

Senator HATFIELD. What are you doing in the meantime in this case? For instance, if it has taken you almost a year, then it shows there is not very much danger involved evidently. What are you doing? What is the procedure you are involved in now on this case? Are you reading letters or are you holding conferences or what are you doing?

Dr. MINCHEW. The immediate status of this implementation is something on which I would have to check with the operating unit in the Bureau that is handling it. I don't have that information available at this moment. I don't know just exactly where this negotiation is at this point in time.

Senator HATFIELD. I would be very interested in knowing your procedures, if you can do something in a matter of weeks, and then at other times it takes you months. I would like to know what your bureaucratic procedure is on that.

Dr. MINCHEW. What would be the question to which you would like to have a direct answer?

Senator HATFIELD. I would like to know in changing the labeling of existing products to base it upon a new standard that you prescribe, because of your research and determinations arrived at on a new product, you tell me that if there is a great deal of danger involved that you can get all this change brought about in the matter of a few weeks. Now you tell me that in this particular instance that you have been almost a year. My question is simply why the great difference? What are you doing in your procedures in your department that you have to take almost a year in some instances when you can do the same job in weeks, a matter of weeks, in other instances?

Dr. MINCHEW. We can provide the committee with a chronology of the negotiations.

Senator HATFIELD. I don't want a lot of that chronology. I want to know the procedure. I want to know why it takes you so little time in some instances and so much time in other instances. If it is a matter of staffing, then I want to know that. I think the committee should know that. If it is a matter of just poor procedures, administrative procedures, I would like to know that, too. I don't want a lot of papers showing a chronology. I just want to know the basic procedures and administrative practices in which you are engaged.

It seems to me ridiculous that you have got the ability to perform in a few weeks in some instances and it takes you so long in others. These are where you open yourself to criticism, and rightfully so. These companies have every right to criticize your operation, when you put one company under that kind of inequitable economic situations, as you are attempting to do, Pfizer here in this case, and then in almost a year you can't get other companies updated in their labeling.

As I say, you admit here that you can really handle such cases under a danger factor in a matter of weeks, then you open yourself up to bureaucratic charges, and rightfully so, when it takes you so long to get moving in other instances. That is my point.

Senator NELSON. I assume one of the problems in the time factor is that if it is a serious matter, that it takes priority over any other backlog material you have got; is that correct?

Dr. MINCHEW. That is correct.