

of course, is to track down the sources of contamination and develop effective preventive measures. In addition to food products, we also plan to have our Districts submit samples of drugs and cosmetics to the National Center.

This pilot program in Minneapolis represents a new approach to further enlarge FDA's capabilities to monitor and control bacterial contamination. As you know, we had previously assigned bacteriologists to each of our District Offices to carry out this essential analytical work. The frequent recalls of products because of Salmonella contamination gave major impetus to the expansion of this program within FDA. And, I must add, industry has also responded to this growing awareness of the health hazard posed by microbiological contamination.

In dealing with a problem such as bacterial contamination, I think it is clear that FDA and industry are not adversaries. We have had to act together to begin to combat this threat to the public health, and I am happy to say that there has been a high degree of cooperation in this effort. I would hope that this same attitude—this mutual appreciation of the importance of the consumer interest—can prevail in other areas as well. Certainly, we will have ample opportunity to test this premise in the weeks ahead.

Very soon now, we will publish a new proposal outlining Good Manufacturing Practices in the food industry. Also ahead are proposed revisions of the Good Manufacturing Practices regulations for the drug industry. I do not expect unanimous support by industry for these proposals. But I do hope we don't encounter automatic opposition either. This is not an adversary contest, a kind of game in which FDA proposes all the regulations it can think of and industry defeats as many as it can. Rather, the fundamental question has to be: What rules are necessary to safeguard the consumer? If we keep that principle in mind, it is much easier to deal with and resolve the disagreements that do arise between FDA and industry.

Now, of course, the FDA has taken on new responsibilities—product safety, shellfish certification, broader pesticide research, and other activities mentioned by Mr. Johnson. In all of these, too, it is the consumer who is our first concern. With the organization of the Consumer Protection and Environmental Health Service, I believe we are in a better position than ever before to translate that concern into effective action.

It's clear to me that we can be most effective when we have the cooperative support of industry in coping with consumer problem. Your participation in this Conference is evidence that we have the kind of dialogue going that can encourage this cooperative effort. I am looking forward to working with you in this endeavor.

Thank you.

Senator NELSON. Now, are you saying that you believe that the peer committee approach is a resolution of the kind of problem, the gray area problem, mentioned by Dr. Goddard and you?

Dr. LEY. Not a total resolution, Mr. Chairman. I believe there has been an improvement in the quality of information flowing into our files. We have taken vigorous steps to insure since Dr. Goddard's speech, and at his direction in the beginning, but with my total support since, that material of the quality he referred to is rejected upon initial receipt, sent right back to the manufacturer. So that there are efforts in progress.

The peer group is not the sole and only answer to this problem, and I must confess quite frankly that I have spoken to several major industry leaders in the pharmaceutical area very frankly in my office. And I pointed out to them that the major problem as I see it today in the development of new drugs is in the poor quality—I have used more vigorous words on occasion, sir—in the poor quality of data coming into our files in investigational drug studies.

Now, our discussions with the National Academy of Sciences are very important steps which would be an equally significant move to try to improve the quality of data. Although there are people who say that I am wrong, I firmly believe, and I believe the scientific com-