Mr. SCHNEIDER. The statement is based upon the report. It did not copy it.

Mr. GORDON. Did you say copies were available?

Mr. SCHNEIDER. Yes, that is true. Copies were available from our office, and the address where it could be obtained was given in the Federal Register announcement.

Senator NELSON. This was filed with the Federal Register?

Mr. SCHNEIDER. Yes, sir.

Senator NELSON. Did it give the reason for the revised labeling?

Mr. SCHNEIDER. Yes, based upon the NAS-NRC report.

Mr. HARRISON. Did that FDA publication, or the publication in the Federal Register, contain the statement that it is not the drug of choice?

Mr. SCHNEIDER. In the labeling you are talking about, are you talking about the disease typhoid?

Mr. HARRISON. I am talking about the presentation in the Register of which you are speaking.

Mr. SCHNEIDER. It gave the labeling as recommended.

Mr. HARRISON. Did it contain the statement that this is not the drug of choice?

Mr. SCHNEIDER. For typhoid?

Mr. HARRISON. Does the labeling state it is?

Mr. SCHNEIDER. The labeling states that the article is a drug of choice in typhoid.

Mr. HARRISON. It does not state that it is the drug of choice——

Mr. SCHNEIDER. It restricted its use for severe salmonellosis and typhoid.

Mr. HARRISON. This appears to be substantially different from what was just stated here.

Senator NELSON. What is substantially different?

Mr. HARRISON. There apparently is no statement—again without having the Federal Register available—that there is a labeling requirement for a statement that this is not the drug of choice.

Mr. SCHNEIDER. You see, the labeling was oriented not toward specific illnesses as much as it is designed or oriented toward specific organisms. You see, that is the difference.

Mr. HARRISON. I understand.

Dr. ANNIS. But am I correct that this basically is the information of the Food and Drug Administration on the basis of which regulations will be instituted to insist on change of labeling?

Mr. SCHNEIDER. This is the labeling that is required, based upon the NAS-NRC review.

Dr. ANNIS. And you give the manufacturer 30 days——

Mr. SCHNEIDER. I don't know if we gave 30 days to anyone that was adversely affected by the statement in this case.

Dr. ANNIS. This automatically would affect the subsequent advertising and labeling for us, because the company, in making up its advertising for our publication or any other publications would have to bring about the changes. Is this not correct?

Mr. SCHNEIDER. That is correct.

Dr. ANNIS. So it is an automatic thing as it pertains to their advertising to the profession. These are their changes that they would therefore institute and would come into subsequent ads submitted to the AMA or any other source.