

Senator NELSON. It is in part 6 of our hearings. All I am saying is that there is no evidence that Dr. Ley knows about, and I guess he would know it, because they have asked us about every single brand of drugs—but they wanted to achieve the same blood level over the same period. So they set that standard.

Dr. ALFANO. Was there any blood level?

Senator NELSON. Oh, yes.

Dr. ALFANO. I saw that thing in a generic product just in dissolving it. Over a half hour, it never dissolved.

Senator NELSON. We have that both ways. We have as many brand names that do those things as generics. As I said, according to the only test we have had on potency that is big, the brand name companies did not meet the standards of the generics.

Dr. ALFANO. I am saying here, Senator, once a generic name is identified, a generic drug is identified with a manufacturer, then it is essentially a brand name. It is identified. There is knowledge of this. I am not saying that the generic drugs are not worthy of being used or that type of thing.

Senator NELSON. As I am sure you know, a number of purely generic manufacturers manufacture compounds for the brand name companies. One of the distinguished companies is Strong, Cobb & Arner. Many brand name companies buy from Strong, Cobb & Arner.

Dr. ALFANO. Oh, yes, but while they have no name of manufacturer as to source, there is a question mark as far as the medical profession is concerned, and there should be.

Senator NELSON. All I am saying is that you hear the flat assertion all the time that brand names are better and yet the only test to date says that generics are better.

Dr. ALFANO. I am only saying that generics with a known manufacturer is a brand name. They do not have identification as you do with an ethical pharmaceutical firm. There are ways of identifying them with name, initials, and so forth.

Senator NELSON. I assume the pharmacist knows whether it is Lannett, American Pharmica or Merck or anything else. He knows. There it is. It is a little label on his jar, manufactured by this company. The tablets, except for one company, are not identified. The identity code is only used, so far as I know, by one company.

All I say is we continue to hear these assertions from the people who come before us, but when I ask for examples, I do not get them.

For example, let us take a recent case. This involves Parke, Davis. Have you heard of the *Tinnerholm* case involving Parke, Davis & Co., a 1968 case which involved a brand-named vaccine, sold under the name of Quadrigen by Parke, Davis & Co. In 1968, the Court said:

Evidence in action against manufacturer of vaccine for damages resulting from infant's having been injected with vaccine by physician established that vaccine was defective and that defect was proximate cause of infant's injuries.

Since that time he has been retarded in his mental development, being classified in the imbecile-idiot range.

... evidence established that there existed sufficient number of both unrealistic and conflicting reports from field to have required manufacturer to take serious second look at its product before placing it on the market.