tives, whether intentioned or accidental, is today a matter of vigorous dialogue between the FDA and industry. The range of such additives is enormous—from colorings and flavorings on one hand to pesticide and antibiotic residues on the other. The FDA has adopted a posture that such additives are acceptable only after evidence or expert scientific opinion is available to confirm that no injury or harm to the consumer will result from ingestion of foods containing the additives. It is not satisfactory, as some would have us believe, to use the additive and wait for ill effects to be reported. If human experience is necessary it must be on a controlled, small-scale basis, rather than a market-scale experiment. Our approach is conservative, but designed to reduce risks to the consumer to a minimum.

I am not going to tell you that FDA has devised the perfect system for keeping hazardous chemicals out of our foods, and you'll simply have to live with it. But I must also point out that our scientific knowledge in this particular field is still extremely superficial. We know too little of potential secondary and long-range effects of man's chemical diet. And we must remember that we cannot consider each new food additive as a single, isolated factor in the environment. The consumer is confronted with combinations of chemicals in his foods, his medicines, even in the air he breathes.

Industry scientists, as well as Government and academic scientists, can contribute, and should contribute, to our understanding of additives and their effects. This is cooperation in a meaningful form. As our knowledge advances, I suspect that testing procedures will change as well. But unless we do learn more, debating whether animal studies should be of two months' or two years' duration is a sterile exercise.

As you know, FDA has given greater emphasis in recent years to preventive programs. We are still committed to effective enforcement action when unsafe or misrepresented products reach the marketplace. But consumer protection is even more effective when there is positive action to insure the consistent production of consumer commodities that meet the highest quality standards.

Preventive programs can be carried out at the research level, as I indicated a moment ago in discussing food additives. They must also be carried out at the production level. And at this level, too. FDA-industry cooperation is an essential to make this approach work successfully for the consumer. I believe the Intensified Drug Inspection Program, begun last July 1, will provide one good measure of how fruitful such cooperative efforts can be.

Plant inspections, of course, have long been an important part of FDA's regulatory program. Since 1962, the Food, Drug, and Cosmetic Act has required inspection of prescription drug firms at least once every two years. FDA's inspectors, over the years, have done a thorough, efficient job of checking plants for violative practices and products. Frequently, their inspections led to enforcement actions against a firm or one of its products. But this, admittedly, was a spot check program, with no consistent follow-through to assure that corrective action was taken.

The Intensified Drug Inspection, on the other hand, is just what the name implies. Mr. Barnard, whom you will hear a little later in the morning, will be telling you more about how the program works in the plant. Let me simply say that the primary purpose of the Intensified Drug Inspection is bringing about whatever corrections are necessary to put a plant in full compliance with the laws.

This program does not foreclose legal action when violations are uncovered during the course of the inspection. There may be, and frequently are, recalls or seizure actions to take off the market substandard drugs detected by inspectors. And an Intensified Drug Inspection doesn't go on forever; if a firm is unwilling, or unable, to correct poor manufacturing practices or other deficiencies, we have no alternative but to go into court to put that firm out of the drug business.

Up to now, however, we have found drug companies both receptive and cooperative. Before the Intensified Drug Inspection actually begins, the FDA District Director meets with top management of the company involved to explain the purpose of the program and to outline what is expected of the manufacturer. We want no confusion about what FDA expects to achieve as a result of the Intensified Drug Inspection.

As I have mentioned, the program began last July 1. Since the inspections are exhaustive and time must be allowed for corrective action, it is still too soon for any real measure of the success of the program. As of the end of last week, 118 inspections of this kind were in progress. Eleven had been concluded. We had