the issue of the Medical Letter to him that demonstrated a cost differential of $2.59 a 100 tablets of prednisone to Schering's price of $17.90. He asserted that his firm's product is of higher quality. The proof is that doctors prescribe it. I said you have one-third of the market; why don't you contract for double blind clinical testing with an independent respected research lab? Then when you prove what you assert, you will have the whole market. The answer to that was it is not worth it.

Dr. GODDARD. On the other hand, I know one representative of a pharmaceutical firm, when this same issue came up in a meeting, who said, "I can assure you we are going to do that with our product and we will be able to say to the physician, ours are superior." I said that they were welcome to do it.

Senator NELSON. Have they done it?

Dr. GODDARD. Not yet. This meeting was within the past month. They have not had time to.

Senator NELSON. We are probably going to find out.

I will recess the hearing until 1:15.

(Whereupon, at 12 noon, the above hearing recessed, to reconvene at 1:15 p.m. of the same day.)

AFTERNOON SESSION

Senator NELSON. The hearing will resume.

Dr. Goddard, just at noon, the Pharmaceutical Manufacturers Association issued a news release taking issue with statements you made—maybe they take issue with you before you made a statement. I am not sure.

STATEMENT OF DR. JAMES L. GODDARD ET AL.—Resumed

Dr. GODDARD. I think they must have. It is a printed statement, Senator Nelson.

Senator NELSON. The statement says:

Commissioner Goddard commented in his statement before the Senate Subcommittee today that many NDA's—New Drug Applications—were "reviewed" by the FDA and "found not approvable." Unfortunately, Commissioner Goddard's statement does not adequately describe the present FDA procedure.

The following four points are important:

1. Commissioner Goddard referred to the "review" of NDA's. It would have been helpful if he had explained the preliminary review by FDA of a submission by a company to determine whether an application should officially be filed under FDA published regulations. The regulations of FDA expressly provide for this preliminary review and exchange of information between scientific personnel of FDA and industry. Under this present procedure, companies will submit—"not file"—NDA's for the purpose of clarifying questions which FDA scientific personnel may have so that the applicant company can expeditiously complete its application for filing.

Do you want to comment on that?

Dr. GODDARD. Senator, could I comment?

I think they have missed the point. The point here is that the statistics I have referred to were based on submissions that we had received. We were not carrying out a preliminary review. These statistics were derived from data compiled from formal, incomplete letters issued to the company, so I think they missed the point.