mistakes are made even by the best manufacturers only proves the importance to physicians and patients of selecting the manufacturing source that has the best record of achieving quality, and the least likelihood of making future errors. Medicine is an art as much as a science, and by prescribing the manufacturing source in which he has the most confidence, the physician minimizes one of the many elements of risk in therapy.

Let me state emphatically that we do not claim that all drug products marketed by brand name are high quality or that all products marketed generically are low quality. Many PMA member companies market some of their drugs under generic rather than brand names. We do claim that two drug products containing a specified amount of the same active ingredient may, depending on manufacturer capability and quality control know-how, vary in quality and therapeutic effect, and that this can be so whether one or both products are marketed by brand or generic name, and whether one or both manufacturers are members or nonmembers of PMA.

You have already heard significant testimony that the exacting laboratory tests run by the Department of Defense often turn up such differences. Congressman Durward Hall placed in the *Congressional Record* on August 9 a letter from the Defense Supply Agency stating that there had been 143 rejections of drug bids tendered by apparent low bidders in competitive Defense Department drug procurements during the 22-month period from August 1965 through June 1967. In each case the drug products were rejected either because the sample submitted failed to meet the specifications or because the bidder failed to meet quality control or housekeeping requirements. Some 58 different firms had apparent low bids rejected for one or both of these reasons. All of the 58 firms are on the Defense Department's list of responsible prospective contractors and many are frequently successful bidders who deliver products that meet all specifications. But in 143 instances these firms failed to meet the Defense Department's requirements. Some firms had as many as 10 and 20 rejections. Others had only one rejection each, and a great many firms, of course, had no rejections at all.

Thus, the experience of the principal procurement agency large enough to conduct rigorous tests of all products it considers buying and possessing a mammoth physician feedback of therapeutic experience shows clearly that drug products which are supposed to contain the same amount of the same active ingredient do differ in quality, and that some manufacturing sources are more consistently reliable than others.

For the physician and pharmacist who cannot conduct his own tests and inspections, manufacturer identification of drug products has proven itself to be the most practical and reliable measure of consistent quality. Approximately one billion prescriptions are dispensed by the nation's retail pharmacists every year in the United States. Surveys have shown that more than 90 percent of them signify a particular drug product of a specific manufacturer. Once a physician has identified a particular manufacturing source for a particular drug product which he considers, on the basis of his own recurring experience, as best for a particular patient, he can have a high degree of certainty that each succeeding prescription of the same drug product from the same source will carry the same built-in therapeutic performance.

Moreover, if anything does go wrong after the prescription is filled—if there is an unexpected side effect or a lack of effectiveness—the doctor who has specified the manufacturing source will be able to communicate promptly with the manufacturer, and obtain the prompt assistance of the company's medical staff in identifying and evaluating the problem and in taking proper corrective measures. He can also assist both the manufacturer and the FDA in maintaining an accurate and up-to-date record of adverse drug reactions for the information of the medical profession. But if the physician has prescribed generically, leaving it to a pharmacist to select the manufacturing source, the physician may or may not be able to take these important steps for the health of his patient and the advance of medical knowledge. He may be unable to ascertain promptly, if at all, the identity of the manufacturing source, particularly if the prescription has been refilled generically from a variety of sources. And if he does learn the producer's identity, the manufacturer may not have a medical staff qualified to evaluate the information. Indeed, many generic manufacturers or distributors have not filed New Drug Applications for the products they market, and under the law, are not even obliged to file periodic experience reports with the FDA.

The physician's identification of a particular brand of drug product, or a particular manufacturer, in turn, justifies the manufacturer's investment, his com-