good cause as to why this information should be considered confidential.

Mr. GORDON. And what do you consider "good cause"?

Dr. FINKEL. Well, I really can't answer that immediately other than one of the examples I just cited. Our proposal is now awaiting comment and has not yet been finalized.

Senator NELSON. This question has been raised here before.

To put it in its sharpest focus, take the case of a drug on which there was a patent, and the patent has expired. Is it the position, then, of HEW that the information on manufacturing processes, and so forth, is still to be kept unavailable from the public or the manufacturers?

Dr. FINKEL. Yes, the manufacturing processes are still considered confidential, but any other firm wanting to market that drug would be required to submit only an abbreviated New Drug Application to establish bioavailability with the marketed drug, except that certain cases would require a full application.

Senator NELSON. Does that get at the problem, similar to the chloramphenicol case? Chloramphenicol was marketed by the Parke, Davis Co. under the trade name of Chloromycetin for quite some time. When the patent expired, three other chloramphenicols came into the marketplace, and then Parke, Davis did some studies on its own chloramphenicol as well as the others in the marketplace, and demonstrated that the blood level achievement of the three products was different. Their charts showed that the blood level of the Chloromycetin achieved a much higher level very quickly, whereas the blood level of the other three or four products, whichever it was, I have forgotten, didn't achieve as high a level but extended apparently over a longer period.

The FDA then decided that they wouldn't permit the marketing of the others unless they achieved the same blood levels. They did not do any studies, and as far as I know nobody did, that demonstrated that that blood level achievement of Chloromycetin was more effective in the treatment of disease for which it was used than the others, but for purposes of consistency in the use of the drug, I suppose, they wanted them to be the same.

As I said, we had testimony in which the FDA said that there were no studies to prove that one was more effective against the target organism than the other. But let us suppose it was a significant factor. Once the patent has run out, since the Congress, the public, has given the company 17 years to protect them and make a profit on the research, shouldn't all information, then, be available to all manufacturing firms respecting this drug, especially since this involves the health of the public?

Dr. FINKEL. Since that episode and another one with tetracyclines which was uncovered by the Pfizer firm, we have required bioavailability studies for all antibiotics, so that they are all required to conform to an acceptable level.

Senator NELSON. Are you requiring that the originator of the drug in its application submit bioavailability studies?

Dr. FINKEL. Yes.

Senator NELSON. And is that public information?