

Senator NELSON. You should have been nodding your head. You are saying exactly what I said.

Mr. CUTLER. It is a violation of law.

Senator NELSON. I said under the law a prescription drug may not go onto the market in this country unless it meets USP standards. And if it doesn't, it is in violation of the law.

Mr. CUTLER. That's correct.

Senator NELSON. You just repeated what I was saying.

Mr. CUTLER. We are quibbling, sir.

Senator NELSON. I am not quibbling, you are.

Mr. CUTLER. It can get onto the market even though it violates the law.

Senator NELSON. Under the law a prescription may not go onto the market in America unless it complies with USP standards. If it doesn't, it is in violation of the law.

Do you agree with that?

Mr. CUTLER. I agree with that; yes, sir.

Senator NELSON. That's exactly what I said.

So there are some problems. One of them is whether or not there is adequate plant inspection. The Chair is well aware of that. We have had many witnesses long before you came here on this exact point. The question is to be sure that the inspection is adequate to assure that only high quality drugs are on the market. Everybody wants that. If the manufacturer cannot meet the standards or won't or is not equipped to, I am the first one to say we ought to close his business. One of your major members had his business closed up by the Government 3 years ago.

Mr. STETLER. Senator, that plant was closed voluntarily by Squibb, not by the Government.

Senator NELSON. It was after a very tough report by the Government.

Mr. STETLER. But it was not closed by the Government.

Senator NELSON. In any event, if drugs meet USP standards, and you have had adequate inspection, then you are all set. I think you probably need some support from PMA that will increase the inspection capacity of the FDA. Do you support a big expansion of their inspection program?

Mr. STETLER. We have supported their request for appropriations for additional inspectors, and think they should be given more of the tools to do that job.

Senator NELSON. Good, I commend you for it. I think that is part of the problem.

Mr. STETLER. Me, too.

Senator JAVITS. I hope you will understand my point. I want to see a compendium or call it what you will where the whole list of availability is there. But when the name "prednisone" appears on a product, whatever else appears, how much advertising they do—it is all private enterprise. When the name "prednisone" appears on a product, that it is a criminal offense if it does not meet a minimum standard, so that the patient knows when he takes a tablet marked "prednisone" somebody is guilty of a crime if it does not at least meet a minimum prednisone standard. I think if you did that, the marketplace would take care of not all the rest but most of the rest.