Cooperation with Others in Assuring Drug Effectiveness

Our concern with the quality of drugs has not been limited to our own efforts nor to the results of the NAS/NRC reviews and subsequent FDA determinations. As I mentioned earlier, we have been consulting for a number of months with officials of government, academic institutions and others concerned with drug efficacy. One of these efforts has involved exploration with officials of the USP of the possibility of that organization undertaking drug efficacy studies for VA, using techniques similar to those employed by USP in establishing monographs for the drugs they list. Such studies would be directed specifically to our drug selection problems; they would include analysis of the relative efficacy of presumably comparable products. Although we shall continue to seek information of this type, we are not satisfied that this particular approach is a feasible one.

In the selection of drug products, we must rely primarily on their chemical equivalency as determined by laboratory assay. In the hope of obtaining a better tool for selection, we have explored the possibility of using bioavailability studies. In February of 1972, the VA formed an advisory panel to consider this approach. This panel consisted of representatives from the Bureau of Drugs, FDA; National Academy of Science/National Research Council; United States Pharmacopeial Convention; National Formulary; Office of Medical Material, Defense Personnel Support Center; the Chairman of the Department of Pharmaceutics, State University of New York at Buffalo; Professor of Biopharmaceutics, University of Cincinnati; the Director, Drug Metabolism Division, University of Tennessee; and key officials of the Veterans Administration,