

It must be emphasized that when a physician prescribes an antibiotic to be administered orally, he must assume that the drug will be absorbed rapidly and thoroughly from the product into the blood stream. A product which does not meet the above criteria may impair the recovery of a patient.

In conclusion, it is evident that information obtained by laboratory and clinical studies is essential in determining the absorption, dosage range, duration of action, excretion rate, and so forth, of a drug. To put it another way, a manufacturer should not have the right to simply copy another company's package insert for a product which has been carefully studied in the clinic by the originator and then imply that the two drugs are therapeutically equivalent merely because his product meets the minimum U.S.P. and FDA laboratory test requirements.

We believe we have demonstrated that laboratory tests alone which indicate that certain drugs contain similar chemical ingredients provide no assurance that these drugs will behave in the same way in the human body. Thus, we have confirmed what experts have repeatedly said, that chemical similarity is not necessarily indicative of therapeutic equivalency.

Thank you, Mr. Chairman. That concludes my formal statement.

(The charts attached to Dr. Lueck's supplemental statement follow:)

