in the past, then how can anyone establish if a mistake has been made, when it was made, where it was made and by whom it was made? It seems to me this is an important matter, Mr. Chairman. I raise this matter in respect of thalidomide not because of what has happened but because I feel that we should surely learn some lesson for the future.

The CHAIRMAN: I think that is precisely the reason this committee was set up.

Mr. ORLIKOW: Therefore, Mr. Chairman, has it not been established sufficiently that judgment must be vested with the department? This does not mean that there may never be medical action, at least from a local point of view, but I think we have to be sure that the department has to widely use its judgment when dealing with these requirements.

Mr. NICHOLSON: It is my understanding, Mr. Chairman, that that is a recommendation of the special committee.

The CHAIRMAN: That is right.

Mr. HARLEY: Mr. Chairman, I should like to ask a few questions in regard to control in Canada. We are concerned with safety, and it certainly does influence the workings of the department. Do drug or manufacturing companies have to prove or satisfy themselves not only as to the safety of a drug, but as to its effectiveness in respect of the reason it is prescribed?

Dr. MORRELL: Dr. Harley and Mr. Chairman, safety is, as you know, a very relative term. First of all, I do not think the manufacturers can prove a drug to be safe in the popular usage of that term. Safety is a relative term. In respect of drugs it is never absolute, and to ask a manufacturer to prove that his drug is safe I think would finally lead to the rejection of most drugs. So that we really look for information as to any possible hazard or danger and the evidence of such which turns up in the clinical trials and investigations of the drug during the investigational period. This is the thing we really look for primarily.

You cannot help but look for evidence also of effectiveness. I think this goes along with your scrutiny of a new drug submission in respect of so-called safety. We have been in the habit, of course, of looking for the effectiveness or evidence of effectiveness which is claimed for it by the manufacturer, or will be claimed for it when it is on the market. We have at times questioned the evidence that is supplied in this respect but it has not been a prime consideration. The prime consideration has been to get evidence as to the proper dosage, proper use, and hazards that accompany its proper use as well as the warnings and information that should go to the doctor in respect of the proper use of the drug. The doctor who is going to administer the drug cannot do so unless he knows when he should not give it and what to expect when he does give it. This is what we are really looking for. We do not ask the manufacturer to prove that his drug is effective, if you mean by "prove" that there is no doubt about it.

I have thought about this often enough. If it is effective in 20 per cent of the people you give it to, is that proof, and if it fails in the other 80 per cent of a certain group, in respect of some types of diseases, this would be a welcome addition, I think you would agree. So that we have got away from refusing to admit a drug altogether on the basis of effectiveness.

I note that the Brien committee has made the recommendation that we should require in our regulations "substantial evidence" rather than proof of the effectiveness of a drug.

Mr. HARLEY: Mr. Chairman, I should like to ask one follow-up question. Perhaps this should be answered by individuals of your staff who review these