

Interestingly, there is nothing at the present time that prevents physicians from prescribing generically. We believe most of our colleagues do in cases compatible with the patient's needs. But when we prescribe, for example, Dicumarol, an anti-coagulant, the dose and the therapeutic action must be precise and reliable. Too much means internal bleeding; too little means clotting. In either instance, the result could be fatal. And once the proper dosage has been established for the individual, it must remain constant. It could be altered by a change from the product of one manufacturer to that of another, thereby causing a dangerous reaction in the patient.

There is no other way to express it. Professionally and ethically—for the good of the patient—we cannot but be seriously alarmed by the possibility that we may be confronted with the unscientific requirement that we prescribe generically for our patients without knowing anything about the medicine that will be dispensed, its pharmacological components, actions and reactions and what manufacturer stands behind it.

Chances cannot be taken with any medicine; they simply cannot be taken in the area of critical drugs. When we prescribe digitalis or nitroglycerin for our heart patients, we must know what we can expect the medicine to do, and our experience with the same product in the past tells us that. We cannot know if the medicine is from an indeterminate or questionable source which may change each time the prescription is refilled. The range between a toxic dose and a therapeutic dose is too narrow to allow room for the slightest doubt about these drug products to exist in the physician's mind.

We previously mentioned Dr. Hall's testimony before this Subcommittee. You will recall that he dealt with the high proportion of rejections of both drug manufacturing plants and drug products by military procurement officers as a result of their analysis and inspection procedures. The facts which he provided, we believe, constitute a devastating refutation of the arguments for generic prescribing, whether enforced by direct or indirect means.

Obviously, there were drugs offered to the government which were not manufactured under effective and exacting quality control methods. There were plants seeking to do business with the government which were found wanting for sanitary or other important reasons.

There are no assurances that the same drugs are not being sold to the public at the present time, or that the rejected plants are not on the market with products of dubious effectiveness. These could be the "inexpensive" generic drugs, the dangerous drugs, which would be dispensed under prescriptions failing to identify the manufacturer of the product desired by the physician or to specify it by brand name.

Proposals are now pending in Congress for the establishment of a national drug formulary from which prescribing physicians would be required to select medicines in order for their patients to be reimbursed for drugs under federally financed health programs. These are complicated measures and raise many questions for which the answers are notably lacking; questions over the selection of drugs for the proposed formulary; the propriety of forcing the use of generic terminology; the prospect of government price fixing of drugs; the adjudication of "acceptable quality" by the federal formulary committee, and the enormous administrative burden which the bills entail.

The effects of the legislation, in our opinion, would be a reduced quality of medical care and direct government intervention in the practice of medicine. For many Americans, it would no longer be a case of the patient's best interests being served according to his individual needs and the physician's judgment. Rather, the therapy available at government expense would be determined by committee. The physician would find himself facing the dilemma of whether to prescribe a drug from the formulary so his patient could be repaid, even though he did not regard it as the most desirable drug, or of prescribing a drug not listed in the formulary because he knew it best to fit the individual circumstances, thereby penalizing his patient financially.

In addition, the establishment of two classes of citizens would also be written into the laws of the United States under these measures. To require physicians to use "generic" drugs for their less fortunate patients would create an unethical double standard of therapy. One class would get those medications which the physician knew were best and in which he had confidence; the other would get those drugs listed in the formulary by the committee.

We mention the legislative proposals in this statement because of their close ties with the issue of generic equivalency about which this Subcommittee has