Mr. GORDON. I am not a doctor. I am just giving you the conclusions reached by a team of doctors.

Dr. ROTHERMICH. I am asking you as a layman, not a doctor. One case in eight. Do you think that proves anything at all, really?

Mr. GORDON. You do not agree with these people?

Dr. ROTHERMICH. I think it has no significance at all.

Mr. GORDON. There is no significance?

Dr. ROTHERMICH. One out of eight, no.

On page 4528, Dr. O'Brien states that "a study of this type was designed in such a way that the bias is in favor of the drug." This is a highly arbitrary statement, but Dr. O'Brien proceeds to use this as a false premise for further condemning my report. As a matter of fact, the study was not designed in such a way that the bias was in favor of the drug, and I have done other studies in exactly the same manner before and since Indocin, and my conclusions were discouraging and unfavorable to the drug under study.

Mr. GORDON. Have these been published?

Dr. ROTHERMICH. No, sir.

Mr. GORDON. Have these been given to the FDA?

Dr. ROTHERMICH. Yes, sir.

Mr. GORDON. Yesterday?

Dr. ROTHERMICH. No, I said yes, sir.

Mr. GORDON. Could you supply them to us for the record?

Dr. ROTHERMICH. I think the FDA has all the material I have given them.

Mr. GORDON. I have looked through the files and I have not seen the studies.

Dr. ROTHERMICH. This is not related to Indocin. This is other drugs.

Mr. GORDON. Oh, you said before and since——

Dr. ROTHERMICH. Yes, I have done this same kind of study on other drugs and they did not come out at all.

Mr. GORDON. I see.

Dr. ROTHERMICH. On page 4529, Dr. O'Brien states that my study, as submitted to the FDA, differs drastically from the manuscript that was published in the Journal of the American Medical Association. This would imply that something about this condemns my report. I would like to say that much of this was due to the fact that the editor considered my manuscript entirely too long and felt that he could not devote that much space to it. We had considerable correspondence, between the editor and myself, but I agreed only to delete the word "blind" because of differences with the statistician-reviewer of the journal. It was the opinion of the latter that the blind and double-blind trial could not be done with Indocin, only because of my thoroughly honest statement that "occasionally patients would suspect the placebo substitution by a change in side effects;" and, in reference to and in deference to the statistician-reviewer, I made the further statement in the journal that "for this reason, from the statistician's viewpoint, the placebo trials in this report (and probably in most clinical drug reports) cannot be considered as true 'blind studies'." My article goes on further to elucidate this point, and I should like to quote the sentences which follow immediately after that:

> Usually there was enough delay in this awareness (of a change in side effects) to permit the therapeutic assessment. Furthermore, the appearances of side effects are often capricious and inconsistent, thus further limiting the patient's ability to detect placebo.