

Senator NELSON. The only statistics we have as of now showing the reduction in the use of the drug are statistics of 1967 versus 1968. If I interpret what you have said correctly, it still is the judgment of the FDA, or of you, that it is still more widely prescribed than it should be; is that correct?

Dr. LEY. This is my belief Senator.

Senator NELSON. Now supposing next year—as the president of Parke, Davis predicted last June, that once the hearings were forgotten, the use would rise again—suppose that occurs, what steps does the FDA intend to take?

Dr. LEY. At that point in time, I would be forced to reconsider this whole matter. I wish in the coming year to place very strong pressures on additional means of communicating the facts relating to the adverse reactions to chloramphenicol to the people who prescribe the drug. And I hope to be able to elicit the help of such groups as the AMA in this effort.

Assuming that this does take place, fine. If it is not possible to obtain assistance from this group, I think we in FDA are going to have to consider our own means of getting significant information of this sort before the medical profession—possibly including still another letter.

But I would say that we should give the steps I've outlined here a trial to see what they are capable of doing, because I do not believe these steps have ever been taken before.

Senator NELSON. I suppose one of the problems here is, or has been from the beginning, to actually bring this matter of the indicated uses directly and forcefully to the attention of the prescribing physician in such a way that he ends up being persuaded.

We had some testimony here on one occasion from a very fine doctor who knew what chloramphenicol was used for but did not realize at the moment that the National Academy of Sciences had revised the indicated uses. In other words, there were substitutes, and so forth, and he wasn't quite aware of that. I think this is part of the problem that one might use this over a period of years. We have had some testimony on its use among the pediatricians to the effect that, because of the historical factor, they know about the drug and they use it. Then the indicated uses change for various reasons and that fact isn't brought home to them. How are you going to bring it home to the physicians of the country that the National Academy of Sciences now says it is not "the" drug of choice for any condition? How do you get that home to them?

Dr. LEY. I think it can be covered in two separate ways; each will have its impact, and yet with both. I cannot assure you that every physician will receive the message. We have plans scheduling an interview between the AMA News and myself in the near future. I wish to feature in that interview not only the types of adverse reactions which have been reported to us over the past several years, but also the appropriate indications for use. And I think we can even support the estimates that have been given by several previous people who have appeared before you, that as nearly as we can tell the drug is appropriately called for perhaps in roughly 10 percent of the patients who receive it.

Senator NELSON. In your judgment that statistic still stands?