It includes the setting up of clinical studies which will determine whether there is sufficient material available to satisfy the Food and Drug Administration for us to apply to the FDA for approval of a new drug application, and these samples or trial quantities during this initial phase are included in research. However, once the drug has been introduced on the market, whatever samples are then being distributed do not fall under research unless they are for indications which have not yet been approved and are still in the experimental stage.

Senator NELSON. So you either do the laboratory research and the research on animals yourself or you contract it out; is that correct?

Mr. CONZEN. Most of it is done by ourselves; yes.

Senator NELSON. Then after you are satisfied that it has some therapeutic efficacy so far as animals are concerned, the next stage is to test it on human beings?

Mr. CONZEN. There is one step in between, and that is toxicology, to satisfy the Food and Drug Administration and ourselves that the side effects or the toxic effects do not endanger the patient, or that the side effects outweigh possibly the beneficial effects of a new drug.

Senator NELSON. And if this drug gets the approval of FDA, then you are authorized to test its efficacy on human beings?

Mr. CONZEN. Well, this is not exactly so. We file an investigational new drug application with the Food and Drug Administration, and in the absence of any notification to the contrary, we are authorized to proceed with clinical trials.

Senator NELSON. These clinical trials include sending samples to specific physicians to test; is that correct?

Mr. CONZEN. They are special studies set up under regulations of our Government, and the investigators have to file very strict protocols and procedures, and we again have to comply with very strict regulations as to what we send, how we send it, and to whom.

Senator NELSON. And then you also do clinical testing by arrangement with teaching hospitals and that sort of thing?

Mr. CONZEN. Yes, sir.

Senator NELSON. Then what you are saying is that to this point all the steps you described are chargeable to research.

Mr. CONZEN. Yes, sir.

Senator NELSON. Beyond that, your distribution to physicians, once a drug is approved, is not chargeable to research.

Mr. CONZEN. Unless it is a new, not yet approved indication which still falls into the realm of experimental research work. For instance, I mentioned leukemia. This is not an approved indication in the high doses in which experiments are being conducted, and this would still be chargeable to research; but in the approved indications, the material which we sell, and the amount of money which we spend would appear in our financial statements under selling expenses, including samples.

Senator NELSON. So, no aspect of the market promotion is chargeable against research?

Mr. CONZEN. That is correct.

Senator NELSON. A few moments ago you said it was not possible to break down the amount spent by your corporation on research on prednisolone or prednisone. It isn't possible then for your corporation