



STATEMENT OF

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FOOD AND DRUG ADMINISTRATION

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INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs at the United States Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to discuss the important issues relating to the role and support of science at FDA.

On December 3, 2007, the FDA Science Board (Science Board) accepted the report of its Subcommittee on Science and Technology (Subcommittee) entitled, “FDA Science and Mission at Risk.” The Subcommittee report reveals a number of areas that recommend increased investment. FDA takes this report seriously. The need to improve science at FDA is not in question. Nor is there any question that we must make a significant investment in improving the science. The hard question we must now answer is how to prioritize the investments needed in the Agency’s regulatory science infrastructure.

In my testimony today, I will first outline FDA’s request for the Science Board report and the additional work underway. I will next describe the Agency’s current and future challenges. I will then discuss our efforts to take inventory and solicit advice, both internally and externally, and our steps to change our practices to address these challenges.

FDA’s CHARGE TO THE SCIENCE BOARD

The FDA Science Board is a Federal advisory committee that advises the Commissioner in discharging responsibilities as they relate to addressing specific and technically complex

scientific issues of regulatory importance to FDA. The Science Board consists of a group of senior scientists with accomplished backgrounds in evolving areas of science. FDA Science Board members provide advice and interact with FDA, industry, academia, and other government agencies on technically complicated issues of regulatory importance. In December 2006, I asked the Science Board to assess whether science and technology at the FDA can support current and future regulatory needs. The Science Board Chair created the Subcommittee to work on this review. Specifically, the Subcommittee's charge was to identify the broad categories of scientific and technologic capacities that FDA needs to fully support its core regulatory functions and decision-making throughout the product life cycle, today and during the next decade.

The Subcommittee, composed of three Science Board members and other external experts, presented their draft report at the December 3, 2007, Science Board meeting. The Science Board accepted the subcommittee draft report and also requested the following additional work:

- A four page Executive Summary of the report;
- FDA leadership's response to the report;
- Public comments on the report (Public Docket opened January 4, 2008);
- A review of the Office of Regulatory Affairs;
- Further review of the National Center for Toxicological Research; and
- A review of priority science topics and emerging areas of science.

We have taken critical steps to begin to develop, articulate, and execute a well-designed plan for moving forward once the review of FDA science is complete.

FDA—MODERNIZING THE AGENCY

For the past century, FDA has been recognized and praised as the gold standard of regulation of food, feed, and medical products throughout the world. In this first 100 years, FDA used science in the acquisition of data that were subject to statistical analysis as a basis for making decisions. Some of that science was developed within FDA, while a large part was derived from the product of efforts and discoveries in the scientific community. As we embark on the next 100 years, FDA must be more than science-based—it must be science-led. The discoveries occurring as a result of scientific exploration must point the way to FDA’s next challenges. The Agency must be equipped with the expertise and infrastructure to meet emerging challenges, such as: foodborne disease outbreaks, whether intentional or unintentional; evaluation of complex drugs and biologics developed by emerging techniques in molecular and cell biology; the potential for pandemic influenza or other emerging infectious diseases; and miniaturized bioengineered medical devices. The world is undergoing a rapid expansion of scientific knowledge and globalization that will have dramatic impacts on the industries and products that we regulate. The world is radically changing around us, and so FDA must change.

FDA —SELF ANALYSIS

FDA has taken a number of steps to support our existing scientific regulatory base and to prepare for future challenges through designing and executing activities based on internal, proactive, strategic thinking. More recently, Secretary Leavitt announced a comprehensive Import Safety Action Plan designed to bolster efforts to better protect the nation from unsafe imported

products. At the same time, the Administration announced the Food Protection Plan which proposes the use of science and a risk-based approach to ensure the safety of domestic and imported foods eaten by American consumers. The plans propose a strategy focused on a risk-based prevention with verification model that allocates import safety resources based on risk.

One recent example illustrates both FDA's application of state-of-the-art applied science, and the Agency's commitment to request peer review and assessment of our work. As part of the Agency's response to the 2007 melamine contamination of animal food, FDA prepared a Multi-Center Melamine Safety Risk Assessment to describe the possible risk to human health associated with eating pork, chicken, fish and eggs from animals that had been inadvertently fed animal feed that may have been adulterated with melamine and its analogues (cyanuric acid, ammeline and ammelide). Just a few months ago, the Science Board's peer-review of the Melamine Safety Risk Assessment yielded general and unanimous consensus that the conclusions of the Safety Risk Assessment were sound and appropriate. The Science Board also found that the collaborative relationship among the Agency participants was an excellent model for other government programs.

FDA has also undertaken many internal reviews at the Center, Office, and Program levels with the goal of ensuring the highest standards of excellence at the Agency. As one example, the Center for Biologics Evaluation and Research (CBER) identified key areas of research needed to facilitate development of safe and effective products in the areas of blood and blood products, vaccines, and cellular, tissues, and gene therapies. These CBER priorities are aligned with FDA and HHS priorities, such as counter-bioterrorism and pandemic influenza preparedness.

External Input

As the Subcommittee noted in its report, the exponential rate of change in science and technology requires FDA to be willing to initiate and continue these diverse self-assessments of the state of science at FDA. But we must also look outside the Agency to benefit from broader expertise. FDA does this in a number of ways. 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 in the real world of post-market approval. In September 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. Shortly thereafter, in January 2007, the Agency gave its response to the IOM recommendations. We are working diligently on a number of initiatives for improving drug safety that we identified in our January 2007 response to the IOM recommendations, and have already made significant progress on several projects.

ADAPTING TO THE CHANGING WORLD

These internal and external reviews are stimulating change. I have asked for this input—and I am using it. These reviews help assess our activities as well as confirm the changes in the world around us, changes to which we must respond. Let me briefly mention some of our ongoing work.

Nanotechnology Task Force

Recognizing the potential for nanoengineered materials to be incorporated into almost all products FDA regulates, I asked FDA staff to create and implement a focused group of FDA experts: the Nanotechnology Task Force. The Task Force Report, a landmark document for regulatory agencies around the world, was issued in July 2007. The Report provides an analysis of the state of the science as related to FDA regulated products and nanoparticles, an analysis and recommendations for science issues, and an analysis and recommendations for regulatory policy issues. To address the information needs and the differences in regulatory authority, the Task Force has recommended a number of activities to address these challenges, and these will be the subject of public announcements in the future.

Critical Path Initiative

In 2004, FDA advanced the idea of focusing on the critical path that medical products must travel, from the earliest stages of development to their use in patients. The Critical Path Initiative is FDA's endeavor to stimulate and facilitate a national effort to modernize the regulatory sciences through which FDA-regulated products are developed, evaluated, and manufactured. The goal of the Critical Path Initiative is to facilitate projects and initiatives that will help move the regulatory sciences into the 21st Century, enabling us to capitalize on the breakthroughs of basic science. For example, our growing understanding of the role of genetics in medical product development is helping us make personalized medicine a reality.

In another area, new bioinformatics approaches are enhancing the interoperability of information tracking systems in the healthcare environment for all regulated products (e.g., adverse event reporting).

Information Technology

As observed in the report from the Subcommittee to the Science Board, information technology is an important cornerstone of Agency activity. Last year, I hired a new Chief Information Officer (CIO) with experience in developing and managing innovative and cost effective multi-organizational scientific and business programs, re-engineering governmental processes and managing the reduction of duplicative systems. The CIO's position was elevated to include centralized management of all previously decentralized IT services in Centers and Offices. This centralized approach provides the CIO the authority and oversight of available IT resources to meet the challenges of the FDA in the 21st Century. Coupled with resource planning and development activities, the Office of Information Management has undertaken detailed succession planning to ensure that the IT organization that FDA is building for the 21st Century remains reliable in support of FDA's mission and sufficiently flexible to accommodate the science and technology advances of the future.

The formation of FDA's Bioinformatics Board (BiB) in 2006 provided an important means of ensuring that business needs and public safety endeavors are equally met by Agency IT services. The BiB oversees the quality and performance of information systems, including business decisions on prioritization, planning, and execution of Agency cross-cutting business automation projects, positioning the Agency to meet external demands on the Agency while, at the same time, satisfying the needs of FDA programs.

Supporting Collaboration, Strengthening our Workforce

As noted at the December meeting of the Science Board, the ongoing relocation of our employees to the White Oak campus in Silver Spring, Maryland, is essential to fulfill the promise of a strong FDA. FDA will eventually consolidate nearly 8,000 employees, currently located in 20 different locations across the Washington, D.C. metropolitan region, into new, state-of-the-art facilities. The facilities on the White Oak campus are already providing critical scientific capacity—scientists working in modern laboratories with access to the latest technologies and tools—to execute mission-critical responsibilities.

The Path Forward

As I have discussed this morning, FDA faces a number of challenges. Assessments and actions are making a difference. The Agency takes the Subcommittee's assessment of the current and future science and technology needs very seriously and looks forward to receiving the report of the Science Board. We will conduct a thorough and substantive review of the report's findings and recommendations when we receive it.

As I noted earlier, we have taken critical steps to begin to develop, articulate, and execute a well-designed plan for moving forward once the Science Board has completed its review of FDA science. We look forward to the results of the current ongoing work to complete the comprehensive science overview.

CONCLUSION

FDA is keenly aware that we must develop comprehensive solutions to face an ever-changing scientific and technological landscape. We look forward to working with Congress and other stakeholders to strengthen the scientific base at FDA and ensure that in the next 100 years, FDA retains its reputation and preeminence as the gold standard through the use of cutting edge science and technology. We will continue to provide consumers with the safest products in the world. I look forward to a dialogue and partnership with Congress and other stakeholders. Thank you for the opportunity to testify, and I am happy to answer questions you may have.