(e) To mask bad flavor of an active ingredient which not infrequently causes adults as well as children to resist and even refuse to take the medicine. The problem is getting a child to take a prescribed and oftentimes extremely necessary medicine is something that every mother and every nurse is familiar with. Pediatricians and general practitioners choose their medicines carefully and by specification with this in mind. The importance of palatability, I should note, is important in geriatric medicine as well.

Mr. Chairman. I am happy to submit for the record a PMA publication entitled "The Importance of Manufacturer Identification" which includes additional information on the points just covered. (Copy attached.)

Recently we undertook a careful search of the published literature on the effects of drug formulation on therapeutic activity of drug products. We collected a total of 211 references. Many of them are reports on variations in therapeutic activity observed in human volunteers and patients; the others cover both *in vivo* and *in vitro* (laboratory) experiences. These articles, I should point out, are solely related to the subject of generic and therapeutic equivalence.

In fact, much additional literature on pharmaceutical sciences, published in thousands of articles annually, bears on this question; much of it relates to corollary subjects, such as stability variations, effects of certain non-drug components on the drug's effectiveness or stability, particle size and form, and other significant factors that can and do affect quality. Gentlemen, there is a whole profession, international in scope, with thousands of practitioners who are dedicated to such scientific studies and, in fact, a new scientific discipline, called "biopharmaceutics" has recently arisen because of the importance of such work. The scientific literature output of these scientists has been estimated to be nearly 10,000 articles each year.

Some witnesses who have appeared here would like to eliminate or to curtail therapeutic duplication of drug products. In my opinion, such a step would serve as a devastating setback to medical progress and deprive patients of essential medication. In illness, patients vary in their response to medication. Patients vary in their idiosyncrasies, sensitivities, allergies and tolerances to drugs.

It is, for example, a well known fact that no one or two drugs are suitable for the treatment of all cases of epilepsy. The wide choice of drugs available for epilepsy exists solely because a half century of experience has shown that there is great variability in response by individual epileptics to available drugs. What we need is more and not fewer strings to our therapeutic bow.

The same is true of almost every disease and disability. The broader the therapeutic armamentarium, the better our physicians can care for the sick and suffering. The harm of eleminating one necessary drug far outweighs the alleged burden of too many drugs.

Mr. Chairman, the evidence of variability in drug product performance is too obvious to be ignored. The inability of FDA to assure even the competence of all drug firms, let alone the clinical equality of their products, is too longstanding to brush aside, and the possibility of that situation soon or ever changing is extremely remote. Of one thing I am certain: tying the doctor's hands, binding him in a kind of pharmaceutical straightjacket, will not answer the problem. It will compound it. It will be more constructive to work toward a Federal drug program that will take cognizance of all the realities of medicine and pharmacy today. And in that task we are most anxious to join you.

BIOGRAPHICAL SKETCH OF DR. A. E. SLESSER, ASSOCIATE DIRECTOR, QUALITY CONTROL, SMITH KLINE & FRENCH LABORATORIES

Born: Lafayette, Indiana.

Education: Purdue University, School of Pharmacy, B.S. in Chemistry M.S. and Ph. D. in Pharmaceutical Chemistry.

Experience:

Four years with Burroughs Wellcome & Co. as Chief Research Pharmacist in product research and development, followed by two years with Bristol Laboratories as Head of Production Development.

Seven years with University of Kentucky College of Pharmacy as Professor of Pharmacy, Chairman of the Department, and Assistant to the Dean.

Thirteen years with Smith Kline & French Laboratories as Assistant Technical Director, involved in Quality Control, production trouble-shooting, formula, process and packaging improvement in commercial products. Currently Associate Director Quality Control for SK&F.