I began my remarks today by saying I was uneasy about the future of the pharmaceutical industry. The examples I have given—the poorly prepared IND's and NDA's, the improper labeling and advertising—these are all symptoms of a disease that drugs cannot cure—but which can undermine the industry as we know it.

That disease is irresponsibility.

You cannot afford to have it in your midst any longer. You, as the leaders of this industry, are capable of insuring that such irresponsibility is corrected. Let's forget, for a moment, about regulation and let's speak of self-regulation. Let's forget, for a moment, the FDA and let's speak of the whole pharmaceutical industry.

You are under pressure from a variety of quarters. You are under price pressures, patent pressures, generic-prescription pressures, as well as regulatory pressures. I am aware of these and I am sympathetic.

But I am also aware of other pressures far more dangerous to your industry than the ones I have mentioned. I am aware—and I know some of you are, too—of pressures to bring the drug industry under tighter Federal control.

Every time one company is caught falsifying IND or NDA data—this kind of pressure builds up.

Every time one company attempts to mislead the physician through its own poor advertising, additional regulatory pressure builds up against the advertising of all.

Every time the pharmaceutical manufacturers see a violation of law made by one of their number—and then look away—the pressure builds up even more for tougher, tighter, more sweeping regulatory action and legislative control over the drug industry.

Because lives are at stake.

And those of us in Government who are responsible for protecting the lives of American citizens cannot look away, cannot ignore, cannot put aside any acts of irresponsibility that may occur in the marketplace.

President Johnson has been clear on this point. In his consumer message to Congress, he said, "The consumer's interest is the American interest. In guarding, in promoting it, we improve the lives of every man, woman, and child in our Nation."

The President and Secretary Gardner are making every effort to protect and enrich American life. The members of the 89th Congress are establishing an historic record in the field of health, also. It is a privilege to be in Government service at this time, for the goals are lofty and the energy being spent to reach those goals is indeed prodigious in every quarter.

But Government alone cannot serve all the health needs of the American people. This is a responsibility we gladly share with private industry.

But you cannot accept the partnership lightly.

And so I am placing this challenge before you today. I am asking you to join us in correcting abuses and in seeking—not what will just "get by"—but what is excellent in the science of drugs.

Let us seek excellence in our research, excellence in our IND's, excellence in our NDA's, excellence in our promotion. Let us try to live up to the mission of this industry, the central dynamic, the cause for it to be: healthful human life.

Thank you.

Senator NELSON. Then in one of your speeches on December 3, 1968, and which I ask that that be printed in full in the record also, you say:

By the same token, the manufacturer can't disregard his responsibility to submit some data that demonstrates safety and efficacy. I must tell you frankly that we have not seen the degree of improvement in the quality of clinical data from drug investigations that we would like.

(The speech referred to, in full, follows:)

FDA TODAY AND TOMORROW

(By Herbert L. Ley, Jr., M.D., Commissioner of Food and Drugs [1])

It is a pleasure for me, speaking in behalf of the Food and Drug Administration, to welcome all of you to this 12th FDLI–FDA Educational Conference. The

[1] Presented at the 12th FDLI–FDA Joint Educational Conference at Washington, D.C., on Tuesday, December 3, 1968.