single office in FDA. These should be in the form of an initial alert on a postal card perhaps, and followed by the completed form when the investigation has been completed or carried on as far as possible by the manufacturer.

2. If copies of these reports are to be distributed to several branches of FDA this distribution should be by FDA and not by the manufacturer.

3. The present FD 1639 form is not adequate for the analysis of oral contraceptive adverse reactions.

4. The initial request for information in the investigations of an adverse reaction should be from FDA on official stationary and signed by a responsible medical officer. If followup and collection of data is to be the responsibility of the medical department of the manufacturer, the initial request should so inform the recipient.

5. The medical officers of the FDA responsible for monitoring adverse reactions, the medical personnel of the pharmaceutical manufacturer having similar responsibility and the appropriate members of the Advisory Committee should evolve adequate forms, requests, and standard procedures to be followed. At present each unit acts independently and with varying interpretations of what is required.

6. Such an organization would make pooling and exchange of information an easy and rewarding experience. An instrumentality for "feedback" would be in existence. Such activity is imperative if reliable and continuous scientific data are to be "fed-in".

7. The pharmaceutical manufacturers' medical departments are enthusiastic about the possibility of working with the Advisory Committee, for whom they have great respect. Perhaps some of the "police activities" required by statute, can be efficiently carried out through the Committee's scientific and consultative activities.

Investigational Patients

Each manufacturer has a number of "investigational patients" who have been under observation for a known period of time or are continuing under observation. These groups include several thousand patients, perhaps as many as 15,000–20,000. The records of adverse reactions are, in general, quite complete. These patients might give more adequate known numerators and denominators for study. The medical people at the manufacturers have indicated to me that they would consider pooling these data for analysis on an anterospective basis. At present, this is awkward because each drug has a different form for the registration of the patient and the collection of followup data. These records are quite variable. Some are very detailed and some are "skimpy." The followup procedures are variable in the rigor demanded in the collection of data. A basic uniform record which was precoded for easy machine handling might be of advantage to both the investigators and FDA. Additions might be made to such a base record to satisfy the individuality of manufacturers and/or investigators.

1. A working group similar to the one suggested in the previous section, could be established to create a basic investigational registration and followup record. These basic forms would be utilized for all oral contraceptive drugs under study. Additions might be made to the basic records to satisfy individual desires of manufacturer and/or investigators.

2. A manual should be prepared containing "guidelines" for the selection of investigators and patients in future studies to be undertaken. This manual should contain standard terms and definitions as well as instructions for completing the various forms. Again single copies should be transmitted to FDA and duplicated by the Agency for internal distribution.

3. There is no uniformity in the procedures to be followed in "closing a case." These should be developed. A decision is needed on the effort to be expended upon patients who "stop coming to the clinic." At present the efforts to follow such patients vary from "nothing" to rather extensive, time consuming, and expensive effort to keep the patient under followup. An important oversight is the lack of followup of patients who are dropped because of pregnancy. This group presents an opportunity for the collection of considerable data. These data might be of importance in both medical and epidemiological areas of interest. Almost without exception, there is a dearth of data on pregnancy outcome in patients who become pregnant while on oral contraceptive therapy. No single investigator has many such patients but the "pool" would make several hundred available for analysis.

4. A computer program, perhaps patterned after the one in use by Eli Lilly & Co., should be established for the recording, storing, and analysis of these data. A program should also be evolved