

with strong political overtones. In jeopardy, too, is the historic right of the physician to prescribe the precise treatment for his patient which he believes to be the most suitable in each instance, based on his professional knowledge. *This is the point of deepest concern to me.*

Under the American system of medical care, the physician *alone* arrives at a diagnosis and he *alone* should decide what medicine is to be administered to his patient. This is a vital part of the physician's professional responsibility and it cannot be delegated without endangering the quality of the care each individual receives.

Much has been said before this Subcommittee about the so-called "therapeutic equivalence" of drugs—regardless of who produces them—if they contain the same active ingredient and meet U.S.P. or N.F. standards. The argument is made that products sold under their generic names are generally cheaper than those bearing the brand name of a particular manufacturer; hence, patients would save money if their physicians would only prescribe by generic names.

The popular appeal of this approach is undeniable. If a less expensive drug will accomplish as much, why pay for the higher-priced one? I would like to answer that by stating categorically, on the basis of some 36 years in the practice of medicine, that the argument is fallacious on its face. There are no such things as identical or equivalent drug products, which can be depended upon to have the same effects on all patients under all conditions—any more than there are identical or equivalent patients, who can be counted on to react the same to the same product under the particular condition of their illnesses.

I am sure I do not have to take your time to discuss the many variables existing among drug products, from different manufacturers, even though they bear the same generic name. In previous testimony, you have heard of the differences in manufacturing processes. You are aware, from the hearing record, that substances such as binders, excipients or lubricants added to the active ingredient by one producer may be omitted or unlike those used by another producer. The active ingredient itself may vary in important respects—degree of fineness, crystalline state, etc., even assuming compliance with standards set forth in the specifications for the drug product in the official compendia.

Each of these differences can have significant effects in the treatment of illness. As a physician, I know—I have learned—that individual patients react differently to same treatment. The physician's task is to find the most effective medicine to meet the situation with which he is confronted. And I believe it must be accepted that the judgment of the therapeutic results of a medicine can only be made by the physician in cooperation with his patient. Thus, it follows, the patient's interests will best be served under a system which continues to permit the physician to specify those pharmaceutical products which the physician knows are of the highest quality and which his experience tells him will most effectively meet the patient's individual needs.

Most of us prescribe by specifying the brand name of the desired drug or by selecting the product of a particular manufacturer. From time immemorial, this has been our means for making sure our patients get their medicines from sources we can trust.

Under legislation, which would require—by direct or indirect means—the prescribing of drugs by their generic names, the physician would lose the control over the medicines he designates for his patient, and the patient would lose this safeguard over the quality of medicines he receives.

We know that substandard drugs are being marketed every day. These are often sold under their generic names. We cannot be certain who produced them or under what conditions. They may or may not give consistent therapeutic results. Yet, one of these questionable products, of indeterminate origin, could be used to fill a generic prescription. I cannot imagine a member of my profession, who would willingly gamble with his patient's health in this fashion.

I do not, for a moment, assert or imply that all generic-named products are inferior to brand-name products. To the contrary, there are excellent generic-named products on the market. Many quality drugs have no brand names. Many of these are produced and sold under generic names by ethical drug houses that also manufacture brand-name drugs. The fact remains that unless the product (whether marketed under generic or brand name) is made by a reputable and qualified manufacturer, there is absolutely no way to tell which is good and which is poor before it is used, without access to analytical and biological laboratory facilities more elaborate than most physicians, pharmacists and hospitals are likely to possess.