Dr. WELLS. Mr. Chairman, I would concede that the conclusion that you have stated is the one we accept for the most part in medical services, that a drug that does meet these standards is likely to be an equivalent, and I really think that what we best do at this point is ask our pharmacy service to submit for the record any evidence that they have that this has not proved to be true.[1]

Senator NELSON. With respect to the widely cited case of chloramphenicol, the specific testimony of the Commissioner of the FDA, was simply that additional brands of chloramphenicol that came into the marketplace simply did not achieve the same blood level within the same time period as Chloromycetin did.

Commissioner Ley's testimony was that there was no evidence that one was more efficacious than the other. One achieved the blood level in a certain shorter time than did the others, but there was no clinical evidence that the therapeutic effect, in fact, was any better for the one that achieved a higher level more quickly. However, the FDA position was that since the first one in the marketplace achieved a certain blood level in a certain length of time they wanted consistency in the achievement of blood levels, so any chloramphenicol could be used and there would not be any differences.

It is not really a case of saying that they were not therapeutically equivalent because to date there have been no clinical tests to demonstrate that this is so. This is the testimony we have from the FDA.

So, that is not a valid example. But, the committee, for the record, would be interested in receiving any clinical tests which demonstrate that two drugs meeting USP standards were not clinically equivalent. We have yet to get this material from the witnesses that we have had.

Dr. Goddard, the former FDA Commissioner, stated that there probably have been a half a dozen such cases. All it means is that the best experts in the country, including the drug companies who participated in establishing the standards, omitted something that they did not understand at the time and then, of course, it was necessary that that be corrected.

The U.S. Pharmacopeia and the National Formulary have the best established standards and exceptions are rare. Frequently we hear that stated, as there were many such cases. I would think this would require some evidence, if it does indeed exist, I would like to have it furnished to the subcommittee.

Dr. WELLS. Mr. Nelson, we do not conduct clinical studies that pertain to this field, but we will have our pharmacy service submit literature on which this statement was based.[2]

Senator NELSON. I think we probably have all of the literature but if you have something that we do not have, we would like to have it for the record.

Thank you. You may proceed.

Mr. JOHNSON. Senator, taking your initial suggestion, and for those who are following the written text, I will skip the last paragraph on page 6, because I think we have covered the balance of that other paragraph.

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[1] No such information was supplied by the Veterans' Administration.
[2] See subsequent information beginning at p. 7478.