I went on to state:

> The placebo substitutions were made in 86 of the patients, and in 70 of these there was a decisive clinical relapse on placebo. This clinical relapse was verified on repeated placebo trials in 55 patients.

In my opinion, these are well controlled observations, despite the fact that some statisticians would deny the validity of "single-blind" trials.

I believe it should be emphasized right at this point that, if the statistician reviewing my manuscript for the Journal of the American Medical Association was of the opinion that the appearance of side effects from indomethacin invalidated any single- or double-blind trials, logic and consistency would demand that he deny the validity of the double-blind trials carried out by Dr. Mainland and his group, and other double-blind trials. Apparently, what is one statistician's meat is another statistician's poison. There is not consistency.

When Dr. O'Brien implied that it was demeaning of me and my report that it was published in "modified form," he is not being entirely fair to this committee. The fact is that medical journal editors are generally assuming more and more of an authoritarian position and demanding modification of practically every article or report submitted to them. These modifications are based on recommendations from editorial boards and reviewers who no doubt are themselves quite human and fallible. And I might add at this point that Dr. O'Brien admitted in his own testimony last week that the article he submitted to Clinical Pharmacology and Therapeutics, to Dr. Modell and three reviewers, was found to contain errors. It was sent back to him, and he had to revise and modify those, so his report was also published in a modified form.

Because of the increasing influence of the statistician in medical reporting, the double-blind trial has been given a position of infallibility which is not entirely justified. For example, does Dr. O'Brien realize that patients will sometimes break open a capsule and taste the drugs to see if there is a difference? If they are taking a capsule one week and getting another one next week and getting a different effect, they may break open the capsule to see if there is a difference. These are difficult things to control when you are dealing with human beings. When you are dealing with animals, it is different. Even though the capsules may look identical, does he realize that some patients will reduce the dose or discontinue the drug if it is giving adverse reactions, but without informing the investigator? I think this is true especially if the work is being done in a large impersonal institutional clinic rather than the atmosphere of close rapport of the personal patient-physician relationship.

This frailty of the double-blind trial is further illustrated in the report of Dr. Mainland for the Cooperating Clinics Committee of the American Rheumatism Association. I should like to add here for the benefit of the committee that this impressive and high-sounding title gives this committee and its work an aura of authority and Olympian omniscience which its own members would be the first to deny categorically and emphatically.

In the first place, with reference to Dr. Mainland's work, it is an extremely attractive hypothesis that a lumping together of observations by a number of different clinics would, because of increasing size