancy. One of these effects provided for by nature during that would constitute a legitimate second result directly imputable to antifertility pills or serums, then that will be the time to consider the possibility of indirect sterilization." Since the drugs now in question do supposedly admit of a legitimate therapeutic use, recourse here to the principle of double effect does not represent a change in principle but rather a change in the medical facts of the case.¹

My information regarding Enovid is taken for the most part from Proceedings of a Symposium on 19-Nor Progestational Steroids (Chicago: Searle Research Laboratories, 1957) and from the same company's reference manual. No. 67: Enovid. The Proceedings of a second conference on the same topic, held in New York some months later, should be obtainable from Searle by the time this article appears in print.

CONTRACEPTIVE USE

When used designedly for contraceptive purposes, the Enovid regimen is begun five days after the onset of menstruation and a prescribed dosage is taken daily for twenty consecutive days. Medication is then interrupted to allow the next menstruation to take place, and bleeding usually occurs within two or three days after withdrawal. This 20-day cycle of medication is then repeated over as long a period as conception remains undesirable. Fertility may be restored simply by discontinuing the treatment. And the Puerto Rico experiment with Enovid, begun in early 1956, has provided some amount of evidence favoring the effectiveness of this type of drug as a contraceptive agent. This is Dr. Edris Rice-Wray's own resume of a report which he submitted in January, 1957:

Two hundred and twenty-one mothers of less than 40 years of age, living in a slum clearance area in Puerto Rico, have been on Enovid for one month to nine months. Adding the time on the medication of those who were on it three months or more, there was a total of forty-six patient years. There were no method failures. There were seventeen patient failures because they dropped the medication; eight of these had reactions.

Seventeen per cent of the patients had reactions. Twenty-five patients withdrew from the study because of reactions. The most typical complaint was dizziness, nausea and headache. Dr. Rice-Wray's conclusion: Enovid gives 100 per cent protection against pregnancy in 10-mg. doses taken for twenty days of each month. However, it causes too many side reactions to be acceptable generally.⁶

Over and above these immediate side effects — which eventually perhaps can be eliminated — the long-term reactions to drugs such as these, if used continually over a long period of time, is a problem yet to be faced. One gets the impression that many doctors are frankly fearful of what nature's penalty may be for tampering in this way with so delicate a mechanism as the human reproductive system. Another incidental but very practical problem is that of expense. At present, for example, one month's supply of Enovid would cost eleven dollars. But to a limited extent the oral contraceptive seems to be already a reality of sorts, although it may be a long time, if ever, before these products will be sold over the counter without a doctor's prescription.

It should be altogether clear that if progestational compounds are employed designedly in order to prevent conception, their use is contrary to moral law. As ex-
In these latter instances, the principle of double effect must be applied. That principle, as it pertains generally to procedures which induce sterility is aptly expressed in no. 31 of the Directives:

**Procedures that induce sterility, whether permanent or temporary, are permitted when:**

- a) they are immediately directed to the cure, diminution, or prevention of a serious pathological condition;
- b) a simpler treatment is not reasonably available; and
- c) the sterility itself is an unintended and, in the circumstances, an insignificant consequence.

If these three conditions are fulfilled in a given case, neither the doctor nor the patient need hesitate to make use of Enovid or similar compounds. If any one of the conditions cannot be verified, the induction of even temporary sterility would be morally unjustified.

**PRACTICAL RULES**

Perhaps the following questions would prove helpful for determining in particular instances whether these requisite conditions for legitimate recourse to the principle of double effect are fulfilled. The doctor's honest answer to each of these questions will provide the basis for a sound moral decision.

a) "According to sound medical judgment, is my patient suffering from some pathological condition sufficiently serious to warrant the use of this medication?" Beyond question there can be and are menstrual disorders which qualify as serious pathology for disturbances of menstruation will not go wrong as far as this first condition is concerned.

b) "Is there conveniently available any simpler treatment which would be satisfactorily effective in correcting this condition?" By 'simpler' treatment in this context is meant principally one which would not result in even temporary sterility. If such a medication were reasonably available and would be satisfactorily effective, there would be no necessity and hence no justification for employing a procedure which results in temporary sterility. Thus, for example, if a particular ailment would submit to Enovid administered on the 10-day regimen (i.e., from day fifteen to day twenty-five of the menstrual cycle and terminated on day twenty-five) it would prove helpful for determining in particular instances whether permanent or temporary sterility would be morally unjustified.

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8 Searle & Co., Enovid, p. 16.
9 Ibid., pp. 13-16 passim.

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of the menstrual cycle, there would be no adequate reason to prescribe the medication on the monthly 20-day schedule which inhibits ovulation. However, if the physician sincerely judges that only the longer cycle of medication will prove effective, he need not hesitate to prescribe it after explaining to his patient that temporary sterility will be one of the side effects of this treatment. It need scarcely be said that medication should not be continued longer than is necessary to correct the pathology for which it was begun. Nor should it be continued after it has proven certainly ineffective as a remedy or control in unresponsive cases.

c) "Can I honestly say that contraception is excluded from my intention when prescribing this medication?" When dealing with genuine menstrual disorders, the sincere and conscientious doctor should have no difficulty in answering this question in the affirmative. In fact, if he has given himself honest answers to the first two questions, there is hardly need to propose this one. Provided that he is intent on relieving some truly pathological condition for which no simpler remedy is available, it is not likely that this third condition would prove a hazard to the moral principle.

"OVULATION REBOUND" and Contraception: *

There remains to be considered: if the alleged "ovulation rebound" phenomenon is a scientific reality, would the use of Enovid for this purpose present any difficulty? For it would appear that sterility in this case is achieved by first suppressing ovulation as a means to a further end and that consequently the suppression of this function is directly intended.

It is not as yet certain that all theologians would agree on the ultimate answer to this question. Only subsequent theological discussion will reveal what differences of opinion there may be. But there would seem to be valid reason for suggesting that the use of Enovid in this way does not contravene the prohibition against direct sterilization.

First, it should be noted that it is not precisely the direct suppression of ovulation which is forbidden as intrinsically wrong, but rather is it the resultant sterility, or inability to procreate, which may not be the direct object of one's intention. That the two are not entirely identical is clear; for example, in the case of a woman who has already undergone hysterectomy. Ovariectomy, if subsequently performed on this woman, surely could not be called sterilization in any proper sense of the word. So, too, in cases where ovulation rebound might be attempted in the infertile woman. Would it not be totally unreal to speak of sterilizing a person who for practical purposes has proven himself to be already sterile, i.e., capable of conceiving? Chiefly for this reason I would venture the opinion that for purposes of solving infertility problems the use of Enovid to induce ovulation rebound is morally acceptable.

12 One gynecologist, who was kind enough to read this article in typescript, offered this comment: "I also wonder if the alleged 'ovulation rebound' phenomenon is a scientific reality. I would be inclined to believe that the patients who conceived after Enovid therapy did so because undiagnosed endometriosis (which is a notable cause of infertility) was controlled by the therapy, allowing pregnancy to occur after the withdrawal of the drug." If the doctor's suspicion should prove correct, these cases present no special moral problem, for medication could then be directed to the control of endometriosis, while the suppression of ovulation could qualify as an incidental side effect of therapy.