

Senator NELSON. I am going to put in the record, a chart showing some major recalls in fiscal 1966-67. I am not inserting it to embarrass the PMA firms, but since the PMA is continuously insisting that other firms do not do well, the record ought to be balanced. I have a list here of nine drugs on which there were recalls. One of them involved 570,374,450 tablets; serious recall; injuries sustained. Only 17.9 percent of that quantity was recovered. They were tablets and they were adulterated. There is another recall listed here involving 17,000,500 tables of Mycostatin. I would like to ask a question about this drug. It is an antibiotic, is it not?

Dr. GODDARD. That is correct.

Senator NELSON. Since you do batch testing, this was not a very serious recall I suppose. It was subpotent.

Dr. GODDARD. I think that is serious, Senator.

Senator NELSON. It is listed here as moderate hazard.

Dr. GODDARD. Any time a subpotent antibiotic gets out, I think that is serious. I am not talking about hazard. I am talking about it is a serious breach of good manufacturing practice.

Senator NELSON. How would a subpotent antibiotic get by your batch testing?

Dr. GODDARD. I can submit for the record the history on this one.

Do not forget, with some of these recalls you have to keep in mind that the drug has a shelf life. Some of the recalls occurred because the drug is obviously becoming subpotent. It was not necessarily subpotent at the time of its manufacture. So this may have simply been an earlier decline in the potency of the drug.

Senator NELSON. This will be printed in the record.

(The documents referred to follow :)