disease process involved. And even more importantly, the use of these measurements alone ignores the subjective benefits enjoyed by the patient. No claim has ever been made that Indocin has any effect on the basic disease processes involved in arthritic disorders. The only claim made has been that in some 65 percent of the arthritic patients who are placed on Indocin, their stiffness, swelling, tenderness, and pain—which are manifestations of their disease—are relieved. These are the reasons that these patients seek medical help, and the relief of these symptoms is an important benefit to the patients and a source of satisfaction to the physicians who have prescribed the drug.

There is nothing new about the purely statistical approach—as opposed to the clinical approach—to the measurement of the effectiveness of a drug such as Indocin in conditions such as arthritic disorders. Few physicians would dispute that the corticosteroids can provide dramatic relief to many arthritic patients in whom all other measures have failed. Yet in 1960, the following statement appeared in the journal, Annals of Internal Medicine:[1]

> Reports of the Medical Research Council and Nuffield Foundation and the Empire Rheumatism Council indicated no significant difference in results of treatment between two groups of patients, one on cortisone and the other on aspirin. However valid these results statistically, purely functional therapeutic effects of steroids in certain individual patients were still impressive. Since none of these drugs affected the disease fundamentally, the question was whether cortisone had not in some instances enabled the patient to "get more out of life," though happiness is not a scientific quality.

The education of the physician is long and intensive. I think it is fair to say that to succeed in the practice of medicine, much more than in most professions, one must be able to make valid judgments of cause and effect. On the basis of his training and experience, the physician tries a drug in a patient. On the basis of his observation of the effect the medicine produces, he decides whether to continue it. His attitude toward the drug, and certainly toward the promotion relating to it, is continuously watchful and thoughtful—just as it is toward his patient. For example, the physician must evaluate the history of the patient's complaints, determine the significance of his findings on physical examination, and assess the results of laboratory tests before he can arrive at a diagnosis. Equally, he must be critical of the results he obtains from any therapeutic regimen. And if for any reason he is not, you can be sure that his patient will be.

I wonder if any of you gentlemen on the committee or its staff ever have suffered from a recurring pain? Speaking as one who has, I venture the opinion that you could not be deceived—certainly not for long—about whether a drug gave you relief. Well, the patient with arthritis comes to his physician for relief. If he does not receive it, he will want an explanation, or else he will seek relief elsewhere—regardless of the drug advertising his doctor may be exposed to.

To suggest that a physician is uncritical is completely to ignore the realities of the situation. Promotion may assure a physician's interest in a drug, but promotion cannot substitute for results.

There is no doubt in my mind that when physicians feel there is a need for a new drug in their practice, promotion can induce them to try one that offers promise. It is equally certain, however, that promo-

[1] "Thirteenth Rheumatism Review": Annals of Internal Medicine, vol. 53, No. 7, Dec. 30, 1960, p. 49.