the brand names are better, and so forth, when, in fact, it didn't prove anything except they achieved different blood levels. You could have, I suppose, a situation where the companies that came in last were, in fact, companies who discovered the drug and then along came another company that achieved a higher blood level 17 years later. Without some clinical tests, it doesn't prove anything one way or another; is that correct?

Dr. LEY. That is the position we have taken. I believe it is a sound one.

Senator NELSON. Mr. Gordon.

Mr. GORDON. Mr. Chairman, I have just one question.

Concerning the succinate form of chloramphenicol, am I correct that the intramuscular and the subcutaneous forms are effective only through the intravenous route?

Dr. LEY. We came a little later to this point in discussing the Academy recommendations. Let me say that current labeling for the succinate labeling that is currently being distributed with new succinate entering the market, limits in its indication the use of succinate through the intervenous route. The instramuscular and subcutaneous routes are not recognized on the basis of clinical data submitted to us as appropriate routes for administration of succinate form at this point in time.

Mr. GORDON. Are there any drugs on the market now of chloramphenicol which is labeled intramuscular and subcutaneous?

Dr. LEY. Material which was distributed into the market prior to the revision of the labeling still contains in the package for that product labeling which was prepared under the old set of guidelines before we received the Academy comments. The other means of getting information on succinate; namely, the Physicians' Desk Reference, and current package inserts which may be requesed from the firm by physicians, are all revised to include the intravenous route only.

Mr. GORDON. If you have a mislabeled drug on the market, you generally recall it, don't you?

Dr. LEY. This is a question that depends upon the particular circumstances. If there is an immediate and clear-cut hazard in the taking of such a drug by a patient, let's say contamination, superpotency or subpotency, the drug itself would be recalled. In this case, we do not question the drug itself.

It is the insert that accompanies the drug which has been modified in the subsequent period since this drug was put into warehouses, pharmacies, and so forth.

Mr. GORDON. What happened with the products of the smaller companies that were on the market when there was mislabeling?

Dr. LEY. That was not simply a question of mislabeling. That was a question in which our laboratory tests demonstrated that the product of the smaller companies, without exception, as nearly as we could determine, had a drug on the market, irrespective of the labeling, which was not capable of performing in a comparable fashion to the original reference product, the Parke, Davis product. That was a defective drug.

Mr. GORDON. Are you speaking of the injectables?

Dr. LEY. No, I am speaking of the oral in that case.

Mr. GORDON. We are now talking about the succinate form, the injectables.