Appendix 6

Review of the Procedures and Reports of the Pharmaceutical Companies Concerned With the Manufacture and Sale of the Oral Contraceptives.

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During February and March of 1966 the seven pharmaceutical manufacturers marketing oral contraceptives were visited at the request of the Advisory Committee of the Food and Drug Administration. The charge was to collect and analyze the deaths in patients taking oral contraceptives which had been reported to the manufacturers and investigated by them. A further charge was to "look into how they keep records and conduct investigations of adverse reactions." This combination of a specific and general charge made the visits easy to arrange and instructive to carry out.

All visits were arranged through the medical directors of the manufacturers. In almost all instances the chief medical officer of each manufacturer was interviewed. Some of the detail work was carried out with his subordinates who were directly responsible for the activities in question. An observation concerning these physicians and medical scientists is unavoidable. I believe these men, almost without exception, to be competent and interested in their work. I am impressed that they are truly concerned about the safety of the medications their firms produce and/or market. They wish to "do a good job." They are aware of the potential dangers of prolonged usage of potent medications and they wish to discharge this responsibility in an intelligent and scientific manner. They appreciate the shortcomings of their present methods of surveillance.

The "medical departments" of the manufacturers are quite variable. Some are very sophisticated in approach and personnel and one occupies a "basement office" and is quite restricted in personnel and outlook. These characteristics are detailed in the attached reports which describe the procedures followed by each manufacturer.

Standardization of Records

It was anticipated, prior to the visits, that there would be a degree of uniformity in the records and investigations of reported deaths. This was not the case. The variability was marked and so was the feeling of responsibility and involvement. Some of the investigations of deaths were associated with repeated visits and telephone calls to physicians whose patients had died. Other investigations were quite cursory and reflected considerable concern over the company's image with the physician. "He cannot be irritated—it's bad for our business relationships." I was surprised that there are no standard forms in use. This is true for the reporting of both deaths and adverse reactions which do not result in death. Thus compilations, tabulations, and analyses are made unnecessarily difficult and awkward.

Some physicians and hospitals hesitate to release patient information to a commercial organization. In fact some refuse to do so. It is of more than passing interest to note that the U.S. Naval Hospital at Bethesda replied that they had filed a report with FDA and would release no information to the manufacturer. This action is in spite of the fact that FDA charges the manufacturer with responsibility for carrying out an investigation. FDA has supplied no report to the manufacturer on this death. My own hospital has refused to release data to manufacturer without the consent of the Corporation Counsel of the city of New York. I am not anxious to undertake the chore of pushing this request through the Department of Hospitals and the Corporation Counsel's Office.

In this general area, I submit the following recommendations:

1. Adverse reactions should be reported on a standard form, rather than in memoranda, to a