At the end of the long line is a human life. Some of you seem to have forgotten this basic fact.

I cannot let you forget, as you cannot let me forget either. That is why I am genuinely concerned. Since becoming Commissioner, I have come upon situations that I did not expect. I know that many of you, were you to sit in my chair for a week, would be as troubled. Therefore, I am bringing to your attention some things that you must be made aware of, for only *you* know how to correct them.

And, for the health of the drug industry, I would hope you *would* rally together and correct them.

Let me begin with Investigational New Drugs. I can say that I have been shocked at the quality of many submissions to our IND staff. The hand of the amateur is evident too often for my comfort. So-called research and so-called studies are submitted by the carton-full and our medical officers are supposed to take all this very seriously.

I cannot, however.

As their chief, I have told them that unprofessional IND's should be cancelled immediately. If the sponsoring company is imprudent enough to waste stockholders' money on low quality work, then that company must bear the consequences of such waste.

The Food and Drug Administration will not waste public money reviewing it.

In addition to the problem of quality, there is the problem of dishonesty in the Investigational New Drug stage.

Ladies and gentlemen, your medical staffs and legal staffs know the laws and regulations as well as we do. Their failure to abide by law and regulation is a matter neither you nor I can take lightly.

Now, I will admit that Government employees do not have a corner on all wisdom. And I will admit that there are gray areas in the IND situation.

But the conscious withholding of unfavorable animal or clinical data is not a gray-area matter.

The deliberate choice of clinical investigators known to be more concerned about industry friendships than in developing good data is not a gray-area matter.

The planting in journals of articles that begin to commercialize what is still an Investigational New Drug is not a gray-area matter.

These actions run counter to the law and the ethics governing the drug industry.

I have already moved, as some of you know, to correct such action as soon as I see it. And I have instructed my medical staffs in all bureaus to follow my example. Will you, in your own organizations, protect the scientific integrity of the industry? Will you stand with me in this effort?

Let us move on to New Drug Applications. This is the take-off stage, as you know, for a new product of this industry. Now we must review the clinical evidence, the labeling and advertising, the promotional materials, package inserts—you are as familiar with the process as I.

But once again, I have been shocked at the materials that come in to us. I have been shocked at the clear attempts to slip something by us. I am deeply disturbed at the constant, direct, personal pressure some industry representatives have placed upon our people. Gentlemen, the NDA situation needs your attention—and now.

Here is one example of an NDA to be used for the treatment of cancer. It was submitted by a prominent member of the PMA. In its labeling, the company suggests the following language:

"Drug X is not recommended for use in children less than 15 years of age because of the lack of clinical experience with patients in this age group."

This is an interesting statement. Interesting—because the record shows that eleven children less than 15 years of age were in fact treated with Drug X and there were no remissions.

In other words, looking at it as a physician, I must say that the drug hasn't been shown to work at all with children under 15—a fact based on the available clinical experience.

And that is why Drug X must not be recommended for use with children under 15.

The same suggested label goes on to say:

"Although the drug has been used in patients with a variety of solid tumors, and has been effective in a few of these, no specific recommendations for such use can be made at present."