This drug is also under review by the National Academy of Sciences, National Research Council for effectiveness. This is another factor that enters into the ultimate development of a final package labeling form. These are the procedures that Senator Hatfield asked about.

We could, of course, withhold certification of all the tetracyclines until this labeling change was made. This is what was done, of course, in some other instances with antibiotics. This was not regarded as that type of a hazard that should be called immediately to the attention of the profession through that type of action.

Instead, we thought it justified discussions with the companies with a view of developing a uniform pattern of labeling to be fully informative, accurate, and would have the necessary warnings in it. Of course, all of us will agree it has taken too much time.

Senator NELSON. So if I understand correctly what you are saying, that the requirement in the labeling of Vibramycin, which at the time the issue was raised was a new dosage form——

Mr. GOODRICH. Right.

Senator NELSON. Coming on to the market.

Mr. GOODRICH. Right.

Senator NELSON. For the first time, you had the information then that there were some animal thyroid effects, and you were requiring that that be included in the labeling in the first instance in the marketing of this product, right?

Dr. MINCHEW. Correct.

Senator NELSON. And you are saying that there are a number of other revisions that are apparently going to be made in the package inserts. They are under review. And so you had the choice of requiring everybody to change his package insert as to this one item.

Mr. GOODRICH. Yes, sir.

Senator NELSON. Or waiting awhile until you could settle all the other issues involved?

Mr. GOODRICH. That is correct.

Senator NELSON. And you are saying that you didn't consider it important enough under the pending circumstances to require them to make this specific amendment as to the animal toxicity question, and then a few months later another amendment to the package labeling? Is that what your testimony is?

Mr. GOODRICH. That is correct, sir.

Dr. MINCHEW. However, similar problems developed with the promotion of the drug.

Senator NELSON. Please go ahead.

Dr. MINCHEW. The first promotional material submitted to us for the initial campaign for Vibramycin included a 22-page "visual aid" to be used by detail men in explaining the drug to physicians.

Such a "visual aid" is particularly important because, among other reasons, it sets a proper basis for oral presentation to physicians by the company's detail men.

In preparation for a meeting between Pfizer representatives and members of our Division of Anti-Infective Drugs on August 15, 1967, Pfizer brought in a draft copy of the "visual aid" on August 8. This draft was discussed in a preliminary manner with Pfizer representatives and it was apparent that there remained a number of differences between us as to how Vibramycin should be promoted. The Division of Anti-Infective Drugs indicated to Pfizer representatives that the