

Editorial

THE PILL

ELEVEN years ago the first field trial of oral contraceptives was undertaken in Puerto Rico. Today it is estimated that no less than five million women throughout the world regularly take the Pill and there are half a million consumers in this country alone. If there are serious side effects, it is remarkable that in a therapeutic trial of this magnitude no statistically valid evidence of serious ill-effects has yet emerged. After the most careful consideration of all the evidence, clinicians and scientists of impeccable authority have concluded that there is no objection to the widespread use of the Pill.¹

It would be quite wrong, however, to believe that these statements imply that no risk exists. Indeed, such a belief would be unwise in view of all previous experience. Several factors in the present situation must be considered unsatisfactory. Although oral contraceptives have been taken by a vast number of women the observation of their side effects has been uncontrolled, and while it is true that the Pill has been in use for 11 years, few women have taken it continuously for more than a small fraction of this time. The precise proportion of women taking the Pill in any defined community is unknown so that attempts to calculate the incidence of any suspected associated morbidity cannot be accurate. Moreover, there is always the disturbing possibility that there may be side effects which are at the moment totally unsuspected.

Even though present knowledge suggests that the risk of taking oral contraceptives is an acceptable alternative to the risk of unwanted pregnancy, each woman, and her doctor, have a right to know that this risk has been precisely measured. The community too, will need to know much more about the effect of such an efficient and aesthetically acceptable form of contraception on the structure and behaviour of society.

If, then, there is no cause for alarm, there is certainly no reason for complacency. Much of the missing information about the Pill can

be collected only in general practice. The Council of the College has recognized its special responsibility here and has approved the formation of a working party from its research committee to plan the investigation.

An essential step in any such enquiry is to define a population of women who are taking the Pill and to select a control group, similar in age, social status and parity who are not. For those doctors who keep age-sex registers and who make regular returns of all their practice morbidity to the College's Records and Statistical Unit in Birmingham, this is a relatively simple matter. A retrospective study of the contraceptive methods of patients who have had venous thrombosis, and a group of controls will shortly be completed and should reveal valid data about the association of this condition with oral contraception.

Unfortunately, the number of these doctors and their patients is too small to provide comparable information about other less common morbidity. The main effort of the working party has therefore been directed towards the planning of a major prospective study of approximately 20,000 women taking the Pill and an equal number of controls. To obtain such figures the co-operation of at least a thousand practitioners will be required. The demands on the individual doctor will be quite modest but the organization of such a large-scale project will require the establishment of a new central statistical and administrative unit and this will probably be located in Manchester. A wide range of morbidity will be recorded and returns from the participating doctors will be subjected to computer analysis at regular intervals so that any suspicious trends will be revealed as the investigation progresses. Such results may suggest that a particular diagnosis requires investigation in greater detail and the plans are sufficiently flexible to allow for those changes to be made during the course of the study. In this way the unit will be capable of an almost continuous surveillance of the medical problems of oral contraception, and an extension into the social field could be contemplated at a later date.

This will be the most ambitious investigation for which the College has been responsible and its progress will be followed with the greatest interest.

REFERENCE

1. Brain, Lord *et al.* 1964. *Lancet*, 2, 1329.