Now, I would like to emphasize that not only do they have less than 10 in many of these, but their duration of therapy was only for a few weeks—3 months, which in my opinion is much too short a time to evaluate any drug. This is what I will try to emphasize later on.

They allowed an unlimited consumption of aspirin in both the placebo and the treated patient. So they have no idea of how many aspirin tablets were taken by either group. Now, it is entirely conceivable that a patient may have been on the active drug and taking two aspirin tablets a day, or four aspirin tablets a day, and when placed on placebo, because of an increase of symptoms, he may have increased his aspirin consumption to 12 or 16 a day, but they do not know this.

Senator NELSON. There is no way to be sure about it, is what you are saying?

Dr. ROTHERMICH. They kept no records of it.

Senator NELSON. Oh, I see.

Dr. ROTHERMICH. I would like to emphasize, too, Senator Nelson, that I am not saying that this is not a worthwhile trial. I do not mean that at all. I think this kind of trial should be done. But I think it is wrong to assume that this particular type of study is the only study that should be done, and I think it is wrong to assume that this type of study has no flaws. It has many flaws, because we are dealing with human beings. When you can take mice and rats and put them in cages and keep them under fixed control, then you can have the ideal, well controlled study. But when you are dealing with human beings, this is something else again.

Senator NELSON. This has always been my view. I have always said politics would be a wonderful thing if you did not have to deal with human beings.

Dr. ROTHERMICH. Yes.

I did think it was rather significant that Dr. Mainland himself testified that if he were treating rheumatoid arthritis—although he disclaimed that he was treating any patients—he would select indomethacin for a cautious trial in those patients who have failed to respond to basic therapy, including salicylates, despite the fact that his report indicated negative results.

In this context, for the information of this committee, I would like to quote from my article in the JAMA in the section under comments:

> However, it should not be inferred that indomethacin replaces or eliminates the need for a sound basic therapeutic program for the patient with rheumatoid arthritis which should include increased rest, salicylates, physical therapy, and other adjunctive or supportive measures. The patient with rheumatoid arthritis who is not responsive to the basic program of therapy may have this supplemented by the cautious prescribing of indomethacin beginning with a dose, et cetera, et cetera.

It would seem that Dr. Mainland and I have identical views on the clinical usefulness of indomethacin.

In my early studies, I was repeatedly admonished by my preceptors that it was unhealthy for medicine generally and unwise for the investigator to rush into publication with short-term observations. For this reason, I went to great pains to delay my report in the Journal of the American Medical Association until I had accumulated more than three and one-half years of intensive experience with this drug. I subjected the drug to the most thorough and penetrating clinical scrutiny.