names. Efforts by the USP and the NF to incorporate bioavailability parameters into their official compendia implies that physicians prescribing by trade names in an uncontrolled situation may have a justifiable point.

At a Conference on Bioavailability of Drugs sponsored by the USP and the Drug Research Board of NAS/NRC on November 22 and 23, 1971 (quote from papers).

At a meeting of the Drug Research Board held March 10, 1972, the position of the FDA and the USP on bioavailability testing was set forth as follows (quote from paper when available).

The Veterans Administration, with its large network of clinical facilities, has under study a plan to develop a medication quality assurance program for drug products to treat veteran patients.

A program leading to the assurance of the bioavailability and quality of drug products administered and dispensed in VA installations was discussed at a meeting held in VACO under the Chairmanship of the ACMD for Professional Services, Dr. Lyndon E. Lee, Jr., with Dr. Benjamin B. Wells, Deputy Chief Medical Director present. This program could be the most comprehensive of its type in the world and its results may have a far-reaching impact on improving the bioavailability and efficacy of drug products. It could be of immeasurable value to the VA in obtaining the permission of fee-basis physicians to dispense the brand of drug commonly available in VA hospitals and thus reduce costs.

The VA Drug Quality Assurance program would be based on a plan to monitor the blood or urine level of drugs in selected volunteers or patients. The plan will concentrate initially on the 100 most frequently prescribed drugs purchased competitively. These drugs, together with those which are available from only one source of supply, represent over 90 per cent of the dollar value of drugs purchased by the Veterans Administration.

Present at the meeting were Dr. T. G. Vitti representing the Food and Drug Administration. Dr. Daniel Azarnoff of the National Academy of Sciences-National Research Council, Dr. William M. Heller of the U.S. Pharmacopeial Convention, Incorporated, and Dr. John Bergen of the National Formulary. Others attending included Mr. Max Feinberg of Defense Personnel Support Center, Dr. Paul L. Haber, Deputy for Clinical Services, Dr. Edward Dunner, Special Assistant to ACMD for Research and Education in Medicine, Mr. Donald P. Whitworth, Director, Supply Service, Dr. Donald E. Francke, Acting Director of Pharmacy Service and Mr. Roland F. Harding, Deputy Director of Pharmacy Service. Also three experts in the field of biopharmaceutics and pharmacokinetics, Professors Milo Gibaldi of the State University of New York at Buffalo, W. A. Ritschel of the University of Cincinnati and Marvin Meyer of the University of Tennessee, attended.

There was agreement that a medication quality assurance program is desirable and that the VA, because of its clinical facilities, is an ideal organization to conduct it. At the next meeting scheduled for March 9th, the group will appoint a Scientific Advisory Panel to recommend drug products to which priority should be given, to develop protocols for studies, and to identify related areas of scientific research related to drugs.

According to this plan, the bioavailability of drug products will be measured by examining blood levels and/or urinary excretion levels in volunteers or patients. Drug products of the same dosage form and purchased competitively will be selected as follows: (1) The three products with the lowest unit price on the most recent bid obtained by VA or other government procurement agency (2) The product VA is now using and (3) The innovator's product. (Some of these may be the same). Dissolution tests will be done on all products, where applicable. Other or additional *in vitro* tests will be done when appropriate, such as friability testing, determination of particle size and particle size ranges, viscosity, etc. The products would then be compared using carefully controlled clinical studies in which plasma levels and/or urinary excretion of unchanged drug would be measured at several sampling times after administration of equivalent single doses on a body weight basis or by other parameters. The samples would be analyzed by specific methods and the data subjected to statistical analysis. The objective would be to determine the comparative biological availability of the products tests. If all three of the lowest priced products and the product VA is currently using showed unfavorable comparison with the original product, then similar tests would be performed on the three drug products which ranked 4th to 6th in price from the bottom of the bid list. If, on the other hand, one or more of the