appendix

PROCEEDINGS OF THE PANEL

To enable the Office of Technology Assessment (OTA) to provide the Subcommittee on Health (U.S. Senate Committee on Labor and Public Welfare) with recommendations regarding drug product equivalence and variation, it was necessary to select a group of representative experts who could review all pertinent technical information and report their conclusions within three months.

OTA initiated discussions with several organizations that might be able to furnish staff support and carry out other responsibilities to assist the expert panel in its deliberations. A proposal from Family Health Care, Inc., Washington, D.C., and ensuing negotiations resulted in the award of a contract to that firm to provide staff assistance to the panel. With the guidance and approval of OTA, Dr. Robert Berliner, Dean of the Yale University School of Medicine was selected as Chairman of the panel.

Under Dr. Berliner's direction and with OTA approval, eight additional members and one ex-officio member (from the OTA Advisory Council) were selected. A press release on April 11, 1974, formally announced the study and the formation of the Drug Bioequivalence Study Panel. The following is a review of the activities and proceedings of the Panel.

The first of four planned meetings of the Panel was convened in Washington, D.C., on April 12. At this meeting, the Panel discussed the scope of the study and developed wording to state its interpretation of the charge it had been given. It was agreed that information regarding bioequivalence should be obtained from a number of organizations

and institutions in order to give the fullest possible consideration to all points of view. Every possible effort was made to obtain the information needed from all appropriate groups within the time available.

A press release on April 23 announced the charge to the Panel and the Panel's desire that all relevant technical information be submitted by May 20, 1974. This announcement was released through a variety of news resources and subsequently printed in the Congressional Record.

Between the first and second meetings of the Panel, the staff was directed to initiate contact and, if appropriate, to hold meetings with selected groups to inform them of the study and its purposes and to determine what information these groups would be able to provide. Contact was made with the following organizations:

American Medical Association (AMA) Department of Drugs

American Pharmaceutical Association (APhA) , including the Academy of Pharmaceutical Sciences (APS) and the National Formulary (NF)

Health Protection Branch, Department of National Health and Welfare, Canada

Ministry of Health, Ontario, Canada, PARCOST Program

National Association of Pharmaceutical Manufacturers (NAPM)

National Pharmaceutical Council (NPC)

Pharmaceutical Manufacturers Association (PMA)

U.S. Department of Health, Education, and Welfare, Food and Drug Administration (FDA)

United States Pharmacopeial Convention (USP)

Several of these organizations were asked to present statements at the second meeting of the Panel on May 1-2. Representatives from the PMA, USP, NF, FDA, NAPM and the PARCOST Program presented prepared statements and responded to questions. Because of possible legal and proprietary constraints, this information was received in confidence, with the Panel meeting privately with representatives of

each group. These groups were also asked to submit additional documentation by May 20.

Since many professional and scientific organizations, government agencies, manufacturers and academic institutions were willing and anxious to present information and to provide assistance, the April 23 news release was used as a public announcement inviting interested groups and individuals to submit statements for consideration. It was made clear that their submissions would be given full consideration although time constraints made their direct testimony impossible. Many statements containing information related to the issues of the study were received, including letters from individuals and organizations and reports from pharmaceutical manufacturers.

After the May 1-2 meeting, the staff was directed to continue its collection of relevant data. Information from two programs in Canada--the PARCOST Program in Ontario and the Federal QUAD Program in the Health Protection Branch, Canadian Department of National Health and Welfare--was of particular interest since the experiences of these two programs were especially relevant to the issues under examination.

In preparation for the third panel meeting on May 21-22, members accepted individual assignments to review and report on the data that had been submitted. Most documentation, however, was submitted on or close to the May 20 deadline, leaving little time for review before the third meeting of the Panel. On May 21, published studies of bioequivalence and the additional documentation that had been received were reviewed and summarized.

Using this information and discussions based upon it as well as the knowledge and experience of its members, the Panel proceeded to formulate a series of conclusions and recommendations about present and future technological capability for assuring uniform bioavailability and quality of drug products.

By the conclusion of the third meeting, a tentative set of conclusions and recommendations had been agreed upon. Members of the group were assigned the task of writing supporting information and providing data that would go into the final report to be submitted to OTA.

The written recommendations were submitted to the Chairman for review prior to the final meeting on

June 13-14; during this meeting, the Panel members worked as individuals, in small groups, and as a whole, to prepare a draft of the final report and recommendations. During this process, Mr. Jack Cooper served as consultant to the Panel.

The draft was then edited and revised by the *Chairman* and the staff and sent to all *members* of the Panel for review prior to publication.