

was by Dr. Theodore Klumpp, the President of Winthrop Laboratories, before the House Committee on Interstate and Foreign Commerce.

Dr. Klumpp testified that:

"Despite advances in scientific techniques, therapeutic representations and claims remain essentially matters of opinion. Different schools of thought with respect to the proper treatment of various diseases are prevalent and sometimes completely contradictory. Not infrequently, it takes years and sometimes decades of widespread clinical experience to evaluate the true or relative merit of a drug in given conditions. From such long experience, a medical consensus generally emerges, but even then some qualified physicians refuse to go along with their colleagues. . ."

"At the present time, there are sharply opposed views among experts concerning the proper treatment of many common diseases. Rheumatoid arthritis is such a condition. There are highly qualified physicians who favor the use of corticosteroid drugs. There are others who feel that the employment of the corticosteroids does more harm than good and that the only meritorious drug is aspirin. Still others are proponents of, respectively, Butazolidin, gold salts, and anti-malarial drugs such as quinacrine, chloroquine, and hydroxychloroquine. The use of pyrimidon, or large doses of vitamin D, still has adherents, and particularly among clinicians in foreign countries. The reaction of experts to any new drug offered for the treatment of rheumatoid arthritis will inevitably be conditioned by the school of thought to which they happen to adhere. By whose advice is FDA to be guided in the evaluation of a new drug for this condition?"

[Dr. Klumpp then considered similar problems with drugs for epilepsy, mucous colitis, and the common cold.]

The above specific illustrations are only a few of the many that can be cited to show that—

- (a) The determination of the effectiveness of a drug is always difficult and sometimes cannot be achieved except by the test of time and widespread use.
- (b) Therapeutic representations are essentially matters of opinion.
- (c) Differing schools of thought frequently exist concerning therapeutic issues, and the school which favors one theory as to the nature and treatment of disease tends to be skeptical of the drugs advocated in opposing schools. Moreover, medical opinions as to effectiveness of a particular drug can differ widely among equally qualified physicians because of basic differences in opinion relating almost entirely to questions of diagnosis and preferred method of treatment, as well as differences as to the comparative efficacy of one member of a class of drugs in relation to others or the mode of action of a particular drug in the complex body mechanism. Hearings at pages 232-235.

CONCLUSIONS

The legislative history of the 1962 amendments establishes quite clearly that Congress did not intend "substantial evidence" to mean a preponderance of evidence. Nor did Congress expect the medical profession to arrive at single conclusions about drugs and treatments. Rather than enacting standards which would require exact proof and which could leave no room for minority opinions, Congress explicitly favored concepts of flexibility which could accommodate the range of responsible professional opinions.

Had Congress disagreed with Secretary Ribicoff's view that the amendments would not change the established pattern of testing drugs, there would have been more discussion on the subject of the methodology of drug testing. But Congress did not take issue with the Secretary's assessment of the law, and the legislative history shows that Congress intended to maintain flexibility in the area of drug testing, just as it so intended with the concept of substantial evidence.

The substantial evidence standard itself, as enacted, requires a comparable openness with regard to differing opinions in the area of what constitutes adequate and well-controlled investigations. It may well be that certain drugs for some kinds of diseases are better investigated with some techniques than with others. A substantial difference of opinion might exist about which methods of testing should be applied in different circumstances. It would be wholly inconsistent with the clear and unambiguous intent of Congress with respect to the substantial evidence standard to conclude that only certain kinds of tests could produce such evidence when there is a body, however small, of reliable professional opinion to the contrary. An "adequate" test for one situation might be inadequate in others; the kinds of controls possible in one instance might be impossible of achievement, or less meaningful, in another; and even the qualifications of