Dr. LAWRASON. I do not think we will ever be fully satisfied, sir.

Senator HATFIELD. Do you think this present lack or, let us say, this underdeveloped reporting system that exists now could become a source of difficulty for you in getting some real evaluations in some of these drugs?

Dr. LAWRASON. They have in the past, but we have spent a great deal of time in examining the issues and rectifying the problems. I would hope that they would not.

Senator HATFIELD. There is no role of Government, then, that you see?

Dr. LAWRASON. No; just that it is part of the requirement for adequate supervision and surveillance of the studies.

Senator NELSON. Please go ahead, Doctor.

Dr. LAWRASON. The committee has heard much of the ARA Cooperating Clinics project and of other approaches to the development of controlled studies. When the ARA project offered the opportunity to have our new drug be the first agent employed in a complex study of this design, we were pleased. We consulted with the committee and we supported its goals, even though all previous experience with such studies indicated that no agent of demonstrated anti-inflammatory and analgesic properties had ever successfully been differentiated this way.

Mr. GORDON. I have been informed by Dr. Donald Mainland of the Cooperating Clinics Committee, that they did a trial on hydroxychloroquine sulfate. This was a 6-month trial using the same method as was used with Indocin, with aspirin permitted in accordance with the committee's practices. The trial showed clear cut differences between the drug and placebo.

Dr. LAWRASON. I am not a clinic witness.

Mr. GORDON. This does not fit in with what you were just saying. You said there was no such study, or that this type of study had never shown any differentiation. This particular study apparently did. I just wanted to bring that to your attention.

Dr. LAWRASON. Has this study been published?

Mr. GORDON. I do not know.

Dr. LAWRASON. We are referring to the fact that a similar study was carried out with cortisone almost 10 years ago. It showed that cortisone was no more effective than the placebo. I believe there was another study that has not yet been published, to our knowledge, and that this also failed to show a difference.

Mr. GORDON. I also would like to read into the record the communication I received from Dr. Mainland on April 24, 1966, with respect to that type of study that they did. It says:

In addition to review by the editor and referees of the Journal in which the report was to be published, Dr. Mainland requested a manuscript of this report be reviewed by Dr. Stanley Shor, who has been director of the Department of Biostatics of the American Medical Association * * *. Dr. Shor was very critical and very experienced in reviewing medical journal manuscripts as exemplified by his report on the subject, "statistic evaluation of medical journal articles," volume 195, pages 41123 to 41128. Dr. Shor commented on April 18, 1966, on the indomethacin report as follows—

that is the CCC report—

"It is, I think, the type of analysis that should be kept as a reference by every clinic investigator. Many times I am asked, are there any studies that have been published that you think are really good in terms of drug trials. Of course, every