MORAL ASPECTS OF PHARMACEUTICAL FERTILITY CONTROL

It is certainly no news to anyone present that serious research has been conducted in recent years in an effort to produce an oral contraceptive which would be effective, inexpensive, medically safe, and conveniently simple. With certain reservations it can be said that this research, from the contraceptionist's point of view, is proceeding satisfactorily. Although the ideal oral contraceptive has not yet been perfected—and perhaps may not be for some years to come—the moral question which it poses is no longer merely an academic one. However, one consoling feature as far as we are concerned is the seeming fact that physiological fertility control presents neither an especially new nor an especially complicated moral problem. Once the moralist is properly informed on the elemental medical facts in the case, it should not be difficult to come to certain very definite conclusions as to the liceity or illiceity of using various drugs which allegedly have an inhibiting effect on the human generative system. It is my function this afternoon, as I understand it, merely to review briefly the pertinent medical facts of the question. That data, I think, will bring into focus several distinct moral problems, each one of which will then submit rather easily to its proper moral principle.

Since this topic was assigned for discussion here, at least two articles have appeared which go a long way toward providing the theologian with the essential facts he needs. Most of you doubtlessly have read in the April issue of *American Ecclesiastical Review* the article, "Physiologic Control of Fertility," by William J. Gibbons, S.J., and a layman, Thomas K. Burch. Father Gibbons for several years had taught ethics and economics at Loyola College in Baltimore; during this past year he has been completing the requirements for a doctorate in economics at New York University, while also lecturing in demography in the graduate school of Fordham University. His interest in population problems is one of long standing. Mr. Burch is currently a candidate for a doctor's

degree in sociology at Princeton University. In my opinion their article is most valuable. Without becoming technical beyond the understanding of the non-scientist, it explains quite clearly the physiological processes which are affected by various antifertility factors. For anyone who is interested in an even more technical treatment of the biochemistry involved, the article provides abundant references to the scientific literature. And, finally, moralists in general would very probably agree quite readily with the substance of Father Gibbons' moral conclusions as based on the facts presented.

The magazine *Fortune* in its April issue carried a very informative article on the current factual state of the question—for the most part a report on the drugs already being produced by several pharmaceutical houses and on the results of various experiments conducted by medical authorities. The article is of the calibre to be expected of such a publication as *Fortune*—apparently accurate as far as it goes, but careful not to exceed the scientific limitations of the intelligent layman. Its one short paragraph devoted to the Catholic position on contraception and rhythm and on our presumed reaction to these newer methods of fertility control, is inoffensive and remarkably accurate, although by no means sufficiently detailed.

For anyone with a flair for chemical symbols, graphs, tables, and statistics, I would recommend the *Proceedings* of a symposium conducted early in 1957 in the Searle Research Laboratories. Also the *Proceedings* of a similar conference held in New York in October 1957 under the auspices of the New York Academy of Sciences. Both publications can be obtained from the Searle Research Laboratories in Chicago. Ultimately, of course, the accuracy of our factual knowledge and the wisdom of our moral judgments on these problems depend on such studies as these. But without involving ourselves in chemical formulae and symbols, I think we can extract from reports such as these information sufficient for the formulation of sound moral opinions.

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Up to very recent times contraceptive devices have been designed in such a way to leave intact the functioning of both the

male and female reproductive apparatus, while preventing, by means of physical or chemical barriers, the ultimate union of spermatozoon and ovum. The condom, for instance, establishes a physical barrier preventing the ejaculate from entering the vagina; the occlusive pessary permits intravaginal semination, but blocks off the cervix; various spermicidal agents, introduced intravaginally either before or immediately after conjugal relations, are calculated to destroy the spermatozoa and thus preclude spermigration. None of these devices is entirely indefectible; none is altogether convenient. All of them manifest certain so-called esthetic disadvantages which simply cannot be totally eliminated from this type of contraceptive. Hence the reason for this present research and experimentation in physiologic fertility control. (The Ortho Pharmaceutical Company, which accounts for approximately two-thirds of the 200-million dollars' worth of contraceptives sold annually in this country, is said to be now spending about seventy-five per cent of its research budget on physiological studies with an eye to the development of an oral contraceptive.)

The objective at present, therefore, is to eliminate the necessity of chemical or physical devices at the time of intercourse. This they are trying to accomplish by inducing certain reversible physiological changes in the reproductive system of the individual male or female. The idea roughly is this: (1) to find in the total complex chain-process of generation, either in the male or female, the vulnerable link which can most easily, most safely, and most effectively be controlled; then (2) by means of some serum, or preferably by some oral medication, to break that essential link in the generative process in such a way that natural conjugal intercourse may be indulged in without any possibility of subsequent conception. It is most correctly called *physiologic* control of fertility because it achieves its purpose by suppressing or diverting *ab intrinseco* some natural generative process. And it is termed *control* of fertility because what is desired is a contraceptive effect which is reversible at will simply by discontinuing the medication in question. Obviously it is a form of sterilization, but it seeks to avoid the finality, the perpetuity, of the more common forms of sterilization.

Because of the complexity of the total generative process, the possibilities of fertility control are multiple. There might, for example, be developed a medication which would inhibit spermatogenesis in the male, or which would destroy the motility of spermatozoa and thus prevent their migration beyond the vagina. In the female, ovulation could be suppressed; changes might be induced in the lining of the fallopian tubes so that an ovum when released would find a medium unfavorable to life or motility; or there might also be effected modifications in the cervical discharge which would make it hostile to sperm in the vagina and have the same effect as chemical spermicides; or the ovum might be made impregnable against spermatozoa. Even after fertilization of the ovum has taken place, the process of nidation might be prevented or disrupted by inhibiting the natural changes which are necessary for that purpose within the uterus. Those and other possibilities have all been considered by scientists.

What actually has been accomplished along these lines?

Some six years ago a Dr. Benjamin Sieve of Boston claimed rather spectacular success with phosphorylated hesperidin as a contraceptive agent. Taken orally each day in pill form and in specified quantities, this compound allegedly would 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 supposedly achieved by creating a viscous barrier around the ovum, making it immune to the penetrating properties of spermatozoa. Dr. Sieve at the time claimed 100% effectiveness in experiments conducted on some 300 couples, and also maintained that 220 of the wives involved conceived within three months after discontinuing the medication. First reactions tended to be rather skeptical; and yet references to Sieve's report will still be found in serious literature on the subject. Whether experiments along this particular line are still continuing, I frankly don't know. At least it can safely be said that this approach is not the one which has received most publicity.

But regardless of the scientific validity of the claims made by Dr. Sieve, the method he suggested is typical of one form of physio-

logic fertility control, viz., a method whose one and only purpose, *ex fine operis* and consequently also *ex fine operantis,* would be to induce a temporary state of sterility for contraceptive purposes. We would all certainly agree that with regard to this 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 the natural law. Furthermore, since the only conceivable reason for taking such medication would be to avoid conception, 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.

A second type of medication, likewise in the experimental stage, is directed against the *fertilized* ovum. This method is calculated to prevent nature's preparation of the endometrium as a fit receptacle for the impregnated ovum as it descends from the fallopian tube. The result is to make nidation impossible; and the fertilized ovum, instead of burrowing into the uterine lining as it should, is forced to pass on and is either resorbed or aborted before it can begin its uterine existence. Ergotoxine is believed to have such an effect, although exactly why and how is not entirely clear. Other compounds (antimetabolites) produce essentially the same results by the effect which they have on metabolism. It should be clear, I think, that drugs such as these are outright abortifacients, and that their use would entail the calculated malice of feticide.

Still a third generic type of antifertility factor is the one which has been most publicized in recent years. The element which distinguishes it from the preceding two is the plurality of immediate effects which it is capable of achieving, as opposed to the single effect produced by the others already mentioned. The common denominator in all three types is one result which all are capable of producing—sterility; and this, perhaps unfortunately, is the aspect which has been most publicized in the popular literature.

But this third category admits also of other immediate effects which in themselves may be legitimately accomplished by direct intent. Consequently the question which immediately arises is obviously this: would the use of these drugs, *servatis servandis,* admit of legitimate application of the principle of double effect? Are there practical situations in which their use for a licit purpose could be justified, even though temporary sterility would also be necessarily induced?

The answer would appear to be yes. Beyond doubt there are actual medical situations in which one can verify the conditions postulated in the principle of double effect. In order to visualize those situations, perhaps we should be a bit more specific about 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. Searle has developed ENOVID and is currently testing it not only for its potential value in the correction of certain gynecological disorders but also as a contraceptive. Parke-Davis uses the trade name NORLUTIN and allegedly claims that its policy is to stay out of the contraceptive field, and that NORLUTIN will never be recommended or even tested as a contraceptive. However, the labeling required by the Food and Drug Administration will make it clear to any doctor that NORLUTIN is antiovulant. Squibb has a similar product, DELALUTIN, which is administered by injection.

Essentially identical, these drugs are synthetic hormones which exercise progestational activity within the reproductive system. In other words, they have many of the same effects which would be produced naturally by the hormones characteristically predominant immediately after ovulation and also during pregnancy. One of those effects, provided for by nature during 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, produce artificially in a non-pregnant woman the contraceptive effect which nature itself provides during actual gestation.

When used for contraceptive purposes, ENOVID is administered according to this regimen. Beginning about five days after the onset of menstruation, a prescribed dosage is taken daily for twenty days. The medication is then interrupted to allow the next menstruation to take place, and bleeding occurs within two or three days of withdrawal. This 20-day cycle of medication is then repeated over as long a period as conception remains undesirable. At any given point fertility may be restored simply by discontinuing the treatment. And the Puerto Rico experiment with ENOVID, begun in early 1956, has provided rather convincing 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 of 1957:

> Two hundred and twenty-one mothers 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.
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> 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% 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."

Over and above these immediate side effects—which eventually perhaps can be eliminated—many doctors are frankly fearful of the long-term reactions which such drugs as these may induce. As one doctor expressed it: "You can't tamper over a long period of time with so delicate a mechanism as the human reproductive system without risking serious consequences." Only time will tell what those consequences might be. Meanwhile the oral contraceptive seems to be to a limited extent a reality, although it will be a long time, if ever, before these products will be allowed to be sold over the counter without a doctor's prescription. (Another incidental

but very practical problem to be solved is that of expense: at present a month's supply of ENOVID would cost $11.00.)

So much for the contraceptive aspect of these compounds. What legitimate uses would they have?

First, they have apparently proven remarkably effective, after several months' treatment, in the correction or control of certain menstrual disorders of a serious nature. Amenorrhea, oligomenorrhea, metrorrhagia and menorrhagia, dysmenorrhea, premenstrual tension—all allegedly have been successfully treated by this means. There seems to be some reason for hoping that the same treatment will prove effective in rectifying irregular menstrual cycles. Beyond any doubt, these are legitimate objects of direct intention. The licitness of achieving such effects by means of medication which is also antiovulant would have to be determined according to the requirements of the principle of double effect. I am quite sure that we will readily come to agreement on this phase of the question.

Another and perhaps most tantalizing feature of ENOVID and allied products is their potential as a positive aid to fertility. This aspect of the problem has several variations. In some cases, for example, habitual aborters have been submitted to this type of medication during pregnancy; and these pregnancies, unlike previous ones, were successfully brought to term. In other instances, with women who previously had not been ovulating, ovulation was stimulated and conception thereby made possible in the same way. Still another phenomenon, which is perhaps theologically most fascinating of all, is the so-called "ovulation rebound." This has been observed in a limited number of infertile women with a history of normal ovulation. Over a period of three months ovulation was totally suppressed. The medication was then withdrawn and within a few months a significant percentage of these previously infertile women had achieved pregnancy. Again we have an ultimate effect which unquestionably may be the licit object of direct intention. The problem for discussion, it would seem, is whether the means employed to achieve that effect is licit.

But in order not to pre-empt any more of our time, let me conclude by summarizing what appears to be our status quaestionis as regards pharmaceutical fertility control. For our purposes, I

would suggest, the possible variations of physiologic control of fertility are reducible to three, or perhaps to only two:

(1) Drugs whose one and only immediate purpose (*finis operis*) is to induce temporary sterility by suppressing or diverting some generative function. Their use, it would seem, can be dismissed without further discussion as patently contraceptive, contrary to both the Fifth and Sixth Commandments, and absolutely forbidden.

(2) Drugs whose one and only purpose is to prevent the natural development of the already fertilized ovum. The only reason for distinguishing this type from the first is to remark the malice of feticide which it entails. Otherwise, I should think, such drugs also can be immediately dismissed as illicit, since their single immediate purpose is to prevent gestation by destroying embryonic life.

(3) Drugs which *ex fine operis* admit of a plurality of effects, one of which (temporary sterility) may not be directly intended, the others of which are in themselves licit objects of direct intent: the correction of menstrual disorders, promotion of fertility, etc. Here, as I see the problem, is our proper area of discussion. If I may specify it a bit more in detail, we might ask such questions as these:

(a) *Servatis servandis,* would not the principle of double effect be applicable to the use of antiovulant drugs for the correction of serious menstrual disorders? Competent and conscientious physicians will admit that such treatment is at present quite frequently the preferred medical solution.

(b) In cases of irregular cycles of ovulation, would the principle of totality, combined with the principle of double effect, suffice to justify the temporary use of antiovulants if they should prove effective in regularizing the cycle and could thus make possible an effective use of rhythm under the usual conditions?

(c) In instances where, despite normal ovulation, women have proven infertile, do our moral principles allow temporary suppression of ovulation in an attempt to produce the so-called ovulation rebound phenomenon?

JOHN J. LYNCH, S.J.,
Weston College,
Weston, Mass.

Digest of the Discussion:

Father Anthony Zimmerman, S.V.D. (St. Mary's Seminary, Techny, Ill.), while admitting as permissible temporary use of antiovulants in order to correct menstrual irregularity, questioned the right of a married woman to use them constantly, thus permanently avoiding conception. Father Lynch here made two preliminary observations: (1) that up to the present there appears to be relatively little evidence that these drugs will de facto correct irregular cycles; and (2) that in the majority of cases in which these hormones are prescribed for other gynecological disorders, it would seem that three or four months only on the medication is the practice generally followed. On these suppositions, he was inclined to suspect of contraceptive intent the informed woman who, merely for the reason here alleged, would continue to use the drugs constantly over a long period of time.

This fact, however, was emphasized by *Father Gerald Kelly, S.J.* (St. Mary's College, Kansas): apart from mere irregularity there are other menstrual disorders, such as those mentioned in Father Lynch's paper, which can be severely painful, debilitating, or otherwise gravely inconvenient. Some cases, in fact, are serious enough to warrant even hysterectomy with its consequent irreversible sterility. Provided that there is no contraceptive intent, reason considerably less serious would suffice to justify a relatively brief period of sterility, such as three or four months. And if long-term medication is necessary in order to cope with a grave pathological condition, the concomitant long period of sterility can also be justified according to the standard stipulations of the principle of the double effect.

Father Joseph Mangan, S.J. (St. Mary of the Lake Seminary, Mundelein, Ill.) expressed as his opinion that a couple who have sufficient reason for making use of rhythm might, in the hope of making the method more safe, use a drug continually to regularize the cycle, provided that they interrupt medication in time to allow ovulation to occur each month. In stating his own agreement, Father Lynch remarked that in the treatment of some menstrual disorders, e.g., premenstrual tension and inadequate luteal phase, the recommended dosage is begun on day fifteen of the menstrual cycle and interrupted on day twenty-five. On this regimen ovulation will normally have occurred in each cycle before medication is resumed. It was Father Lynch's conviction that, if this should be the case when the drug is used for regularizing the cycle, there would seem to be no moral problem.

But on the supposition that ovulation is temporarily suppressed (as would necessarily happen if a monthly 20-day period of medication were observed), *Father Charles O'Leary, C.SS.R.* (Mt. St. Alphonsus, Esopus, N. Y.) questioned the licitness of taking the drugs merely to become as regular as the calendar, since some variation in the cycle is to be considered

quite natural and normal. *Father Robert Kelly, S.J.* (St. Mary's College, Kansas) also expressed doubt as to whether mere irregularity qualifies theologically as a pathological condition toward the correction of which such medication could be immediately directed. What degree of irregularity, he asked, would constitute an anomaly? It was suggested by *Father John Connery, S.J.* (West Baden College, West Baden Springs, Ind.) that normalcy in this regard might be considered roughly to be one ovulation per calendar month, and that any notable deviation from this regularity might legitimately be termed an anomaly. Father Lynch proposed as a rule of thumb that one might judge as abnormal, and hence as legitimate reason for medical intervention, that degree of irregularity which would preclude a reasonably effective use of rhythm—in other words, an irregularity which would prompt a competent gynecologist in a particular instance to advise against rhythm as an effective means of avoiding pregnancy.

In reference to the "ovulation rebound" phenomenon, *Father Thomas Donlan, O.P.* (St. Rose Priory, Dubuque, Iowa) questioned the lawfulness of the procedure on the grounds that the preliminary deliberate suppression of ovarian function—even though undertaken for a legitimate and laudable purpose—would appear to be a direct temporary sterilization. While agreeing that the suppression of ovulation in the circumstances would be directly intended, Father Lynch was unwilling to identify the procedure in this case with sterilization properly speaking. Is it realistic, he asked, to speak of sterilizing a woman who for all practical purposes has proven herself to be already sterile? In the course of subsequent discussion it was suggested 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 necessarily 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 a sterilization in any proper sense of the word. So, too, in cases where "ovulation rebound" might be attempted in the infertile woman: the ovarian function is temporarily suppressed, but the woman cannot be said to be thereby sterilized since she is already sterile.

Father Zimmerman proposed the case of a tennis player whose period is due to occur during the time of a tournament: may she take these drugs in order to postpone menstruation and its concomitant inconvenience? and if married, may she have conjugal relations during the period of induced infertility? Several divergent opinions were expressed in the ensuing discussion, the substance of which is perhaps best summarized in the observations made by *Father John Ford, S.J.* (Catholic University). No one solution, he suggested, would apply to all such

cases. Engaging in athletics on a given day is sometimes objectively very important and sometimes not, as can be exemplified by the professional athlete who thereby earns her living and by the week-end dufferette who plays for fun; likewise the handicap of menstruation at such a time can range from very serious to relatively slight. But Father Ford expressed himself as willing to concede the possibility of circumstances in which both of Father Zimmerman's questions could be answered in the affirmative.

There was general agreement with *Father Eugene Moriarty* (St. Paul Seminary, St. Paul, Minn.) that the pastoral implications of these various problems should not be overlooked. Especially because of the publicity accorded these drugs as potential contraceptives, care should be taken to prevent misunderstandings on the part of the faithful when cases involving these drugs are presented for solution. But it was readily conceded that one should not be denied their legitimate use because of actual or possible abuse on the part of others.

Just prior to the time of adjournment, Father Connery raised the tantalizing question of suppressing ovulation in order to prevent conception after rape. The problem was variously paraphrased by several—including *Father Joseph Duhamel, S.J.* (Woodstock College, Woodstock, Md.), Father Gerald Kelly, and Father Robert Kelly—in an effort to determine the limits of lawful self-protection against the unjust aggression of rape. Does a parallel exist between this case and that of wartime night workers who (licitly, according to a number of theologians) protected themselves with occlusive pessaries against possible conception resulting from rape? May this form of unjust aggression, viz., threat of enforced conception outside of marriage, be repulsed by means which are contraceptive by reason of their being temporarily sterilizing? It was generally acknowledged that the greatest obstacle in the way of a favorable solution to this problem is the apparently absolute condemnation of direct sterilization, whether perpetual or temporary. Thus the meeting terminated with a question mark.

Recorded by: Robert H. Springer, S.J.
Woodstock College
Woodstock, Md.