views concerning the proper treatment of many common diseases, and each school of thought has a strong champion. Many highly qualified physicians are convinced of the value of corticosteroid drugs in relieving rheumatoid arthritis; there are others who prefer aspirin; still others are proponents of a variety of other treatments . . .'

"At the completion of Mr. Beesley's statement, Senator Kefauver agreed with Mr. Beesley's determination of effectiveness in the following language found on page 2007 of the printed hearings.

" 'You agree, as we have also recommended, that the Food and Drug Administration should pass upon whether a new drug is substantially efficacious for the claims made for it by the manufacturer, and that is the intent of the language in the bill, although it may need some clarification. Your language was "substantial evidence not only that the drug is safe but also that it produces the results claimed." That is exactly what we had in mind in connection with that.

" 'Mr. BEESLEY. Mr. Chairman, I think we agree in the principle involved. The precise language of the statute is very important, bearing, of course, upon the interpretation that will be given to the statute, and the points which we have made here we think further clarify the statute and are exceedingly important to the way in which it will be administered.

" 'Senator KEFAUVER. I would certainly accept, as far as I am concerned, your further statement on page 10:

" ' "Thus if a number of tests by competent clinicians show that in well-conducted clinical trials a drug produced the claimed effect on their patients, the drug would not be barred simply because other tests did not produce the identical results with different patients," the key words are "well-conducted clinical trials by competent clinicians." I agree with that.

" 'Mr. BEESLEY. Mr. Chairman, the key words here from our point of view are "substantial evidence." What do we mean by efficacy? What do we mean by effectiveness of a drug? And that is the thought, the new thought, that we are producing there, which, may I submit, is exceedingly important.

" 'Senator KEFAUVER. Substantial evidence is required in most Government procedures and that is inherent in what we have in mind with the bills.' " S. Rep. No. 1744, 87th Cong. 2d. Sess., pp. 57–58.

After further consideration, on August 21, 1962, the Senate Committee on the Judiciary issued a second part to its earlier report. At that time, the Senate bill was further amended to include the effectiveness test, including the definition of "substantial evidence" that was ultimately enacted into law. The August 21, 1962, Senate Report further elaborated what was meant by "substantial evidence."

"The proposed committee amendment clarifies and strengthens the previously reported bill by restating and carefully defining the quality and quantum of evidence which the Secretary must find to exist as a basis for clearance of the drug or for withdrawal of a previously approved new-drug application. In the course of committee deliberations a distinction evolved, in this connection, between two tests—the 'proponderant evidence' tests and the 'substantial evidence' test as now specifically defined. Under the former a claim would not be accepted under the new-drug section unless it represented the preponderant view of experts qualified by training and experience in the subject that the claim was supported. The committee recognizes that in the difficult area of drug testing and evaluation there will frequently, if not usually, be a difference of responsible opinion. The committee feels that the existence of such a difference should not result in disapproval of a claim of effectiveness if it is supported by substantial evidence defined in the manner set forth below and evaluated by the Secretary in the light of all the information available to him at the time.

"As the result of subsequent study, a definition of 'substantial evidence' has now been added to the bill concerning what would constitute such evidence. The amendment provides that 'substantial evidence' means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. That is to say, a claim could be rejected if it were found (a) have the investigations were not 'adequate'; (b) that they were not 'well controlled'; (c) that they had been conducted by experts not qualified to evaluate the effectiveness of the drug for which the application is made; or (d) that the conclusions drawn by such experts could not fairly and