Senator NELSON. I see. That was action of the FDA then?

Dr. LEY. That is right.

Senator NELSON. So then I would guess that you have to conclude from this that you just about have to measure year versus year rather than particular months, although at certain times of the year, there is a rise in the number of certifications which I assume is associated with the incidence of the cases for which it may be indicated; is that correct?

Dr. LEY. Yes.

Senator NELSON. Please go ahead.

Dr. LEY. The committee saw no need for any further labeling changes in the warning section or in the indications for use of the drug. A number of other suggestions which had been made in the past for controlling the use of this antibiotic were also considered by the committee. This includes such steps as restricting the use of the drug to hospitals, requiring a procedure of countersigning prescriptions, or licensing the drug as a narcotic. The committee was unanimously opposed to such restrictions. Neither did the committee consider it advisable to add warning information on the labeling provided the patient. The commitee did, however, recommend the exploration of further means of emphasizing to the medical community the proper uses for this drug and its possible adverse effects.

On the basis of the committee's recommendations and our own consideration of this matter, we have started, or will promptly initiate the following actions:

1. We have asked the American Medical Association for assistance in communicating at the county medical society level information as to the misuse of chloramphenicol, the limited areas of its proper usefulness, and the grave hazards associated with the drug.

2. The AMA News has agreed to give further publicity to the chloramphenicol problem in an early issue.

3. Both the American Hospital Association and the Joint Commission on Accreditation of Hospitals will be asked to support and encourage the broader use of pharmacy and therapeutic committees in hospitals, a point that Dr. Wehrle made in his testimony to you yesterday.

4. The AMA Council on Drugs has proposed that these committees exercise more effective control over drug use and improve the reporting of adverse reactions. We intend to fully support the council in this recommendation.

5. We have received the Parke, Davis promotional material, noting the discontinuance not only of the "reminder" ads, but also of a group of ads headlined to promote the drug for respiratory and urinary infections, which we discussed here earlier.

6. We have checked the detailing piece used by Parke, Davis in the promotion of the drug and it is in conformity with the package insert.

In summary, Mr. Chairman, I believe we have made considerable progress in dealing with an exceedingly difficult problem. I intend to make every possible effort in the months ahead to assure that this progress continues.

I thank you for your time and attention, and if there are any questions, I will be happy to answer them.