Dr. LEY. That statistic is as good an estimate as we can make, and I believe your prior witnesses here could get no better statistic. We have not been able to find anything closer ourselves.

Senator NELSON. If I understand you correctly, about 90 percent of the people receiving chloramphenicol are getting it for nonindicated cases. Is that what you are saying?

Dr. LEY. Nonindicated cases under present labeling, that is correct.

Senator NELSON. And that is in 1968 as well as 1967?

Dr. LEY. It is too early, Senator, to really make this judgment. The course of aplastic anemia is a protracted one. We would normally not receive the report until the patient's death which may be a year after the initiation in the fatal cases.

Senator NELSON. Let me understand this. The question of whether or not somebody died from aplastic anemia may not have anything to do with others who received it for an indicated case? You might receive it for a sore throat or infected gums or acne, without getting aplastic anemia, and it is still prescribed for a nonindicated case?

Dr. LEY. That is correct. Yet, we have to enter the data system at some point and the only point available to us to enter it is the terms of the adverse reactions reported to us. In other words, we see the adverse reaction reports. In looking over the adverse reaction reports, it is our best judgment at this point in time that about 10 percent of the patients reported as having reactions of a whole spectrum of types receive the drug on appropriate indications. The indications are also outlined telegraphically in the reports.

Now, if we are to see any change with time in the incidence of aplastic anemia as a result of your committee hearings last year and the increased interest this year, it will take us at least a year because of the delay in reporting such tests to have any evidence statistically of a change in incidence of aplastic anemia. That was the point I was trying to make earlier.

Senator NELSON. Of course, the only study that has been called to the attention of the committee is the California study which heaven knows is skimpy enough when you are dealing with a factor of 10 deaths and trying to extrapolate from them. The other factor, of course, is that literally tens of thousands of people may receive chloramphenicol for a nonindicated case, and get no reaction at all, and that statistic is nowhere to be found. I don't suppose it would be possible.

Dr. LEY. Dr. Best in his review several years ago of serious side reactions, I believe, arrived at the same figure of appropriate usage of 10 percent, 10 percent of the patients who were reported to him as having reactions had been given the product on the basis of what would be an acceptable indication.

Senator NELSON. I was thinking it was 1 percent, but I believe it was Dr. Weston, the pathologist, who thought that 99 percent received it for nonindicated cases. And as I recall his testimony from a year ago, he had never seen a case in which death resulted from aplastic anemia in which the drug had been given for an indicated case, not one.

Well, now, what concerns me is getting the information out. It is perfectly understandable that doctors become acquainted with the drug at some period in history—there are thousands of drugs—and they may not have reason or have gotten around to keeping up on the changes for its use.