

goes into the final decisions as to what the chemical tests should be. Is that not correct?

Mr. STETLER. There is no question that the people that work on the compendia are well-qualified people, and the standards that are there are well done. Our quarrel is only with what you can assume, having those standards, and recognizing they are good standards.

Senator NELSON. I guess we have been through that before. The point is, it applies to any drug, whether it is trade name or any other.

Go ahead.

Mr. STETLER. Bottom of page 11. On this subject, there appears to be a rather common, mistaken belief that the Federal drug laws somehow guarantee a uniform high level of quality in all drug products which reach and are dispensed from the shelves of a pharmacy. This is not so and, as a practical matter, can never be so.

Although Food and Drug Administration personnel do a conscientious job, it is impossible for them to inspect every manufacturer and distributor often enough to insure that every drug product meets every bare minimum quality standards.

Maximum quality and reliability can only be built in by the manufacturer. Even antibiotic drug products, every batch of which FDA tests before shipment, have turned up with variations in quality and potency.

Mr. GORDON. Mr. Stetler, your testimony suggests that simple reliance upon a product meeting official compendia tests and specifications is not sufficient.

Mr. STETLER. Correct.

Mr. GORDON. You also suggest because of this situation the physician or pharmacist should rely upon the reputation of the particular manufacturers. Is that correct?

Mr. STETLER. Correct.

Mr. GORDON. Apparently you feel that some firms are not performing adequately insofar as their quality control, good manufacturing practices, and so on are concerned with the result that they do not produce reliable drugs.

Is that a correct interpretation of your statement?

Mr. STETLER. For some manufacturers; yes.

Mr. GORDON. Will you name some of these firms?

Mr. STETLER. Will I name some?

Mr. GORDON. Yes.

Mr. STETLER. No.

Mr. GORDON. If you have such knowledge, it should be made part of this record.

Mr. STETLER. I think it is obvious to you that this statement is not meant as an indictment of any firms. What I am saying is that there are varying capabilities in drug manufacturers. Some produce consistently poor drugs. Some do it sometime. My purpose is not to identify them, it is not my job, and I do not propose to do it.

Mr. GORDON. If you won't disclose this information, and if the information is not generally made available, how, then, is the physician who writes a prescription out in some small isolated town to know this? Certainly we cannot expect a busy general practitioner to be familiar with all of the qualifications of personnel, or adequacy of facilities and