tive of Parke, Davis or to us that you intended to ask some question today about those ads and you would like have a witness qualified on that subject?

Senator NELSON. We intend to ask questions about the whole spectrum of issues related to the drug industry as we have of every other witness who has come here. You are the first one to complain and you have not yet been a witness. I can't predict every question we will think of as various issues arise. But if you think this is unfair, as I say, you can notify my office as to when Parke, Davis wants to go through these ads with us and we will pick out a time very soon for Parke, Davis to bring their advertising people. Let them talk about the morality of this ad.

But it shocks me that you do not even blush when you defend a company advertising drugs in another country without the warning required here when the reason it is required in this country is because the ad without the warning does mislead doctors, it does cause people to prescribe a dangerous drug for illnesses that are not serious. That is why the ad is run with the warning. And you know it and everybody else knew it, too.

I would like an answer to that. If this is the standard of ethics by which the industry operates, I tell you, you fellows are in for some sad trouble. I do not think this country will stand for it.

I do not have any more questions of this witness.

Thank you, Dr. Lueck.

(The complete prepared statement and attachments submitted by Dr. Lueck for presentation on November 16, 1967, follows:)

STATEMENT OF LESLIE M. LUECK, PH. D., DIRECTER OF QUALITY CONTROL, PARKE, DAVIS & CO.

TOTAL QUALITY CONTROL OF MEDICINAL PRODUCTS

Mr. Chairman and Members of the Committee: My name is Leslie M. Lueck. I am director of Quality Control for Parke, Davis & Company. I am representing the Pharmaceutical Manufacturers Association today to provide you and members of the Subcommittee with an insight into the quality control operations of reputable drug firms.

I am a native of Wisconsin and a graduate of the University of Wisconsin having received a Ph.D in pharmacy from that school in 1954. After receiving my doctorate, I joined the Research staff of Parke, Davis & Company and spent the first seven years of my professional career in Product Development. Since 1961, I have devoted my efforts to Quality Control, becoming Director of Quality Control in April 1963.

My interest in the quality of medicinal products was, of course, first generated as a stuednt of the pharmaceutical sciences. However, it was enhanced to a great degree after joining Parke, Davis & Company for it was there, in Product Development, that I experienced *firsthand* the true meaning of quality in a medicinal product.

The philosophy of quality control of pharmaceutical products has changed a great deal since its inception in the late nineteenth century.

There is often a tendency to associate the quality control of drugs with enactment of the first Food and Drug laws in 1906. This, however, is not the case. Quality control was practiced by certain pharmaceutical manufacturers before this law came into being and long before the term "quality control" was used to express the idea.

For example, prior to about 1880, there were no standard tests applied to a medicinal product. Compendia were primarily concerned with methods of preparation; recipe books, rather than books of standards.

The first standardized pharmaceutical product was controlled by a determination of the total amount of alkaloids present in various preparations. Subsequent