

Senator HATFIELD. Yes.

Dr. GARB. And potency in terms of active ingredient being what it is supposed to be.

Senator HATFIELD. Labeling?

Dr. GARB. Yes, not necessarily in terms of therapeutic potency.

Senator HATFIELD. No.

Dr. GARB. Questions of therapeutic potency will require another approach.

Senator HATFIELD. Do we have evidence or do you have evidence or any knowledge of drugs that have been used and have created illness or other ill effects due to the improper handling in the manufacturing of such drugs related to purity or cleanliness or wholesomeness?

Dr. GARB. Oh, yes. Recently many batches of drugs were recalled because they were contaminated with penicillin in the manufacture. That is, the machines making the tablets or vials had been used for penicillin and there were residues of penicillin around and they got into other medications.

Also, there have been recalls because small amounts of hormones got mixed in with other drugs. This is a common problem. You see, here is another problem that comes up, Senator. When we hear about a recall of a drug, we have to remember that that drug was probably not recalled until a large number of patients had already taken it.

Senator HATFIELD. They had evidence?

Dr. GARB. Sure.

Senator HATFIELD. That there was some ill effect?

Dr. GARB. It reminds me of a joke that we had as children.

"What is worse than biting into an apple and seeing a worm?" The answer is "biting into an apple and seeing half a worm."

I think the worst thing for a patient is to have taken a drug and then hear that that drug has been recalled, and then have to worry about what has happened to him.

Senator HATFIELD. Do I understand you then to say that manufacturers do not have sufficient quality control programs within their own structures?

Dr. GARB. Some do and some do not, but I have no way of knowing which do and which do not.

Senator HATFIELD. You have no way to identify except by the evidence of those manufacturers which have had to recall certain drugs?

Dr. GARB. Yes, but unfortunately, even the biggest and the best manufacturers have had drugs recalled, so this leaves me without clear-cut guidelines.

Senator HATFIELD. Do you know of any of them who have had to recall their drugs who have had quality control within their organization?

Dr. GARB. Yes, sir.

Senator HATFIELD. In other words, their quality control program did not prevent such drugs reaching the market?

Dr. GARB. That is correct, sir.

Senator HATFIELD. Was this an inadequate quality control of the human factor, or if Government had been in the picture on continuous inspection, would it possibly have been prevented?

Dr. GARB. This is a little difficult to answer. I do not know if it would have been prevented by Government inspection or not.