FOOD AND DRUG ADMINISTRATION, BUREAU OF MEDICINE

12TH MEETING MEDICAL ADVISORY BOARD

August 31 and September 1, 1967, Crystal Plaza Office Center, Arlington, Va.

Members of the Board present: Dr. Mark W. Allam, Dr. Harry F. Dowling, Dr. William M. M. Kirby, Dr. John G. Morrison, Dr. Arthur P. Richardson, Dr. Wesley W. Spink, Dr. Norman Kretchmer (September 1 only).

Member of the Board absent: Dr. William R. Mann.

Executive Secretary: Dr. Jean D. Lockhart.

PROCEEDINGS

Dr. Minchew welcomed the Board and announced that Dr. Ley was at the American Society of Pharmacology and Experimental Therapeutics meeting being held at Howard University on the same day.

Dr. Paul Shurin presented the first agenda item: dicloxacillin. After discussing the general pharmacology of this semi-synthetic penicillin he pointed out that in the past, labeling for such agents included a statement advising the physician to switch to penicillin G if culture showed the infecting organisms to be sensitive to it. However, the three companies producing dicloxacillin are resisting the inclusion of such a switch statement in the labeling of these drugs, all of which are ready for new drug approval in other respects. Questionnaries sent both by FDA and by the pharmaceutical firms to antibiotic experts have not resolved the issue.

Dr. Hodges pointed out that if Bureau policy is changed on dicloxacillin it should also be changed for methicillin, nagcillin and oxacillin. As things stand now manufacturers of the latter three drugs may not promote their drugs as the drugs of choice for routine use against susceptible gram-positive cocci.

Dr. Minchew indicated the concern of the Bureau of Medicine, that the semi-synthetic penicillins will be used for routine practice and that in the next few years resistance to these organisms will develop. Already seven strains of staphylococcus at Boston City Hospital have been shown to develop complete cross-resistance.

Dr. McCleery explained the implications of the labeling as they apply in advertising.

Dr. Kirby doubted that there was a sound rational basis for placing these restrictions on the labeling of semi-synthetic penicillins. During the past seven years, there is little or no evidence of any resistance developing. Dr. Dowling agreed with Dr. Kirby that the evidence is slight, but was impressed with the strains found at Boston City. Dr. McCleery expressed the wish that the switch statement be strengthened rather than deleted.

Dr. Dowling expressed reluctance to label a drug advising the physician to use one or another drug, since this comes close to deciding relative efficacy, something the Congress did not wish the FDA to do at the time of the 1962 amendments.

Dr. Morrison pointed out that the care of many patients especially the aged is conducted not in hospitals but in nursing homes or in other sites where no culture facilities are available. Several Board members expressed concern at the physician's choice being restricted.

Dr. Morrison moved that the labeling for dicloxacillin contain 3 general statements; 1) "When the infecting organism is susceptible to penicillin G the physician is advised to use penicillin G, V, or phenethicillin, because of the possible appearance in the environment of organisms resistant to the penicillinase-resistant semi-synthetic penicillins." 2) "The principle indication is in treating infections due to penicillinase producing staphylococci or in initiating therapy when there is the possibility of a resistant staphylococcic infection." 3) "This product is also effective in treating streptococci, pneumococci, and penicillin-sensitive staphylocci."

Dr. Dowling seconded the motion. Those in favor were Drs. Allam, Dowling, Morrison and Spink. Those opposed were Drs. Kirby and Richardson.

Following lunch the Board reconvened and Dr. Charles N. Rice, Chief, Toxicology Information Program, National Library of Medicine, described his program and its relationship to the recommendations of the President's Science Advisory Committee on the handling of toxicological information as well as to the FDA handling of toxicologic data. The program headed by Dr. Rice aims to develop a user-oriented system which will supply information services and