responsibly be derived from their investigations." S. Rep. No. 1744, Part 2, 87th Cong., 2d Sess. p. 6.

The Report of the House Committee on Interstate and Foreign Commerce [1] and the Conference Report [2] do not elaborate further on the substantial evidence concept.

The legislative history could not be more clear in establishing that Congress understood the wide range of opinion that exists in the medical profession as to the effectiveness of any particular drug. Thus, Congress provided a definition of substantial evidence which allows the Secretary to find that a drug's effectiveness is supported by substantial evidence even if that evidence is, in volume, outweighed by opposing views.

"Adequate and Well-Controlled Investigations"

The issue of the manner in which an applicant should assemble evidence necessary to constitute "substantial evidence" was not directly in question during the hearings. The issue, however, was mentioned in debate as a necessary adjunct to the question of how much evidence would be substantial.

The Senate Judiciary Committee, in its second report, recognized that:

"[I]n 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." S. Rep. No. 1744, Part 2, 87th Cong., 2d Sess. p. 6 (emphasis added).

In the vast number of pages which the Senate hearings consume, there is only scant reference to the question of the correct methodology for testing drugs. The absence of long debate on this subject is probably best explained by Secretary Ribicoff's observation that the amendments did not "contemplate and basic changes in the established pattern of testing the effectiveness of drugs."

"Secretary Ribicoff. Let me make it absolutely clear that we are not dealing here with what some have called 'relative efficacy.' The claim has been made before this subcommittee that the proposed amendment would enable us 'to decide the relative or comparative efficacy of a new drug in terms of drugs already on the market,' or allow us to refuse clearance for a new drug merely because, in the Food and Drug Administration's opinion, it is 'not the most efficacious drug for the purpose intended or was not as efficacious as one might ideally wish.'

"The bill furnishes no basis for such apprehensions. The proposed amendments would merely require a showing that the new drug described in the application is safe for use and is effective in use, under conditions prescribed recommended, or suggested in the labeling thereof. This would not require a showing of relatively greater efficacy than that of other drugs. It would merely require that a drug claimed to be effective for a particular purpose has been demonstrated *by sound scientific procedures* to be effective for that purpose. In short, it must live up to the claims made for it.

"It should also be pointed out that this proposal *does not contemplate any basic change in the established pattern of testing the effectiveness of drugs. . . .*" Testimony of Secretary Ribicoff before Senate Subcommittee on Antitrust and Monopoly, September 13, 1961, pp. 2585–2586 (emphasis added).

The subject itself is extremely complicated, as the testimony of Dr. David P. Barr illustrated:

"Every one who has tried to test drugs knows how extremely difficult it is to determine whether a drug is or is not effective, and the establishment of its effectiveness requires extensive facilities and team efforts which may require joint services of many participants, physicians, certainly, and pharmacologists, and others." Testimony before Senate Subcommittee on Antitrust and Monopoly, July 19, 1961, p. 259.

That differences of opinion among responsible clinicians as to effectiveness and testing occur frequently was amply demonstrated in the course of the legislative history.

"The committee recognized that legitimate difference of opinion may exist among responsible clinicians with respect to the effectiveness of a particular

[1] H.R. Rep. No. 2464, 87th Cong., 2d Sess.
[2] H.R. Rep. No. 2526, 87th Cong., 2d Sess.