submissions, but I was wondering whether in the study there is a placebo test, so that some idea can be gained as to whether the drug is effective or not?

Dr. MORRELL: I am afraid they do not, Doctor Harley, but if you wish details in this regard you will have to ask some of the individuals who do the reviews themselves.

The CHAIRMAN: Would you like to reserve that question until we have individuals familiar with this situation before us?

Dr. MORRELL: Doctor Pugsley and Doctor Murphy are both here, Mr. Chairman.

Mr. HARLEY: Mr. Chairman, perhaps it would be of information to some members of this committee if I explained that "placebo" means the use of a substance of no chemical action at all, involving the use of a capsule or tablet containing sugar instead of a drug in order to see if there is any reaction to it.

The CHAIRMAN: Would you like to ask any question in that regard?

Dr. MORRELL: The answer to your question is, not always.

Mr. HORNER (*Jasper-Edson*): Mr. Chairman, I should like to ask Dr. Morrell whether or not teratogenic studies are required in respect of new drug submissions particularly where the new drugs are associated with women of child bearing ages?

Dr. MORRELL: Teratogenic studies were not required prior to the development of thalidomide.

Mr. HORNER (*Jasper-Edson*): Are they required now?

Dr. MORRELL: Yes, not by regulation but by administration.

Mr. HORNER (*Jasper-Edson*): I should like to ask a supplementary question. Is there a reasonably good study in this regard which can be standardized?

Dr. MORRELL: The answer is no. I do not think that you can predict from animal tests what will happen in humans. It is true that several groups of people have been able to produce malformed rabbits in litters, the mothers of which have had thalidomide in high doses, but this has not been uniformally obtained. Other people have been unsuccessful. Several at least have been successful in this regard.

One of our projects, and I am sure a project that is being studied by a great many people not only in industry but in universities, is aimed at defining some reliable teratogenic tests which can be done on animals, embryos or tissues.

Mr. HORNER (*Jasper-Edson*): I have just one further simple question. Do manufacturing firms having large submissions of new drugs have to pay a substantial fee for these processes?

Dr. MORRELL: No, sir, they pay nothing.

Mr. BALDWIN: Mr. Chairman, I was interested in that exchange between Doctor Morrell, Doctor Orlikow and Mr. Valade. In this respect I should like to point out that I have noted from reading the regulations that regulation C.01.303 provides that no person shall sell a new drug where certain material changes are made in the conditions of use, labelling, pharmaceutical form, dosage, strength, quality or purity for manufacturing methods or facilities for control, and I wondered whether we could achieve the purpose behind this discussion by adding thereto, that if it becomes apparent to the manufacturer, or if he discovers that there are side effects or contra-indications, that did not appear in the new drug submission or in the original investigation, that he