

Senator NELSON. If it is just a product differentiation, as the phrase is used——

Dr. SCHIFRIN. Yes, sir.

Senator NELSON. And if it does duplicate a product on the market and is efficacious, does the FDA have the authority to prevent the firm from marketing it?

Dr. SCHIFRIN. No, sir.

Mr. GROSSMAN. One further point on this:

If it is efficacious and if the FDA is agreeable to let it go on the market, you pointed out when you used the word "it will provide competition"—isn't that something we are trying to do here? In other words, if it is going to be a competitive drug, does it not have some value as far as our inquiry is concerned?

Dr. SCHIFRIN. That may be a contribution.

Mr. GROSSMAN. That is a pretty important point.

Dr. SCHIFRIN. Yes, but it may be offsetting negative contributions. In other words, these drugs that are duplicated may be very heavily promoted. I think that is a waste of resources that could be used for other purposes.

Secondly, they may be promoted under brand names, which creates confusion and the fact that they are duplicates may be obscured in the promotional literature. They may be represented as new therapeutic factors when in fact, a large majority are not.

Senator NELSON. The only way in which a company can come onto the market with a duplicate but differentiated product is if a patent has expired on the one they are duplicating. Is that not correct?

Dr. SCHIFRIN. I would say that is the usual way. There are rare circumstances under which it could obtain a license, usually as the result of some antitrust activity.

Senator NELSON. But that is a license from the patentholder?

Dr. SCHIFRIN. The patentholder, yes.

Senator NELSON. But usually in that case, if it is a differentiated product, it is a product, as I understand it, of the same chemical composition with some insignificant difference and then is put on the market and advertised to the medical profession as something better or something——

Dr. SCHIFRIN. Yes, sir, the differentiation is nominal. It is not in its chemical composition and many opinions maintain that it is not in its therapeutic action, either. It is a nominal differentiation, and therefore the professional thrust is to make a claim that this is a new and better product. But it is really an identical product to many products already on the market.

Senator NELSON. So that the reason for doing it really is to benefit the company in a competitive situation?

Dr. SCHIFRIN. Yes, because if the product is made from a drug whose patent has expired or is not patented, there are likely to be many such items on the market and an item comes out to fill out a company's catalog and will get promoted. The company, hopefully, will want this thing selected by its brand name. They will put a high price on it, very often; but it does not give the doctor additional medicine to use for his patients.

Senator NELSON. What I do not have clear in my own mind is whether product differentiation by definition is another product with