

Dr. KRANTZ. No. I do not know his name, but I have it in my records at home. It has been about a year ago since he appeared. He came and told me one day that they had purchased a number of these items by price and they had not worked well in the patients. They have not given the required therapeutic results that they expected.

So I delineated a series of tests that we could do on animals that would enable him, in turn, to be sure within a reasonable doubt that the item that he was purchasing would be tantamount to the trade mark item. At the present time, we are considering the same situation for the Maryland Hospital Association, which includes some 56 hospitals and spends roughly \$13 million a year on drugs.

It is their contention that if they could buy with certainty a drug that was generically labeled instead of trade mark labeled, they may save some money.

So if we apply these tests, I think we can assure them that they are, within reason, the therapeutic equivalent.

Senator NELSON. I see no indication here of the test that was made on each of these drugs, if it was made, to determine whether it might be up to USP standards. Who made that test?

Dr. KRANTZ. Some of these products are not in the Pharmacopeia, you see. Tedral, for example, one of them, is not an official product.

Senator NELSON. Of those that are, where was the test made to see whether it met the USP standards? Who made it?

Dr. KRANTZ. I presume it was made by the laboratory of the Army procurement group, but I do not know.

Senator NELSON. So you are not certain whether or not any of these drugs met USP standards?

Dr. KRANTZ. No; I did not have any of the drugs.

Senator NELSON. I think that this is a crucial question.

The testimony before the committee has been that if the drug meets USP standards, it is their judgment that it is therapeutically equivalent and there has not been any significant evidence except as perhaps to one drug, and that is a maybe, that if they met USP standards, they were therapeutically equivalent. We do not know, then, whether the drugs you mentioned, met USP standards?

Dr. KRANTZ. I agree.

Senator NELSON. We recognize, and I know you do, as an expert, that brand name companies and generic companies manufacture drugs and, for reasons of quality control, a certain percentage of them do not meet USP standards. As I have said earlier in the hearing, the one big test made showed that generic companies had a better percentage in meeting a potency test than did the brand name companies, by 1 percentage point.

So these are not submitted, then, as part of that?

Dr. KRANTZ. Oh, no, no.

Senator NELSON. I see.

Mr. GORDON. I might also mention that tolbutamide is not sold by the generic name. It comes only under the brand name of Orinase. It is manufactured by only one company, Upjohn.

Dr. KRANTZ. I thought the patent had expired.

Mr. GORDON. Not yet. It will expire soon, but has not yet. As of now, only Upjohn manufactures that.

Dr. KRANTZ. Up to this time, and this was about a year ago, the patent had not expired on Miltown and Equanil, which was the same