Second, I was not satisfied that the FDA was properly tooled up to monitor the drug supply so that the public had the assurance it wants and deserves—that all drugs in the marketplace will perform as intended.

To answer my first dissatisfaction, we have brought to the attention of the drug industry—through the seminars and workshops I mentioned, as well as through personal contacts between our people and industry quality control managers—our serious concern about adherence to Current Good Manufacturing Practices.

To answer my second dissatisfaction, we have established a National Center for Drug Analysis in St. Louis to act as the public's control laboratory. Using automated equipment, the newest assay techniques, and a constantly evolving technology, this National Center will help our agency keep abreast of industry's output and assure the consumer that drugs in the marketplace are closer to perfection than before. Let me repeat, Senator Nelson, that this National Center is an endpoint, it is after the fact. The samples are collected from commercial channels providing us with a consumer-level reading of the drug supply—but leaving us with the disadvantage of having to go back through the entire drug distribution system, if we find anything seriously wrong with one of them.

We believe probably as many as 300,000 samples a year will be required in order to have good statistical sampling, but this has to be worked out in detail at the present time.

We have begun modestly at the National Center, checking out our equipment and giving our chemists and pharmacists the experience which the later expanded efforts will necessitate. Our goal is to examine many thousands of samples a year. We are making good progress, but it is too early to draw any conclusions from the relatively few samples that have been tested. We are still in the "shakedown" period.

Mr. GORDON. Although you say it is too early to draw any conclusions so far from the National Center, can you give us any indication of what the results have shown to date?

Dr. GODDARD. Dr. Banes, do you wish to comment?

Dr. BANES. There are two programs now in progress, one on anticoagulants and the other one in mild tranquilizers. There are 870 samples that have been collected in each of these two categories, but this is not enough to give significant results. On the basis of what we have already seen, the ratio of samples outside of the required limits runs about half a percent in the minor tranquilizers and about 2 percent in the anticoagulants. The anticoagulants are considered a much more significant class of drugs and the 2 percent is something to cause us concern.

Dr. GODDARD. Again, may I caution that these are preliminary results and one cannot draw conclusions from them. The additional samples are programed for both of these categories in the very near future—in fact, in a matter of weeks, and we could perhaps, before your hearings have ended, give you a readout on these first two categories.

Senator NELSON. We would like to have that at a later date when it becomes available.

I have something I would like to clarify for the record. When