lished as official notice to the manufacturer so they can submit comments with respect to the action that is proposed to be taken, or whatever would be involved. That is official notice.

I thought if we had a copy of it, we could look to see what is involved in this particular instance.

Dr. ANNIS. Merely as a citizen, I am a little surprised, Senator, that after all the publicity that has redounded from your investigation on this drug, a finding of this kind, if it were a final decision, would not have gained more currency if it were really put into the distribution channels.

In other words, here is an essential finding that is very important to the Food and Drug Administration. We find when they begin to investigate mixed drugs like Panalba and Mysteclin and others—this we found in the medical press as well as other press, so someone made it immediately available.

I must admit I may be derelict, but I read a great deal and it has only come to my attention in the last few days.

Senator NELSON. I think it was in the public press.

What I am curious about is when the National Academy of Sciences issues an evaluation of the drugs in some detail, and the FDA announces it in the Federal Register, does not the American Medical Association get these filings and look at them?

Dr. ANNIS. In this particular instance, without seeing it, I would not know.

Mr. HARRISON. If you are asking, Senator, whether we review the Federal Register as to items that are and should be of interest to medicine, the answer is "Yes," we review the Federal Register on a regular basis. I am inclined to believe that the notice you are speaking of, and I do not recall it, may have been notice to the manufacturer with respect to some finding and an opportunity for the manufacturer to provide some additional information. I do not know.

Senator NELSON. No, this was an evaluation, a new evaluation of the drug by the National Academy of Sciences, the National Research Council, Division of Medical Studies. It is a drug efficacy study. It was a formal study done on it. They reached their conclusion and this is an 11—a 10½-page evaluation of the drug. It is then made public by a filing in the Federal Register.

Mr. HARRISON. This is with respect to the changes agreement that may be required in labeling?

Mr. GORDON. Yes.

Senator NELSON. That would be part of it.

Mr. HARRISON. Most likely it was intended to provide notice to the manufacturer for the purpose of giving him an opportunity to comment.

Senator NELSON. But it evaluates the drug for all purposes. Staphylococcal infections—it makes a statement about that, evaluates it "possibly effective." It gives documentation; ricketsial diseases, and the evaluation is "effective, but * * *." Evaluation of typhoid fever, "effective, but * * *" and so on.

The NAS–NRC review of chloramphenicol is filed in the public record. AMA reviews it, you tell me. I would assume you would. The Federal Register is a public record, of public notice.