

I realize an effort is made through the FDA and the Food and Drug Act to attain this. But it doesn't exist today. And this is not critical of the Food and Drug Administration.

Senator JAVITS. I am sorry, sir. You and I have one point that we don't see eye to eye. All I want to know is that the end product meets a certain standard when tested. I don't care how he made it. If he has a better way to make a mousetrap, bless him. If his employees work 8 hours instead of 8½, that's his business. Performance is the only thing I care about. I don't care about all the other things you talked about—except I ask you, How do you get to the point where if a person goes in and buys a particular item that is designated by a particular name—not a trade name, but a generic name—that he knows at least it meets such and such minimum performance standards? That I think is the real issue.

Mr. STETLER. I thought I was being responsive to that. Maybe I am not. I am interested in performance, too. But you don't get performance in the drug industry unless you have the other ingredients.

Senator JAVITS. That is not our business or the consumer's or the Government's business.

Mr. STETLER. It may be the Government's business in this way. In our present Food and Drug Act, we anticipate that the FDA can do a continual surveillance on whoever is in the drug manufacturing business.

Now, we don't look initially at the credentials of people that are in the drug business, and given the number and variety of people that manufacture drugs, we burden the FDA with an impossible situation, in my opinion. At least to that extent, maybe we ought to look again at what the Government might do properly in terms of the credentials, first of all, of the people that manufacture drugs. That will get down to the end process, the end product.

Senator JAVITS. All right.

I think we have made our respective points of view clear. I don't think they are necessarily parallel yet.

I would like to ask just one other question.

You have talked about a formulary. We have been up and down that track.

What about this compendium?

Now, are the industry and Goddard together on getting this out? He says it will take 18 months and you people think it will take 2 years.

Well, that's not too much difference.

Are you people and Goddard together in getting that out, and if not, what's holding it up?

Mr. STETLER. May I have a moment to discuss this. This has a little history to it.

This discussion of a compendium has gone on now for two and a half years. It was initiated at that time by the Food and Drug Administration when they asked representatives of the PMA and the American Medical Association to consider the possibility of eliminating the package insert that is now a regulatory requirement with respect to drugs and substituting a compendium.

Those discussions broke off. They did not get very far along because Mr. Larrick, who was then Commissioner, indicated that such a com-