tion have doubled the blood levels and halved the therapeutic dose of the drug. These were not clinical impressions but carefully designed and accurate studies. I am, therefore, convinced that there is no such thing as a generical equivalent unless proven by adequate experimental data." (Congressional Record 9/12/67).

U.S. Comptroller General Elmer B. Staats told the United States Senate Monopoly Subcommittee of the Select Committee on Small Business, January 19, 1971:

> "A compilation of testing reports received by the Veterans Administration from the Food and Drug Administration for 1970 through December 29th shows a total of 784 tests made - - 254 brand name and 530 generic. The total rejections were 29 for a rate of 3.7 per cent. All rejections were on generic drug items."

Scientific evidence strongly refutes the November 15 Federal Register statements, Section 1, "Drug Costs," namely, "The Department (of HEW) is aware that a number of drugs containing the same active ingredients in the same dosage form are available from different producers and labelers at significantly different prices."

In his book, Chapter 24 of Biopharmaceutics and Relevant Pharmacokinetics, (1971), John G. Wagner, Ph.D., University of Michigan College of Pharmacy, and Assistant Director for Research and Development, Pharmacy Service, University Hospital, demonstrates the fallacy of the assumption that so-called generically equivalent drugs have identical bioavailability factors. In discussing a Drug Efficacy Study of some 3,000 FDA-approved drugs undertaken by the National Research Council of the National Academy of Sciences, Dr. Wagner points out that 27 review panels . . . "made no attempt to consider therapeutic equivalence of drugs of identical chemical composition formulated and marketed by different firms under generic or trademark names."

He also noted, "Although approximately 3,000 drugs were involved in the Drug Efficacy Study, apparently only 12 drugs in two or more commercial drug products have been studied in man under controlled conditions with the objective of assessing rate or extent of drug bioavailability." He stressed that, of 24 reports of bioavailability studies of those 12 drugs, large differences in bioavailability of the drug from different manufacturers were demonstrated in 58 per cent of the cases.

Of those 24 studies, all but three were conducted in academic, governmental or institutional laboratories.

Under Section II of the proposed rule, "Drug Quality," the assumption is made that The Department, through the Food and Drug Administration, maintains an extensive drug surveillance program designed to assure adherence to drug standards.

The Food and Drug Administration would find it impossible to survey every lot of every drug manufactured every day in the United States. From the point of obtaining the basic ingredients to the shipping of the packaged drug to the pharm-