labeling. 107 Cong. Rec. 5638. The original Senate bill did not consider the quantum of evidence necessary to establish sufficient information as to "efficaciousness," nor did it consider the manner in which such evidence should be assembled for presentation to the Secretary.

"SUBSTANTIAL EVIDENCE"

During the Senate hearings on S. 1552, the issue of the amount of evidence which would be sufficient to allow the Secretary to determine "efficaciousness" was thoroughly considered.

On July 19, 1962, after the Senate hearings on S. 1552, the Senate Committee on the Judiciary reported out a revised bill. At that time, the previous language regarding "efficacious in use" was amended to provide that the Secretary should refuse to approve a new drug if:

"[T]here is a lack of substantial evidence (including clinical evidence), supported by investigations of experts qualified by scientific training and experience to evaluate the effectiveness of drugs, 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 proposed labeling thereof . . ."

The thorough debate on the issue of what would satisfy "substantial evidence" of effect resulted in a firm consensus, which is illustrated in the Senate Report.

"The term 'substantial evidence' is used to require that therapeutic claims for new drugs be supported by reliable pharmacological and clinical studies. When a drug has been adequately tested by qualified experts and has been found to have the effect claimed for it, this claim should be permitted even though there may be preponderant evidence to the contrary based upon equally reliable studies. There may also be a situation in which a new drug has been studied in a limited number of hospitals and clinics and its effectiveness established only to the satisfaction of a few investigators qualified to use it. There may be many physicians who would deny the effectiveness simply on the basis of a disbelief growing out of their past experience with other drugs or with the diseases involved. Again, the studies may show that the drug will help a substantial percentage of the patients in a given disease condition but will not be effective in other cases. What the committee intends is to permit the claim for this new drug to be made to the medical profession with a proper explanation of the basis on which it rests.

"In such a delicate area of medicine, the committee wants to make sure that safe new drugs become available for use by the medical profession so long as they are supported as to effectiveness by a responsible body of opinion.

"In his testimony supporting new authority for the Food and Drug Administration to pass on the effectiveness of new drugs before they are marketed, Secretary Ribicoff said that questions of 'relative efficacy' are not here involved, and that the requested authority 'would not require a showing of relatively greater efficacy than that of other drugs' (hearings, pt. 5, p. 2585)." S. Rep. No. 1744, 87th Cong., 2d Sess., p. 16.

The views of Senators Dirksen and Hruska, in the same Senate Report, confirm the view that substantial evidence can be less than preponderant evidence, and that room for minority opinions should exist.

"We wish to augment the discussion of the effectiveness of drugs as now provided for in the majority report. Two quotations from the Senate hearings on S. 1552 are especially notable. Eugene N. Beesley, president of Eli Lilly & Co., and chairman of the Pharmaceutical Manufacturers' Association, in his testimony before the Senate Antitrust and Monopoly Subcommittee at page 1998 stated:

"'Also, it is our understanding that the manufacturer would be required to provide only substantial evidence that a drug produces the effects claimed for it. He would not be expected to prove that scientific opinion was unanimous, or even preponderant, in supporting the effectiveness of a drug. 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. In other words, a drug should be made available for the benefit of those patients for whom the individual physician thinks it would be useful.

"'In the entire realm of medical science nothing is more difficult and more subject to honest differences of competent opinion than the determination of the therapeutic merits of drugs in human beings. Experts have sharply opposed