FDA Commissioner Edwards is quoted in the July 1970 issue of the Journal of the American Pharmaceutical Association as follows:

"I refer, of course, to the problem of generic equivalence. It has become increasingly apparent that drug products which purport to be equivalent and which may satisfy chemical and other analytical tests of equivalence may not be therapeutically equivalent."

FDA has indicated that the problem is as complex as we had originally envisioned. They recognize that it is not presently possible to determine bio-availability in the entire armamentaria. DOD is not fully informed on all FDA action regarding bio-availability. We do know that the subject is under intensive study. We know also that the University of Michigan is currently under contract to FDA for a study titled "Generic Equivalency of Marketed Drug Products". As these data are developed, they will be required in new drug applications, and we, in turn will include them in our EC's.

In mentioning the NAS/NRC study, I have raised the collateral issue of the efficacy of drugs. This group reported to FDA that they could find no substantiating evidence that many drugs on the market are effective for treatment of the conditions for which they are labeled. DOD follows the actions of FDA very closely. It is our policy that central procurement of these drugs is suspended immediately upon FDA announcement that certification of the drug has been questioned. Unless there is an indication that the drug may be harmful, we do not suspend issues of the drug until FDA completes its administrative reviews and directs regulatory action. When that action is directed by FDA, DOD complies. Our immediate interest at the initial announcement, however, is a logistical one—we want to preclude further investments in an item which may be eliminated from the stock list.

Perhaps an example is the best explanation of our procedures when the efficacy of a drug has been questioned. Tolbutamide has been much in the news of late.

The University Group Diabetes Program (UGDP) has studied a 10 year period of the administration of tolbutamide in the treatment of diabetes. Their statistics suggest that patients on tolbutamide suffered a higher death rate from cardiovascular events than did patients on insulin or those without medication. The UGDP report was one of three presented at the meeting of the American Diabetes Association on 14 June 1970. Papers were also presented by Dr. Harry Keen, speaking for the British Diabetic Association, and Dr. J. Paasikivi of the Karolinska Institute of Sweden.

The UGDP findings were totally unexpected. No adverse effects were suspected by clinicians throughout the world.

The findings of Dr. Keen do not refute the UGDP data, since Keen's study is of shorter duration in years, and the UGDP study does not indicate an increased cardiovascular disease mortality in the tolbutamide group until about six years.

The study by Dr. Paasikivi is somewhat different design, and is difficult to compare with the UGDP work. However, the data to date are not conclusive, and other undetected risk factors may be involved.

The statement issued by Dr. Harding for the American Diabetes Association (exhibit 5), appears fully representative of the current attitude of diabetologists toward the use of tolbutamide, and the other oral agents. After consultation, DOD concurs that it would be wrong at this time to withhold tolbutamide from patients who need it. On the other hand, the indiscriminate use of this drug merely to correct mild blood sugar abnormalities must be discouraged.

To return to our example drug—when we first standardized calcium carbonate and aminoacetic acid tablets—may I digress to say that I hope the subcommittee is successful in its objective of simplified generic names. Dr. James E. P. Toman, Ph.D., of the University of Illinois College of Pharmacy has some particularly pungent and appropriate words on this subject in a 1964 McGraw-Hill book: "The Evaluation of Therapeutic Agents and Cosmetics". But, to return to my subject, when first type classified, this drug was patented, and was sold under the trade name of Titralac. Although the patent expired some months after our first purchase (October 1964), it affords us an opportunity to discuss this subject.

With respect to the patent aspects of DOD drug procurement, DPSC contracts for drugs incorporate the "authorization and consent" clause set forth in ASPR 9–102. Briefly, this clause authorizes and consents to any unnecessary