

11852 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

relegating them to the role of second class citizens in that they, under the proposed regulations, would be forced to receive the cheapest drug rather than the best drug.

7. Reject the long-standing position of the U. S. Department of Health, Education and Welfare, as reported to the Congress in 1967, that charity medicine is being abandoned in favor of those programs that give needy persons the resources to purchase medical services they need on the same basis as more affluent citizens.

8. Violate Section 1802, Public Law 89-97, which prohibits intervention by a federal agency or federal employee into the doctor-patient relationship, or interference in the doctor's right to determine what best meets his patient's needs.

The proposed regulations do not address themselves to the problem, which is over-utilization. Studies by the National Pharmaceutical Council (Terkhorn et al) have clearly demonstrated the factors of over-utilization, the abuses in the program, and have offered a simple and effective means of correcting these problems without infringing on the rights of recipients to have the high quality medical care they deserve. Instead, the regulations are an attempt to punish all beneficiaries for the over-utilization sins of some of the beneficiaries.

The proposed rule fails to recognize established scientific facts that drugs and combinations of drugs react differently in different individuals. Also, action and reaction time, as well as efficacy, can vary from zero to 100 per cent because of several factors, including systemic condition of the patient, other medications the patient may be receiving, the binder, sealing and capsulating properties of individual medications, etc.

For example, the Food and Drug Administration itself has experienced wide variances in so-called generically equivalent drugs, such as digoxin, succinylsulfathiazole, thyroid tablets, atropine sulfate, reserpine, vitamins, mineral oil and isopropyl alcohol, to name a few.

Dr. Alfred Gilman, co-editor of The Pharmacological Basis of Therapeutics, lists 32 known factors, besides chemical content, which affect the therapeutic action of a drug.

The U. S. Department of Defense was forced to abandon so-called generic purchasing because manufacturers were not meeting recognized standards. (See "Drug Standards in Military Procurement," Journal of American Pharmaceutical Association Vol. NS9, No. 3 3.69).

Alfred Gilman, Ph.D. Associate Dean for Graduate Education, Albert Einstein College of Medicine, has written, "I am appalled by many of those statements which imply that generic drugs, marketed cheaply by small drug companies, are the equivalent of established trade-marked preparations merely because chemical analysis indicates that the preparation actually contains the specified amount of the drug . . . "I have seen instances where slight changes in formula-