we should exhaust the scientific method to get an answer one way or the other before moving those drugs out of the marketplace, since they do have some real possibilities of proving out effective.

Senator NELSON. Let us see. What is the time schedule now?

Mr. GOODRICH. 6 months on the "possibly effective" and 1 year on the "probably effective," and those times may have to be adjusted at the end of that time frame, depending upon what research has come out during the 6 months or during the 12 months.

For example, if at the end of 6 months there is good research underway giving a reasonable assurance that it will prove out the effectiveness, the Commissioner has said he would extend the time in terms of what would be needed to finish that piece of research.

Dr. EDWARDS. I think this is terribly important. We certainly do not want to take any effective drugs off the market. By the same token, we certainly are not going to procrastinate any longer.

I realize it is very reasonable to say, look, they have had 6, 7, 8 years in which to develop this particular evidence but I think the fact of the matter is that the industry by and large did not take this very seriously until recent months, and I think that we have a responsibility at this point in time to the patient and we certainly do not want to be caught in a position of having taken effective drugs off the market.

Now, granted, how many of these are effective is another question.

Senator NELSON. Go ahead.

Dr. EDWARDS. Moving on to the subject of drug quality, reliability of claims of effectiveness, of course, are of first importance, but we must be equally concerned with product reliability.

We have developed and published improved regulations applicable to good manufacturing practices.

We have several programs to enforce those requirements. The first is the Intensified Drug Inspection program. This is an effort to improve overall industry performance by concentration on specific manufacturers. In this process the FDA learns practical problems of implementing what may be considered theoretical requirements. The industry learns what concerns the FDA in a concrete rather than an abstract fashion. I think object lessons may be applied across the board. Marginal operations can be brought into compliance and hopeless ones identified and eliminated.

Since July of 1968, FDA has initiated intensified inspection of some 287 drug manufacturers and associated commercial testing laboratories. In 147 of the terminated cases, voluntary compliance with the Good Manufacturing Practices regulations was achieved through a dialogue between FDA district personnel and plant management. In some 44 remaining cases are 23 firms which are now the subject of legal action, and 21 firms which are giving up the drug business because of their inability to come into compliance.

Senator NELSON. You refer to an intensified drug inspection program and improved regulations applicable to good manufacturing practice. Can you elaborate on that a bit?

Dr. EDWARDS. Would you like to, Dr. Simmons?

Dr. SIMMONS. Yes. The current Good Manufacturing Practice regulations which we have just repromulgated, Mr. Chairman, are