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INFLUENCE THAT RESEARCH AND TECHNOLOGICAL DEVELOPMENTS HAVE HAD ON THE ABILITY OF THE FDA TO PROTECT THE PUBLIC HEALTH

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Professor Pocchiari, distinguished guests, and friends, I am delighted and honored to join in commemorating — and in celebrating — the fiftieth anniversary of the founding of the Istituto Superiore di Sanità.

My colleagues and I in the United States Public Health Service feel a special kinship with this Institute and its staff because, in many respects, your work and your responsibilities parallel those assigned to us by the people and government of our country.

Your task, like ours, is protection of the public health — surely one of the most basic obligations and highest objectives of any society. And although the scientific and technical activities of this Institute reach beyond those of my agency, the US Food and Drug Administration, there is much that we share in common, especially our responsibilities with respect to the safety and effectiveness of drugs.

The US Food and Drug Administration was founded 78 years ago at a time when forces in American society were rapidly transforming the ways in which American lived. The production and marketing of basic commodities — notably foods and medicines — had begun to be commercialized and industrialized. As a result, our people had little way of knowing whether a food product of a purported remedy for illness was safe, wholesome, or reliable.

And in fact, a good many of the foods and drugs on the American market at the turn of the century were far from safe. The use of borax and formaldehyde as food preservatives and copper sulfate to give canned vegetables a "wholesome" green color was common practice. Many drug products on the market were equally dangerous. Drug labeling and advertising gave no hint that heavy concentrations of alcohol and narcotics were being dispensed. Worthless nostrums were being promoted for the cure of every ailment from dyspepsia to cancer.

Responding to this state of affairs, the US Congress passed and President Theodore Roosevelt signed into law the Pure Food and Drugs Act of 1906, the first comprehensive legislation to protect the American public from unsafe, impure, and falsely labeled food and drug products.

This early legislation and the Federal program that carried it out seem primitive to us today. They came into being at a time when industrial and analytical chemistry were in their infancy and the biological sciences had scarcely begun to recognize how much remained to be learned about living cells. Not surprisingly, the legislation enacted in 1906 said virtually nothing about the place of science in the regulation of food and drugs. It took instead what I might call a moral tack–directing drug makers to label their products truthfully, to identify a handful of dangerous ingredients if they were incorporated in the drug product, and to make no claims not honestly believed to be valid. Yet despite its non–scientific approach to the control of drugs, the 1906 Act worked remarkably well to protect the public health. Countless dangerous drug products were removed from the marketplace because they secretly contained alcohol, an opiate, or some other substance that both public opinion and Federal law held to be too hazardous to be kept secret.

Food regulation in those early years received the lion's share of the Federal effort. Yet here, too, science was employed with a vigor that made up, perhaps, for its lack of sophistication. The law banned from commerce any adulterated or misbranded food product without specifying which ingredients would render a food adulterated nor establishing a process by which standards for food purity could be adopted.

Nonetheless, enforcement of the 1906 Act succeeded in removing many injurious preservatives from the Nation's food supply and improved the overall quality of foods and the honesty with which they were promoted. It also helped accelerate the development of analytical technology in food regulation, a small but significant hint of the tremendous growth of regulatory science that was to come.

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In the intervening years, the scope of United States law for consumer health protection and the responsibilities of the Food and Drug Administration have broadened enormously. FDA now administers laws governing the regulation of foods, cosmetics, drugs, biologics, medical devices, and radiological products. With a staff of nearly 7,000 people, more than 2,000 of whom are trained scientists, FDA has regulatory responsibility for products that account for 25 percent of consumer's spending in the United States.

To describe the full range of FDA's health protection activities in detail would take far longer than is appropriate for this occasion. But in view of the international character of this gathering and the fact that we are commemorating the fiftieth anniversary of an institution devoted to the science of public health protection, I would like to focus on these two important aspects of the work of the Food and Drug Administration.

Let me touch first on our role as a scientific regulatory agency.

In essence, it is our responsibility at the Food and Drug Administration to employ science to determine whether or not a product we regulate can enter the marketplace in the United States. Under our system, the manufacturer or sponsor of an article subject to FDA regulation must supply data to support an application for marketing approval. Our task is to review those data and decide to approve or disapprove the application. The actual steps in this process vary depending on whether approval is sought for a drug, a medical device, a food additive or whatever. But the fundamental mechanism is the same for all regulated products.

The burden of scientific proof rests with the applicant for FDA approval. That means the agency must have the scientific competence to review and evaluate the mass of information required to support, for example, a new drug application data that may run to thousands of pages covering pre-clinical and clinical studies, chemistry, pharmacology, microbiology, pathology and other scientific fields.

But the sheer volume of scientific information required to establish the safety and effectiveness of a new drug or medical device, or the safety of a food additive for human consumption, represents only part of the picture. Equally challenging is the need for FDA's scientific capabilities to advance stride for stride with the incredible changes that are taking place in the sciences involved in the discovery and development of new products.

In the drug area, I need only mention the accelerating pace of recombinant DNA research, hybridoma technology and pharmacokinetic engineering to suggest the literally exposive environment in which we and the industries we regulate are working. And the same is true in food technology, medical device development and radiology.

We long ago realized that it would be difficult, if not impossible, for the Food and Drug Administration to employ on its staff, the array of scientific talent required to make expert judgments in all the highly specialized fields of research and development that bear on our regulatory responsibilities. For that reason, FDA makes rather extensive use of scientific advisors — experts in fields from radiology to toxicology and from medicine to electrical engineering — who give us the benefit of their judgment on many of the scientific–regulatory issues we face.

But I do not want to leave the impression that science and scientists are engaged only in FDA's review of product applications. Many other kinds of scientific activity are at the heart of FDA's program:

- identification of previously unrecognized hazards associated with products that have come on the market;
- research on food toxins and contaminants;
- basic work in toxicology, including toxicology and carcinogenesis;
- work on the safety and potency of vaccines;
- epidemiological and behavioral research on the effect of regulatory initiatives, such as changes in food labeling or efforts to increase public understanding of the use of prescription drugs;
- development of new, improved analytical tests;
- analyses of marked products to determine that they conform to established standards or to develop precise information when a product–related hazard is suspected;
- the establishment of benchmark standards and criteria for use by industry and other governmental agencies to monitor the performance of products in the marketplace.

Science, in short, is central to everything FDA does in the interest of protecting the public health.

The consumer health protection work of the Food and Drug Administration demonstrates that science is not an end in itself, but the means to an end — the means to assuring the highest possible levels of public health. In that sense, our scientific endeavors are somewhat like a screen that gets progressively finer as science and the fruits of science become more sophisticated.

We need to make sure that the scientific screen is able to hold back those things — in our case, food substances, drugs, biologicals, medical devices, and so forth — whose benefit to the public is not justified by their risks. But at the same time, we must never permit that screen to inhibit the public health benefits that advancing science and technology can and do provide.

It is a delicate balance and a shifting one. And, I would emphasize, it is a balance that no organization and no single nation can hope to maintain in isolation from the rest of the world.

Protecting the public from unsafe foods and drugs is a goal of individual nations which they approach according to their individual needs, perspectives, and resources. But the science base on which such efforts rest knows no national boundaries.

That fact was, in a sense, the underlying reason for the International Conferences of Drug Regulatory Authorities, the second of which was held here in Rome in 1982 under the dedicated leadership of Dr. Duilio Poggiolini and the Italian Ministry of Health. The Food and Drug Administration had the privilege of organizing the first of these conferences in 1980, and the Third International Conference of Drug Regulatory Authorities will take place next month in Stockholm. Sponsored by the World Health Organization, these meetings bring together officials of organizations throughout the world who share a responsibility for ensuring the safety and effectiveness of the drugs upon which the health of the people of the world increasingly depends.

Similar meetings concerned with veterinary product registration — the first in the United States in 1983 and the second to be held in Oslo next month — attest to the fact that international consultation in that field is seen as necessary and useful. And I am pleased to note that preliminary discussions involving the World Health Organization may lead to international meetings concerning the registration of medical devices.

These meetings, at which people concerned with the problems and processes of protecting the public health through product registration, regulation, and surveillance, are an invaluable adjunct to the conventional exchange of scientific information among nations. They demonstrate that those of us who have responsibility for consumer health protection have much to share with and learn from our colleagues in other nations. This idea is fundamental to work at the Food and Drug Administration — to information sharing, to technical assistance, and to collaborative programs in which we are engaged with our colleagues throughout the world.

In the last 50 years, virtually every field of endeavor in which this Institute is engaged, from immunology to nutrition, from cellular biology to environmental hygiene, has undergone quantum change. In many of those fields of inquiry, advances have been recorded that have led to dramatic improvement in public health — whole new classes of drugs, new vaccines, new understanding of the role of nutrition in human health and disease, new devices and technologies for diagnosing and treating illness — the list is all but endless.

And in that half century, organizations like this Institute, and its counterparts and colleagues around the world have faced new challenges and opportunities that pioneers in the science of public health could scarcely have imagined.

To have worked in that era of remarkable progress, to have contributed to it, is a marvellous privilege. I am happy to congratulate the Institute on its 50th anniversary of service in the field of public health science, and I wish you many more years of fruitful effort toward advancing the health of the people of Italy and of the world.

Thank you very much.