

Japan and the Philippines reported very serious reactions of hallucinations and even convulsions from taking the drug.

There was a meeting of the New York Academy of Science discussing it and these facts were brought out, and in the end the feeling of our scientists here was that it was not a drug that should be distributed as mass distribution out in the country, because under such circumstance it could not be controlled. It was a good drug for use in the hospital.

The drug companies, as I understand it, said well, it does not cause liver damage and the untoward reaction is not irreversible if the drug is stopped, we think it is safe for mass distribution. Our scientist did not agree.

Now Parke-Davis has a drug that is a suppressant. I do not know that they will, but it is the natural thinking that the drug companies try and consider "Now can we produce a better drug that has this benefit but not this bad side effect?"

Well now, if they do, certainly that drug ought not to be sold massively in that country, if we have not had some trial or supervision here, at least know that they have had a careful clinical trial there to know that it is safe before it is widely sold.

I think we ought to have some regulation. If the drug is never going to be used in this country, we should have some check of a controlled clinical trial before we give our approval for sale, or large scale, in foreign countries.

I think you will see that this is a little different question than that which we consume in our country and then export and that which is merely made for export, and yet I think we should be honorable there and as careful as we reasonably can be, and certainly I would feel very badly if I thought that we even could allow, permitted the drug company to export a drug that had not been carefully tested, or reasonably carefully tested. I suppose, nothing is perfect.

Senator NELSON. Do we allow a company to sell a drug overseas that has not been adequately tested to meet the FDA standards in this country?

Dr. TAUSSIG. Well, I think that if the drug is not used in this country, it does not have to pass any FDA standards in this country, if it is not for sale in this country.

Senator NELSON. I did not realize that.

Dr. TAUSSIG. I think so. I think if it is not for sale in this country, just as much as within a State as I understand it, the company can produce anything. They cannot produce a great deal that is not interstate, and when it is interstate the FDA regulates and puts in its regulations.

I think that is straight, that any small pharmaceutical firm can produce anything for sale within its State that does not pass the FDA.

Senator HATFIELD. Mr. Chairman, Dr. Taussig, do we have any problems with imported drugs from other countries on this same basis?

Dr. TAUSSIG. Well, I think the imported drugs from other countries, major ones, are imported and sold through some pharmaceutical firm to which they sell the rights. I think the FDA does not allow drugs to be sold interstate that have not passed regulations. Of course, that is where they were able to hold up thalidomide. And they wanted