

Almost from the first year of the Kefauver amendments, the FDA found itself embroiled in disputes over the manner in which it was interpreting its widened regulatory functions under the new laws. For example, the issue of the drug package insert alone—how much, if any, legal weight it carries and how binding it is, or should be, on medical practice—has been a continuing source of contention between clinicians and pharmacologists on the one hand and the agency on the other.

CONCURRED WITH COMMISSIONER

Dr. Dripps and his colleagues said that they concurred with a recent statement by FDA Commissioner Dr. Charles C. Edwards, who had described the agency as being in a "particularly difficult environment because, in a sense, we are in the middle."

The Commissioner's statement continued: "We are, on the one hand, criticized for being 'soft' on industry and, on the other, called repressive, an enemy of free enterprise: on *every* major decision we are accused by some of acting too fast without sufficient evidence and by others of acting too slowly and too timidly to prevent unnecessary harm."

In their statement to the House Subcommittee, the Dripps group suggested that it was significant that the FDA has "long been the subject of study and investigation," with the Executive Branch alone conducting three studies of the agency in the past five years. But these appraisals, the scientists said, did not get to the heart of the problem because they focused primarily on the internal structure and workings of the FDA.

"As important as it is to improve the efficiency and scientific procedures and capabilities of the agency itself," the experts declared, "there still remains the crucial question as to the effect the agency's administration of the 1962 drug act has had in actual practice on drug research, innovation, and therapy."

They continued: "We believe a change in the drug regulatory system is badly needed. The system too often stifles creativity and escalates costs of research; perpetuates a continuing decline in the number of new drugs entering the market in this country; and may be depriving the practicing physician of agents beneficial to patient care. The reasons for all this are not clear, are undoubtedly complex, and require thorough investigation and study."

SUBCOMMITTEE PROPER BODY

The group concluded: "Your subcommittee, it appears to us, would be the proper body to direct a full-scale review of the effect of the 1962 drug act and regulations on the practice of medicine and the conduct of academic and industrial drug research."

Chairman of the Subcommittee on Public Health and Environment is Rep. Paul G. Rogers (D.-Fla.). Two members are physicians, Rep. Tim Lee Carter (D.-Ky.) and Rep. William R. Roy (R.-Kans.).

OTHERS SIGNED STATEMENT

Other signers of the statement to the subcommittee were: Drs. Robert F. Bradley, *medical director, Joslin Clinic*; Eugene Braunwald, *Professor of Medicine and chairman of the department, University of California, La Jolla*; James E. Eckenhoff, *dean, Northwestern Medical School*; Edward D. Freis, *Professor of Medicine, Georgetown University and a Lasker Award winner*; Nathan S. Kline, *director of research, Rockland State Hospital, New York, and a Lasker recipient*; Louis Lasagna, *chairman, Department of Pharmacology and Toxicology, University of Rochester, N.Y.*; Walter Modell, *Professor of Pharmacology, Cornell University*; John A. Oates, *Professor of Medicine and Pharmacology, Vanderbilt University*; Irvine H. Page, *senior consultant, Research Division, Cleveland Clinic, and a Lasker recipient*; E. M. Papper, *vice-president for medical affairs and dean, University of Miami*; Burtrum C. Schiele, *Professor of Psychiatry and principal investigator, Clinical Psychopharmacology, University of Minnesota*; George W. Thorn, *physician-in-chief, Peter Bent Brigham Hospital*; Robert W. Wilkins, *chairman and director, Division of Medicine, Boston University, and a Lasker recipient*; William R. Wilson, *chairman, Department of Clinical Pharmacology, University of Iowa*; Robert I. Wise, *Magee Professor of Medicine, Jefferson Medical College*; and George D. Zuidema, *Professor of Surgery and department director, Johns Hopkins*.