At the moment, two drugs are to be included under schedule H. The first is thalidomide which, of course, has already been withdrawn from the market in Canada. The other drug to be included under schedule H merits a word of explanation.

Lysergic acid or LSD as it is often called, is not to be associated with thalidomide because its purpose is quite different. LSD has never been on the market commercially but has been used experimentally in psychiatric treatment. It has been effectively controlled up to the present time through co-operative action by the manufacturer in consultation with the department. The patents which were owned by the manufacturer have now expired and there is the possibility that the strict controls may not be as effective in the future as they have been in the past. After consultation with the manufacturer, it is considered that the proper action to be taken at the present time is to put lysergic acid on schedule H.

Having explained our purpose in putting lysergic acid in schedule H, I should also draw attention to section 24 (1) (j) of the present act which provides authority to the governor in council to exempt a drug from all or any of the provisions of the act and to prescribe the conditions of such exemption. Under this authority, we would be prepared to consider a regulation which would exempt lysergic acid from complete prohibition to the extent that might be necessary to permit its availability under rigid conditions in a research program.

This could involve the drug being made available to certain approved institutions provided that its use were confined to purely experimental research and for the purpose of ascertaining further evidence respecting its value and efficacy. I might say that we have already received certain representations in this regard and we would be prepared to give consideration to an appropriate exemption to meet the needs of experimental research under competent auspices.

Hon. members may have seen in the press some suggestions relating to the possibility of thalidomide being valuable in cancer research. I might say that similar action to exempt thalidomide from absolute prohibition could also be taken in this particular research area if it should seem desirable to make it available for that purpose.

Turning now to the third item of Bill C-3, this as the house will note, provides authority to make special regulations relative to new drugs. While we have had authority in the legislation to make regulations in this field, the recent experience with thalidomide has, I believe, served to focus attention on this particular area. We have, therefore, thought it appropriate to separate the authority to make regulations concerning new drugs from the general regulation making authority. This is the purpose of the present amendment.

[Mr. Monteith.]

At this point, it might be useful for me to outline briefly the scope of the regulations regarding new drugs which have been in force for over ten years. These have required the manufacturer prior to the sale of a new drug to file with the department a submission containing all available information with respect to the drug—its properties, its dangers, its recommended use, and other facts which the manufacturer has obtained in connection with his preliminary research activities. This material is carefully examined in the food and drug directorate to ensure that the requirements of the regulations have been met.

The manufacturer's reports must, of course, refer back to experimental and clinical trials involving the drug. There are special regulations applicable to clinical investigation of a drug. If the directorate considers that the material furnished by the manufacturer adequately demonstrates that everything reasonable and possible has been done to investigate the drug, to find out its dangers as well as its benefits, to provide the medical profession with adequate directions for use, then the drug is considered to have met the requirements of our regulations.

In many cases, however, further information is requested, further tests required and there are new drug applications in the department at the present time which have been pending for many months and in some cases for years. After a drug is introduced, the directorate continues its interest in the product to ensure that the medical profession is kept advised of new information or evidence arising out of experience with its use. I might add that in the course of nearly 11 years, some 2,000 new drugs have passed through the screen of our new drug regulations and have been placed on the market in Canada with great benefit to Canadians.

In view of the current study by the Royal College of Physicians and Surgeons of our new drug procedures, I am not in a position at the moment to indicate what changes may be made in our regulations under this new authority. Certainly, we would wish any changes to reflect to the extent appropriate the recommendations which we expect may be contained in their report. I might say that we have been studying the new legislation recently introduced in the United States with respect to the introduction of new drugs. We have received from manufacturers useful information respecting their procedures in this regard. These also are being given careful consideration.