

Finally, I think we should have authority to stop a clinical trial promptly at any stage in the investigation if the minister finds that there is some danger to the public resulting from this clinical trial.

The CHAIRMAN: Could I interrupt for one second, Dr. Morrell? Do you have an example where some of these regulations that you would like to have put into effect were not put into effect because of the law? Let us take as an example the Liefcort situation in Montreal with Dr. Liefman. Were you hampered in any way in putting your mechanics into effect because of the regulations?

Dr. MORRELL: I think we were hampered to a certain extent. It revolves largely around what is a qualified investigator. I think we disagreed with Dr. Liefman's definition of the qualified investigator. This was one of the hampering features in dealing with that problem.

Mr. ORLIKOW: Did you have the authority to tell Dr. Liefman, and to make stick, what you considered were qualified investigators, failing which he could not really put his drug on the market?

Dr. MORRELL: Not really, Mr. Orlikow. I know we do not define in the regulations a qualified investigator so it becomes a question for a magistrate to decide. The actual objection we had to the so-called study that Dr. Liefman was undertaking was based on the fact that the reports from the investigators that had been returned to him were unsatisfactory under the terms of section C.01.307.

Mr. HADASZ: Mr. Chairman, could Dr. Morrell tell us what is the present status of the drug Liefcort? Has the department recommended to the government to put it on schedule H, or are they still studying this problem?

Dr. MORRELL: The present status of Liefcort is that it may not be used by anybody else but by Dr. Liefman. Dr. Liefman is now a qualified licensed medical practitioner and we feel that we cannot interfere in his practice, but no one else except Dr. Liefman is to use the product. Actually, the product itself labelled as such is not now distributed. He can, of course, prescribe to his own patients any medication or treatment that he sees fit.

Mr. HADASZ: I have one more question on the drug Liefcort. Does the director or does the department feel that the drug Liefcort is safe for humans?

Dr. MORRELL: That is a difficult question. Evidence has not been presented that it is. We felt at the time that we were examining the files of Dr. Liefman that there were no reports on the side effects which we would anticipate from our knowledge of the drug at that time. We had to analyse that drug to find out what was in it, and when we knew what was in it we felt that there was not the kind of information we could anticipate, in the report. We have read about the side reactions since, but in so far as we are aware from the information we have we could not say that it was safe or really unsafe. If we took the evidence available to us, it seemed to be safe, but we were still suspicious because of what we considered the inadequate information that was presented.

Mr. PATTERSON: Dr. Morrell, you made reference to the studies that had been carried out by Dr. Liefman in connection with that particular drug. I wonder if there is any significance in the fact that you qualified that reference and said "so-called studies".

Dr. MORRELL: I did not feel that they were proper, thorough and suitable studies to demonstrate what we expected them to demonstrate. I do not think he could have ever submitted a new drug submission that would be acceptable