

it shows that the United States originated 502 of the 823 new weapons against disease and suffering which have been placed in the physician's armamentarium in the last 27 years. And the U.S. shares credit with foreign sources for several others. Of the U.S. discoveries, the laboratories of American manufacturers were responsible for 87 percent. The others came from university, non-profit or government sources.

*The Issue of Generic Prescribing and Dispensing*

A great deal has been said during these hearings about prescribing by the generic name of the drug. I would like the record to be perfectly clear that the prescription drug industry and the PMA do not oppose the physician's freedom to prescribe in this way. We believe a physician should be entirely free to prescribe as he wishes, whether by a manufacturer's brand name, by the generic name with the manufacturer identified, or by the generic name alone.

In a true generic prescription the physician delegates to a pharmacist or nurse the selection of the manufacturing source for the product prescribed. If the physician considers such a delegation not to be contrary to the interest of his patient, he should be free to prescribe in that manner. If the physician prefers, he should also be free to designate a brand name or to specify the manufacturing source by designating the generic name of the drug together with the name of the preferred manufacturer.

We also believe that, in prescribing, doctors should supplement their medical judgments and decisions regarding drug quality and effectiveness with considerations of cost to the patient. If the doctor believes that two manufacturers market drug products of substantially identical therapeutic effectiveness and quality, he should, of course, prescribe the less expensive one for his patient. Contrary to a general impression, most prescription products are not fair-traded, and therefore manufacturers impose no restrictions on the prices charged by retailers.

I would like to say a further word on the subject of prescribing by using the generic name of the drug. While we favor the right of the doctor to prescribe as he wishes, we emphatically disagree with the assumptions and statements advanced by certain earlier witnesses before your Subcommittee that generic and therapeutic equivalency go hand in hand. As has been pointed out in papers by a number of leading physicians and pharmacologists and in previous testimony before this Subcommittee, the term "generic equivalent" refers only to the name of a drug product and does not necessarily connote its safety or therapeutic effectiveness. Although two drug products may contain, or are supposed to contain, the same amount of the same active ingredient, this provides no assurance that both products will produce the same clinical effect in any particular patient.

Mr. Chairman, you have asked several previous witnesses whether they can present any scientific evidence that drugs with the same generic name do not have the same quality and therapeutic effect. The witnesses who follow me today have such evidence to present, and they are prepared to discuss it in depth.

Drug manufacturing is a complex and exacting process. In our member companies 18 percent of all production employees are directly engaged in quality control. Even that does not guarantee perfection, but these unflagging efforts provide the best means of achieving the highest degree of quality that is realistically possible.

On this subject, there appears to be a rather common, mistaken belief that the federal drug laws somehow guarantee a uniform high level of quality in all drug products which reach and are dispensed from the shelves of a pharmacy. This is not so and, as a practical matter, can never be so. Although Food and Drug Administration personnel do a conscientious job, it is impossible for them to inspect every manufacturer and distributor often enough to insure that every drug product meets even bare minimum quality standards. Maximum quality and reliability can only be built in by the manufacturer. Even antibiotic drug products, every batch of which FDA tests before shipment, have turned up with variations in quality and potency.

Clearly, the public interest must ultimately be served by private responsibility. Deeply ingrained in the business philosophy of the reliable manufacturer is the desire to excel in product quality as a competitive measure. This system of striving to produce only the best is the physician's and the patient's strongest safeguard.

Mr. Chairman, although our member firms strive for perfect quality, even the best companies do not always attain it. You have read into this record lists of drug recalls that illustrate that mistakes still are made. But the fact that