would be routine to the American Medical Association in a matter as important as this, that it would be automatically acted upon.

Dr. ANNIS. It would have been, Senator, if it had come to attention of the right people. But we are talking about something that we do not even know what was printed in the Register.

Senator NELSON. I understood the witness to say that they did regularly review the Register.

Dr. ANNIS. They do.

Mr. HARRISON. Yes. I do not know the particular item at the moment. I do not know what it was about in the Register.

Senator NELSON. I beg your pardon?

Mr. HARRISON. I am saying that, as a routine matter, we do go through the Federal Register and a number of other publications that come from Washington and the Federal Government. I would assume then that as a routine matter, we would have seen this particular item. I am not familiar with the contents of the item at this moment.

Senator NELSON. I would be concerned about two things: one, if the drug evaluation efficacy study, and there is a big one going on as, of course, you are well aware in the medical profession ——

Dr. ANNIS. Many of them all over the country. We are very proud of it.

Senator NELSON. Yes, and it is being reported to the Food and Drug Administration. One, is the communication so bad between the National Academy of Sciences, the FDA, and the distinguished medical societies that 5 months would go by on an important issue like this without the societies knowing it? That would be the first question.

The second question is, if that is not the case, if attention were called—I mean, if the AMA reviews the Register, why was not the publicity given by AMA? That would be the second question.

Dr. ANNIS. I would be able to answer that question when we know what we are talking about.

Mr. GORDON. There is an official from the Food and Drug Administion present. I just asked him what was in the Federal Register.

Mr. Schneider would you step forward for just a moment, please?

What was in the labeling?

Mr. Schneider is with the Food and Drug Administration.

Senator NELSON. Would you identify yourself, please, and give your agency and title?

STATEMENT OF MORTON M. SCHNEIDER, CHIEF, CONGRESSIONAL SERVICES, FOOD AND DRUG ADMINISTRATION

Mr. SCHNEIDER. My name is Morton M. Schneider; I am Chief of Congressional Services for the Food and Drug Administration.

Mr. GORDON. What was in the Federal Register?

Mr. SCHNEIDER. The Federal Register announcement contained a statement to the effect that, based upon the NAS-NRC report, the following labeling is recommended for the drug. It then set forth the complete labeling for the drug.

Senator NELSON. The new labeling?

Mr. SCHNEIDER. Yes, sir.

Senator NELSON. Did it recite the National Academy of Sciences' efficacy study?