



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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STATEMENT BY

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FOOD AND DRUG ADMINISTRATION

BEFORE THE

COMMITTEE ON OVERSIGHT

AND

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INTRODUCTION

Mr. Chairman and Members of the Committee, I am Andrew von Eschenbach, M.D., Commissioner of Food and Drugs and head of the United States Food and Drug Administration (FDA or the Agency). I am pleased to be here today to talk about the importance of the work that FDA performs every day to protect and promote the public health. I also want to share my vision for the future of FDA and how we are planning to address the new challenges of the 21st Century the Agency is facing.

FDA is responsible for ensuring the safety and high quality of more than a trillion dollars worth of products that are critical for the survival and well-being of all Americans -- products that include some 80 percent of the United States food supply, all human health care products, electronic products that emit radiation, animal drugs and feed, and cosmetics.

For over 100 years, FDA has been recognized and praised as the gold standard of regulation throughout the world. Being given the opportunity to lead the Agency at this time, it is my responsibility to continue the excellent work of my predecessors and ensure that the Agency is equipped to handle the challenges of today and the future. The world is experiencing a rapid expansion of scientific knowledge and globalization that will have dramatic impacts on the industries and products that we regulate. The Agency must be equipped with the expertise and infrastructure to meet emerging challenges, such as: foodborne disease outbreaks, intentional or unintentional; evaluation of complex drugs

and biologics brought about by emerging progress in molecular biology; the potential for pandemic flu; and medical devices bioengineered, miniaturized, and increasingly autonomous in evaluating and modulating our state of health. Even cosmetic safety is becoming more complex through incorporation of the products of rapidly expanding technology, such as nanoparticles.

FDA's COMMITMENT TO PROTECTING PUBLIC HEALTH

FDA's Commitment to Food Safety

FDA is committed to ensuring that America's food supply continues to be among the safest in the world. But we face challenges. For example, consumption of produce, particularly "ready-to-eat" products, has increased dramatically during the past decade. This is a positive development from a nutrition perspective, but a new dynamic that challenges our food safety efforts. Americans usually consume these products in their raw state, harvested from the vine, stem, or soil and without processing to reduce or eliminate any pathogens that may be present. Consequently, the manner in which these products are grown, harvested, packed, processed, and distributed is crucial to ensuring that microbial contamination is minimized, and the risk of illness to consumers reduced. Even if a small percentage of a harvest is contaminated, severe and widespread illness can result.

FDA has addressed produce safety for a number of years. In response to the recent produce-related outbreaks, however, FDA is sharpening its focus in this area. To reduce the risk of foodborne illness at all points in the food chain, FDA has adopted a "farm-to-fork" approach

to food safety, an approach that systematically applies risk management principles at each step as food moves from growers and producers to consumers. For example, FDA has conducted foreign and domestic training and outreach on Good Agricultural Practices and has assisted industry in the development of several commodity specific guidances. In addition, FDA has issued a Produce Safety Action Plan and launched a Leafy Greens Safety Initiative in cooperation with the state of California, California growers and producers.

FDA is examining the recent outbreaks to determine what changes may be necessary to improve the safety of fresh and fresh-cut produce. We continue to work closely with states, produce growers, processors, and distributors to develop and implement programs at each point in the supply chain to prevent and minimize contamination from harmful micro-organisms. FDA recently issued draft final guidance to industry entitled “Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables” to enhance the safety of fresh-cut produce by minimizing the microbial food safety hazards. This guidance recommends that fresh-cut processors consider a state-of-the-art food safety program such as the Hazard Analysis and Critical Control Points (HACCP) system, designed to prevent, eliminate, or reduce to acceptable levels the microbial, chemical, and physical hazards associated with food production. Also, in response to the recent outbreaks, FDA held two public hearings to share information about recent outbreaks of foodborne illness associated with microbial contamination of fresh produce, and to solicit comments, data, and additional scientific information on this issue. We are soliciting input from all our stakeholders on ways to improve the safety of fresh produce.

In view of the recent recalls involving wheat gluten and rice protein concentrate in various pet food, FDA, in conjunction with state regulatory authorities, is testing for the presence of melamine in a variety of plant protein ingredients and finished products commonly found in the U.S. food and feed supply. FDA and state authorities also are raising awareness of food protection and defense measures by discussing the Federal government's new ALERT awareness initiative and the need for food manufacturers to ensure the safety of the ingredients they use as well as the packaging and processing supplies.

Reducing the risk of foodborne illness requires science-based methods capable of identifying both the sources of risk and effective control measures. For example, we are using molecular technology to identify foodborne illnesses and their causes by tracking the DNA fingerprints of the suspected contaminants. Regulations without science supporting the required interventions are a hollow promise, and ineffective at protecting consumers. We are collaborating with industry and state/local governments responsible for food safety. In addition, we are strategically deploying inspection resources toward the greatest risks to the food supply, including imported food.

FDA's Commitment to Drug and Medical Product Safety

New drugs, biologics, devices, and diagnostics present significant opportunities for improvements in health care. Ensuring the safety and effectiveness of medical products is a key focus of our commitment to protect and promote public health. FDA only approves new therapies if their benefits (lives saved, extended or enhanced) outweigh the risks they pose. Toward that end, FDA continually assesses its medical product safety programs. In

particular, over the past few years, FDA has reassessed its medical product safety programs due to rapid advances in science and technology resulting in increasing complexity of medical products, as well as the increased attention to safety-related issues by consumer advocates, health professionals, and academic researchers.

FDA has maintained its reputation for excellence over the past 100 years through its willingness to look internally to see what transformations are necessary to sustain this standard. For this reason, in 2005, the Agency asked the Institute of Medicine (IOM) to study the effectiveness of the U.S. drug safety system, with an emphasis on the post-marketing phase, and to assess what additional steps FDA could take to learn more about the side effects of drugs as they are actually used post-market.

On September 22, 2006, the IOM released its report entitled *The Future of Drug Safety — Promoting and Protecting the Health of the Public*. The report recognized the progress and reform already initiated by the Agency and made a number of recommendations for additional improvements. The Agency subsequently issued a report responding to the IOM recommendations. We are working diligently on initiatives for improving drug safety that we identified in our response and have already made significant progress on several projects. For example, in March we issued final guidance that describes FDA's current approach to communicating drug safety information, including emerging safety information, to the public. The guidance affirms the Agency's commitment to communicate important drug safety information in a timely manner, including in some situations when the Agency is still evaluating whether to take any regulatory action. FDA's drug safety communications are

available through the FDA website. In addition, we have issued guidance designed to make our Advisory Committee operations more consistent, transparent, and predictable.

The Agency's response to the IOM also details a series of initial steps to strengthen the drug safety system in three key areas: science, communications, and operations and management.

1. Strengthening the Science

First, I am committed to strengthening the science that supports our medical product safety system at every stage of the product life cycle, from pre-market testing and development through post-market surveillance and risk management. As part of the recent reorganization of the Office of the Commissioner, the Office of the Chief Medical Officer was created to provide oversight of scientific and planning related operations for the Agency. Led by Dr. Janet Woodcock, Chief Medical Officer, this Office shares responsibility and collaborates with me in planning, organizing, directing, coordinating, controlling, and evaluating the Agency's scientific and medical regulatory activities in order to achieve the mission of FDA.

We will be focusing our resources on enhancing three areas of scientific activity: (1) benefit and risk analysis and risk management; (2) surveillance methods and tools; and (3) understanding adverse events. We propose that these activities be supported, in part, by Prescription Drug User Fee Act (PDUFA) IV funds.

Specifically, new scientific discoveries are generating a *science of safety* that will help prevent adverse events by improving the methods clinicians use to target specific drugs for use in patients for whom benefits are maximized relative to risks. This new science

combines an understanding of disease and its origins at the molecular level (including adverse events resulting from treatment) with new methods of signal detection, data mining, and analysis. This enables researchers to generate hypotheses about, and confirm the existence and cause of safety problems, as well as explore the unique genetic and biologic features of individuals that will determine how he or she responds to treatment. This *science of safety* encompasses the entire life cycle of a product, from pre-market animal and human safety testing to widespread clinical use beyond original indications. It should be applied to all medical products so that safety signals generated at any point in the process will robustly inform regulatory decision-making.

2. Improving Communications

Second, I am committed to improving communication and information flow among all stakeholders to further strengthen the drug safety system. This will require a comprehensive review and evaluation of our risk communication tools.

In agreement with the IOM's recommendation, we are working quickly to establish an FDA Risk Communication Advisory Committee to advise FDA on communication policies, practices, and strategies for all regulated products. Numerous administrative steps required by the Federal Advisory Committee Act have been completed, others are currently under review, and we are on target to announce a call for member nominations in the near future.

In addition, FDA proposed two new draft guidances for which it has sought public comment: "Draft Guidance for Industry, Advisory Committee Meetings - Preparation and Public

Availability of Information Given to Advisory Committee Members” (February 2007) and “Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation on FDA Advisory Committees” (March 2007). The Agency also has posted new information on its website to encourage applications for membership on FDA advisory committees as part of its ongoing efforts to recruit qualified experts with minimal conflicts of interest. Numerous nominations have already been received.

3. Improving Operations and Management

Finally, I am committed to improving operations and management to ensure implementation of the review, analysis, consultation, and communication processes needed to strengthen the U.S. drug safety system. Under my direction, the Center for Drug Evaluation and Research (CDER) has initiated a series of changes designed to effect true culture change that will strengthen the drug safety system. CDER has reinvigorated its senior management team and charged its members to lead the Center in an integrated manner. In addition, we have engaged external management consultants to work with CDER’s senior managers to lay the foundation for an ambitious, comprehensive strategy for improving CDER/FDA’s organizational culture. We are enlisting the help of external experts in organizational improvement to work with employees at all levels of the organization in implementing this transformation. Our goal is to provide CDER with the tools and expertise necessary to create a credible and sustainable environment of open and transparent communication, collaborative decision-making, and improved morale and staff retention.

For example, CDER has employed process improvement teams comprised of staff across organizations, including the Offices of Surveillance and Epidemiology (OSE) and New Drugs (OND), to recommend improvements in the drug safety program. Two significant recommendations, (1) to establish an Associate Director for Safety and a Safety Regulatory Project Manager in each OND review division, and (2) to conduct regular safety meetings between OSE and all of the OND review divisions, are now being implemented. We are committed to providing the management attention and support necessary to effect sustained culture change in our drug safety program.

FDA's COMMITMENT TO PROMOTING PUBLIC HEALTH

FDA is committed to promoting public health, as demonstrated by our dedication to making safe, effective, innovative and life-saving new medical products promptly available to patients. During my tenure as Commissioner, FDA has made major strides in implementing the Critical Path Initiative, a cooperative program that seeks to bring safe and effective medical products to patients faster by making their development more predictable and efficient. In the past year, we advanced this top-priority project through the following actions.

Releasing the Critical Path Opportunities List: FDA set forth 76 research projects, most of which are focused on the creation of smarter tools for early evaluation of candidate medical products suitable for further development. The Opportunities List, the central component of the Critical Path blueprint, invites scientists in academia, government agencies and industry to

cooperate in finding answers to unresolved issues in six broad topic areas: development of biomarkers; clinical trial designs; bioinformatics; manufacturing; public health needs; and pediatrics. By the end of 2006, almost one-half of the listed projects were in progress.

Advancing Critical Path research: FDA advanced research involving the two most important predictive instruments -- reliable biomarkers and focused clinical trials -- through the following actions:

- FDA released guidance on how to conduct very early clinical studies in people, and how to safely produce and test small amounts of experimental drugs;
- FDA, the National Cancer Institute of the National Institutes of Health, and the Centers for Medicare and Medicaid Services agreed to collaborate on improving the development of cancer therapies through biomarker development and evaluation.
- FDA and the Critical Path Institute announced the formation of the Predictive Safety Testing Consortium with five of America's largest pharmaceutical companies. FDA is assisting the Consortium in its prime function, sharing internally developed laboratory methods to predict the safety of new treatments before they are tested in humans.

Spurring medical device development: To help provide patients with new medical devices sooner, FDA launched an initiative to encourage early consultations between FDA and industry. The goals of the initiative are to promote scientific innovation in product development; focus device research on the latest science; modernize FDA's review processes;

and facilitate a least burdensome approach to clinical trials. As part of this effort, FDA issued draft guidance on the use of Bayesian statistical methods to design more efficient clinical trials by using safety and/or effectiveness data from previously developed medical devices.

CONCLUSION

FDA's mission is vital to the health and well-being of people, in our country and around the world. And, as you know, the Agency's most important resource is its employees. For this reason, I cannot overemphasize how important it is for the FDA to continue to have the ability to recruit and retain the best and the brightest personnel. A critical element of preserving this ability is for Congress to pass the user fee reauthorization bills without delay.

FDA and this Committee share the goal of a healthier, safer nation. I appreciate the valuable input I have received from Members of Congress and my predecessors, and I want to thank this Committee for focusing your attention on the important work being done at the Agency. I look forward to continuing to work productively together to address the challenges and opportunities of the future.

Once again, thank you for the invitation to testify before the Committee today. I am happy to respond to any questions.