Drug Administration as an adverse reaction report. This is to be done, I believe, within 15 days of the time we acquire the information.

Senator HATFIELD. This is by regulation?

Dr. LAWRASON. By regulation.

Senator HATFIELD. So that all pharmaceutical houses subscribe to or are required to follow this same procedure?

Dr. LAWRASON. That is right.

Senator HATFIELD. Do you think it is an adequate procedure? Do you thing it is an effective one at the present time?

Dr. LAWRASON. I believe it is working fairly well; yes, sir. I think one of the problems, if I might say so, is the handling of massive amounts of data . . . we are talking about enormous amounts of information.

Senator HATFIELD. What I did understand you to say was the period of time that this system of reporting continues after the initial introduction of the drug?

Dr. LAWRASON. As long as the drug is registered as a new drug, it will continue on for years.

Senator HATFIELD. You mean you are on a continuing research and accumulation of data and facts on the use of this drug all of the life of the drug?

Dr. LAWRASON. It depends on which aspects of research with the new drug we are pursuing and how it relates to the reporting of adverse reactions, but the accumulation of data continues throughout the lifetime of the drug.

Senator HATFIELD. Do you have a pill—the pill? You do not manufacture the pill?

Dr. LAWRASON. No, we do not.

Senator HATFIELD. Well, in my opinion, that is something.

Mr. GORDON. You mentioned the various studies that are going on. Are these conducted, sponsored, or directed by your company?

Dr. LAWRASON. Yes, sir; they are all sponsored—the double-blind studies, the ones I reported. They are all under IND's.

Mr. GORDON. You talked about recent ones, the ones that are going on now.

Dr. LAWRASON. That is correct. They are all established under the IND system and sponsored by us.

Senator HATFIELD. Could I ask you one followup question, Doctor?

Are you satisfied with the kind of reporting you are getting from physicians on their own experiences in the use of these drugs? What kind of conflict does a doctor face in possibly being fearful of malpractice charges if he reports some of most, say, erratic kinds or the most undesirable kinds of reactions? Is there an inhibition on the part of the physician, or what kind of relationship do you have on that?

Dr. LAWRASON. I would say that one of our greatest problems, as it is in most circumstances these days, is communication. However, we have established within our research group, at least, a good working relationship with physicians so that reporting and constant surveillance of ongoing studies are handled as well as we possibly can. We are always attempting to improve this. Distance, time, these are factors. We try to minimize any delay in communications with physicians.

Senator HATFIELD. You are not really, then, fully satisfied with the kind of reporting which you now have from physicians?