BUREAU OF DRUGS, RESEARCH COMMITTEE

FORTY-SEVENTH MEETING, OCTOBER 29, 1970 AT 10:00 A.M., CONFERENCE ROOM C, PARKLAWN BUILDING

Present:

Dr. John T. Litchfield, Jr., Chairman
Dr. William W. Wright
Dr. Charles Anello
Mr. Theodore Byers
Dr. Marvin Siefe
Mr. Richard Terselic
Dr. Robert A. Littleford
Dr. C. H. Maxwell, Secretary
Dr. Edward Kravitz
Dr. Edwin Ortiz
Dr. Jule K. Lamar
Dr. Arthur Ruskin

Absent:

Dr. John Palmer, Miss Zelda Schiffman.

Guests:

Dr. Knox, Dr. Milliken, Dr. Johnson, and Dr. Duffy.

PROCEEDINGS

The meeting was called to order at 10:05 a.m. by Dr. Litchfield, Chairman who presided. He called attention to the slowness with which some of the material for the Research Committee had been submitted and stated that the material must be in the office of the Division of Extramural and Clinical Research ten days prior to the meeting of the Research Committee. The order of the material to be reviewed was discussed and the present order first, correspondence, committee reviews second, and the protocol third was continued.

Seven projects were considered. For all of them the essential material or the complete protocol had been circulated prior to the meeting. The following were considered:

1. *Blood types in thromboembolic diseases, Stolley and Sartwell, Johns Hopkins University*

This was deferred for a statistical review.

2. *Effects of oral contraceptives on cervical cytology, Dr. Spector, Temple University*

There were considerable discussion as to whether studies of this type should be sponsored by the FDA. Mr. Terselic thought they should not as demographic material was not FDA responsibility and projects of this nature should be under the auspices of the NIH. Dr. Litchfield agreed with this. By a unanimous vote it was recommended that the FDA support the cytological studies, but not the demographic part of the study as proposed by Dr. Spector. The priority was 222 for the cytology study.

3. *Action of sulfonylureas in animals and man, Foe, Wayne State University*

The feeling was that support for this type of proposal should come from sources other than the FDA. Preferably, the funds should come from the Drug companies, but it was not considered the responsibility of the FDA to support such work. The project was rejected by unanimous vote.

4. *Anorectic drugs in obesity control, Knox, FDA*

Dr. Knox gave a very detailed account of the difficulties in evaluating the efficacy of anorectic drugs. Tolerance develops quickly so that they are used for only a short time. The drug companies will make short-term studies, but will not make long-term studies. The FDA needs the information which could be obtained from long-term studies for guidelines for use of these drugs. The proposal as presented by Dr. Knox did not have a cost estimate, except on very general terms. By vote of 5 to 3, the Committee disapproved the proposal as presented, but suggested that a well developed detailed proposal with realistic cost estimates would receive very sympathetic consideration.