once that inspector is satisfied that the output of that firm is fine, that is it; they accept the drug.

I have no quarrel with that either, because we, too, have to rely on the drug firm. But it would seem, and it is FDA's position, that a good quality assurance program operated by Government has to take into account post-manufacture analysis of finished product. It just has to be.

Mr. Feinberg said in one of his speeches that the inspector has the right and the duty to utilize the drug firms' laboratory facilities to make whatever laboratory analyses he thinks are indicated.

I said I have difficulty with this, because I know in my own experience that when I was a drug inspector I would have been thrown out of the plant if I tried to use somebody's laboratory facilities to do analyses. He agreed, and he said no, they do not do assays. They do not do content uniformity. They do not do sterilization. But they watch the professional in the firm who does.

We asked them what happens if a piece of equipment is out of calibration. Obviously, the results are going to be wrong. What check have you here? And he says, we will be wrong, too.

Okay. I was satisfied with that, but it does not help.

Senator NELSON. But your inspectors check the calibration, do they?

Mr. LOFTUS. Well, they may or they may not, but they certainly do check the finished product.

Senator NELSON. Well, do they have the qualification to check the calibration of the material?

Dr. SCHMIDT. Mr. Chairman, I think the point here is we do not rely on their laboratories at all; and that is not whether the issue is in or outside of calibration. What we do is take the drug, take it to our own laboratories where we know the calibrations are accurate, and do the analysis of the finished product.

The point is that he is relying on their labs but we do not. We rely on our own laboratories.

Mr. LOFTUS. The qualifications of analysts vary. The way to check that is to check the output of those analysts.

Dr. CROUT. Again, if you are interested in a comparative size figure, I can supply or will supply a more precise one. But we run on the order of 10,000 drug analyses in a year.

Senator NELSON. Is this against the 800?

Dr. CROUT. One hundred, as I understand. This is on marketed products.

Senator NELSON. They do about 100, and you do about how many?

Dr. CROUT. Ten thousand.

Senator NELSON. And these are done in your own labs?

Dr. CROUT. Yes.

Mr. GORDON. Do I understand correctly that they do not do any testing of finished products?

Dr. CROUT. Again, I think we have to keep in mind that our objectives are somewhat different. We run a monitoring system designed to assure to the extent possible that drug manufacturers are making a quality drug product. They are running a system