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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 But because these drugs can also inhibit ovulation and consequently produce a state of sterility until withdrawn, some of our doctors have raised the question of the licitness of prescribing them for their patients.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

[1] "A New Antifertility Factor," *Science* 116 (Oct. 10, 1952) 373-85.

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 are 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?[3] In other words, are there

[2] For a more detailed moral appraisal of Dr. Sieve's method of fertility control, cf. J. J. Lynch, S.J., "Fertility Control and the Moral Law," LINACRE QUARTERLY 20 (Aug., 1953) 83-88. and "Another Moral Aspect of Fertility Control," *ibid.* (Nov., 1953) 118-22.

[3] In the first of the two articles cited in the previous footnote, this conclusion will be found (p. 87) regarding phosphorylated hesperidin as an antifertility factor: ". . . in the light of currently available data regarding proposed methods of fertility control, it is simply impossible to justify their use as an instance of double effect. There just is no second effect involved. The sole intrinsic purpose . . . of such therapy is contraceptive, and no other direct effect, which could be admitted as licit, has yet been seriously alleged. If . . . physicians should ever discover any genuine therapeutic value

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 moralist perhaps should be more specific as to his 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 dur-

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.

[4] 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.

ing gestation is the suppression of ovulation in the expectant mother. Without further ovulation, obviously, there can be no further conception. Once pregnancy is terminated, hormonal activity reverts to the predominantly estrogenic, ovulation resumes, and conception is again possible. These synthetic hormones, therefore, can produce in the non-pregnant woman the same contraceptive effect which nature itself provides during actual gestation.

CONTRACEPTIVE USE

When used designedly for contraceptive purposes,[5] 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 résumé 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.[6]

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."[7]

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-

[5] Cf. Edris Rice-Wray, M.D., "Field Study with Enovid as a Contraceptive Agent," *Proceedings etc.*, pp. 78-85.

[6] *Art. cit.*, p. 85.

[7] *Ibid.*

pressed in no. 33 of the *Ethical and Religious Directives for Catholic Hospitals*:

> **All operations, treatments, and devices designed to render conception impossible are morally objectionable. Advising or otherwise encouraging contraceptive practices is not permitted.**

From the moralist's viewpoint there is no essential difference between a medication whose one and only effect is contraceptive and a medication whose effects may be plural but which is employed with the direct intention of producing its contraceptive result.

LEGITIMATE USES

However, the majority of doctors who are currently making use of Enovid and allied products are prescribing them for purposes which are entirely legitimate. These drugs, for example, have apparently proven remarkably effective, after several months' treatment, in the control or correction of certain serious menstrual disorders. Amenorrhea, metrorrhagia and menorrhagia, oligomenorrhea, dysmenorrhea, premenstrual tension — all have reportedly been successfully treated with the progestational steroids. Another feature attributed to Enovid is its potential as a positive aid to fertility. In some cases, for instance, with women whose cycles had previously been anovulatory, ovulation was stimulated after several months of treatment and conception thereby made possible. Finally, in a limited number of infertile women with a history of normal ovulation, the so-called "ovulation rebound" has been observed. Over a period of several months ovulation was totally suppressed. The medication was then withdrawn and within a few months a significant number of these previously infertile women had achieved pregnancy.

Beyond any doubt these effects are legitimate objects of one's direct intention. The only question which remains is this: is one justified in achieving such effects by means of medication which is also antiovulant?

In a number of cases in which Enovid would be prescribed, there would appear to be no moral problem whatsoever, since the medication is taken only at such times during the cycle as would still permit ovulation. Thus, for example, in the treatment of premenstrual tension and inadequate luteal phase, the recommended dosage is begun on day fifteen of the menstrual cycle and terminated on day twenty-five.[8] On this regimen ovulation will normally have occurred in each cycle before medication is resumed. Since in these cases there is no question of inducing even temporary sterility, no moral reason can be advanced against this particular cycle of medication when medically indicated.

But when dealing with certain other disturbances of menstruation, a 20-day regimen — from day five to day twenty-five — is apparently considered either necessary or preferable,[9] and in these cases ovulation will be made impossible. In order to determine the licitness of using Enovid and similar products 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 unavoidable effect.**

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 seriously pathological in the sense that they involve considerable pain, discomfort, disability, or other inconvenience for the patient. "Serious" in this context certainly does not mean that any danger of death need be involved. It suffices that the patient's ailment be of such a nature that competent medical judgment would conclude that relief is advisable even at the cost of temporary loss of the reproductive function. Some menstrual disorders are such as to justify even hysterectomy and consequent irreversible sterility.[10] Far less serious pathology would be required to justify temporary sterility as the indirect result of a procedure immediately directed to relief from pain or from some other considerable inconvenience. The medically honest doctor who prescribes Enovid or similar drugs *only as medically indicated* 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

[8] Searle & Co., *Enovid*, p. 16.

[9] *Ibid.*, pp. 13-16 passim.

[10] Cf. Gerald Kelly, S.J., *Medico-Moral Problems* (1958 edition) pp. 206-217; or Vol. I of the original 5-booklet edition, pp. 30-34. (For details of the 1-volume revision of Fr. Kelly's work, see advertisement in this issue of LINACRE QUARTERLY.)

of the menstrual cycle), there would be no adequate reason to prescribe the medication on the monthly 20-day schedule which inhibits ovulation.[11] 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 doctor of principle.

[11] Under the heading "Clinical Applications and Dosages," the Searle manual *Enovid* (pp. 13-16) several times uses this type of direction: "Such patients should receive one tablet daily from the fifth or from the fifteenth to the twenty-fifth day, depending on the importance of maintaining ovulation in individual patients." Since this statement as it stands is morally ambiguous, I can only repeat that if the shorter cycle of medication is effective as a remedy, it must be chosen in preference to the 20-day regimen. Otherwise one would equivalently be directly intending sterility.

"OVULATION REBOUND"

One further doubt remains to be resolved: 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 fertility 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 all practical purposes has proven herself to be already sterile, i.e., is incapable 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 above reproach.[12]

[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 prenancy 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.