

to do a cost accounting, so to speak, of the costs that went into the development of prednisone, so that you can price in accordance with the cost of your development?

Mr. CONZEN. I don't think so, because the clinical staff and the laboratories are used for all drugs, whether they are in research or continuing research, and we can't intelligently allocate all these expenses to a specific drug.

Senator NELSON. I understand.

Mr. GORDON. May I interrupt for just a moment? Can we say that NIH was the first to introduce prednisone into clinical medicine?

Mr. CONZEN. I wouldn't say that, no. As far as I remember, the first clinical paper was published under the auspices of NIH using Schering's prednisone, namely Meticorten.

Mr. GORDON. I have here excerpts from hearings on drug safety before a subcommittee of the House Committee on Government Operations. NIH stated that the first clinical studies of these new steroids were conducted on patients with rheumatoid arthritis in the National Institute for Arthritis and Metabolic Diseases. The results were encouraging and so on and so forth, and NIH reported these findings to the scientific community in November 1954.

Mr. CONZEN. Yes, sir.

Mr. GORDON. Now, wouldn't you say that the report of these findings by NIH was really the introduction of prednisone to the scientific community?

Mr. CONZEN. I would say the introduction to the scientific community was made by Schering Corp. when it made the product available to NIH.

Mr. GORDON. I mean the medical community, clinical medicine.

Mr. CONZEN. As far as the clinical findings are concerned, this would be correct as to this particular work.

Mr. GORDON. Now, isn't it also true that in getting a new drug application, you depended to a considerable extent on work done by or for the National Institutes of Health?

Mr. CONZEN. Only for one part of the new drug application, because the new drug application has to satisfy the Government that the manufacturing procedures and processes are sound, that the toxicology is good, that you observe the usual standards of manufacture and quality control, and they would also undoubtedly expect clinical trials beyond those from one source.

Mr. GORDON. Did you mention efficacy? Efficacy has to be proven, too, does it not?

Mr. CONZEN. Yes, efficacy and safety.

Mr. GORDON. And you used the work done at NIH?

Mr. CONZEN. Oh, yes.

Mr. GORDON. As part of your contribution.

Mr. CONZEN. Absolutely.

Mr. GORDON. To the FDA.

Mr. CONZEN. Yes.

Mr. GORDON. And you are not trying to claim, as I see it, that Schering alone was responsible for the research and development of prednisone?

Mr. CONZEN. I would say that we were alone responsible for the discovery of the drug and the development of the drug, but that we