

Partnerships and Coordination

FDA's primary challenge in the 21st Century is to minimize product risk to the consumer as the complexity of FDA regulated products grows exponentially, and as trade, regulation, new health threats, and consumption patterns continue to change. To meet this challenge, FDA must call upon the capabilities of its various stakeholder communities – regulators, health partners, industry, and consumers – to generate effective solutions to these public health and safety challenges.

During the past two years, FDA has engaged stakeholders in a series of dialogues to determine how to narrow the gap between current Agency performance and public expectations. FDA has listened closely to stakeholder suggestions and has incorporated feedback into many of the collaborative initiatives outlined in the FY 2003 Performance Plan. The following paragraphs are examples of these initiatives as they apply to FDA's Strategic Goals.

*Using Risk-Based Management Practices**

- *NCI/FDA Taskforce*

One of the most significant collaborations FDA has entered in is with the National Cancer Institute (NCI), to facilitate the development and use of better cancer treatments. The goal of this venture is to reduce the burden of cancer for all Americans through the improved development and delivery of safe, more effective therapies.

The FDA has agreed to work with NCI to develop clinical trial management software that makes it easier for cancer research groups and the FDA to work collaboratively. As a first step, NCI and FDA will work together to build tools that facilitate electronic interaction, focusing in particular on IND applications. The two organizations will work together to coordinate standards and develop tools to streamline regulatory interactions and accelerate the overall regulatory review process for new cancer drugs. These activities will become part of the NCI's cancer Biomedical Informatics Grid, in which the FDA has agreed to participate.

The program will also initiate Cancer Fellowship Training Programs aimed at developing a corps of physicians and scientists, expert in clinical research, the regulatory approval process, and translation of research breakthroughs to clinical practice.

The names of FDA's strategic goals have been changed to reflect revised titles as shown in FDA's Progress and Priorities in FY 2004 (see <http://www.fda.gov/oc/initiatives/reports/priorities2004.html>.)

Partnerships and Coordination

Under the new Fellowship Training Programs initiative, fellows will work in clinical oncology programs at NCI, where cutting-edge therapies are evaluated in patients. They will also work in the technical and regulatory review programs at the FDA. As a result, fellows will bring state-of-the-art knowledge and technology to bear on the design, conduct, and review of clinical trials. These model programs will inform and harmonize all phases of cancer drug discovery, development, and regulatory review for the benefit of cancer patients.

These initiatives result from the ongoing work of the two organizations' Interagency Oncology Task Force. The task force was established to improve the efficiency of all aspects of cancer drug development and regulatory review.

- *The Product Quality Research Institute (PQRI)*

The Product Quality Research Institute (PQRI) initiative will continue to be emphasized as a method of leveraging external scientific expertise to help support sound regulatory policymaking. PQRI is a nonprofit foundation that serves as a vehicle for FDA, industry and universities to collaborate on key issues in pharmaceutical product quality through research and expert group analysis. Participating members such as the American Association of Pharmaceutical Scientists, the Generic Pharmaceutical Industry Association, and the Nonprescription Drug Manufacturers Association work with FDA and other government and private organizations to determine the optimum type of information that should be submitted in drug approval requests.

- *Research*

FDA also continues to benefit from the Agency's two food partnership institutes: the Joint Institute for Food Safety and Nutrition in partnership with the University of Maryland; and the National Center for Food Safety and Technology a partnership with the University of Illinois.

- *Standards Setting*

FDA participated in a joint venture with the National Institutes of Health, Centers for Disease Control and Prevention (CDC), American Red Cross, American Association of Blood Banks, and state agencies to set standards and the development of health education.

FDA scientists play key roles with many national, international and interagency organizations involved in establishing vaccine policy and practice. Examples are the National Vaccine Advisory Committee, the Committee on Infectious Diseases of the American Academy of Pediatrics; the World Health Organization; and the National Institute of Biological Standardization and Control (in the United Kingdom). FDA works on committees related to AIDS, such as the NIH HIV Vaccine Selection Committee, as well as working groups on Influenza Pandemic Preparedness, the Adult Immunization Plan, and the TB vaccine development plan.

Partnerships and Coordination

- *Inspection*

FDA will continue to test the concept of utilizing third parties as independent reviewers, inspectors and testers of FDA-regulated products. One example of successful third party inspections is the Mammography program. Over 90 percent of inspections of mammography facilities are conducted by states under contract to FDA. Another example is the expansion of third party reviews of medical devices. FDA has developed a third party review program and is expanding the number and types of devices that are eligible for third party review.

FDA will also continue to coordinate with the U.S. Customs Service to strengthen the Operational and Administrative System for Import Support. This is a monitoring system that screens unacceptable products from entry into U.S. commerce. As information on products and country of origin is further developed, FDA can improve their systematic profiling capabilities in order to more accurately target potential risk.

Empowering Consumers for Better Health

FDA has worked with partners in health care to confront a very serious problem – patient compliance. About half of the patients who fill the nearly 3 billion prescriptions from their doctors each year don't take the medicine as prescribed, which can lead to serious health consequences. Under its Take Time To Care program, FDA has partnered with the National Association of Chain Drugstores and 80 national organizations to distribute millions of copies of the brochure My Medicines to patients to educate themselves and their families about using medicines wisely. The brochure delivers four key messages: read the label, avoid problems, ask questions, and keep a record.

Patient and Consumer Protection

FDA strives to improve surveillance of medical products and foods by developing synergistic surveillance systems throughout the nation. One priority is to further develop an integrated sentinel surveillance network that includes hundreds of participating hospitals across the U.S. Through these sentinel systems, a select group of reporting facilities with highly trained staff can provide high quality, informative adverse event reports that are representative of device problems in similar facilities. The Agency collaborates with other organizations to improve the monitoring of adverse events associated with medical products by developing standard data specifications and vocabulary terminology used to evaluate products for safety and effectiveness and by collaborating with the Centers for Disease Control and Prevention to add a device and drug module to the National Healthcare Safety Network (NHSN). The NHSN combines surveillance systems for nosocomial infections, dialysis, and healthcare worker safety. FDA is also engaged in activities to better identify problems associated with the use of medical products by strengthening relationships with reporting and quality software vendors and with health systems that use electronic medical records.

Partnerships and Coordination

The National Antimicrobial Resistance Monitoring System (NARMS), initiated by FDA, CDC and the U. S. Department of Agriculture, helps detect whether foodborne pathogens are developing resistance to drug treatment. The system will be enhanced by increasing the number and source of bacterial isolates (human and animal) collected and the number of states covered by the system.

Protecting the Homeland -- Counterterrorism

From May 12-16, 2003 FDA participated in the government-wide TOPOFF 2, a full-scale, fully functional counterterrorism exercise intended to simulate two separate terrorist attacks: detonation of a 'dirty bomb' in Seattle and aerosol release of pneumonic plague in Chicago. FDA activated its Emergency Operations Center, deployed representatives to the field, assessed the safety of potentially affected products, issued guidance and press, and FDA Centers and Offices collaborated with other government agencies to address issues related to availability and safety of medical countermeasures. FDA has made improvements to the Agency's Emergency Operations Center, which will allow coordination with the HHS Secretary's Command Center (SCC), and also strengthen and formalize links to other Federal and State agencies and other entities that may be involved in emergency response to a terrorism event.

In the Federal Government's response to various agents of mass destruction, drugs will be mobilized from the CDC's National Pharmaceutical Stockpile (NPS). However, not all drugs in the NPS are FDA-approved for medical countermeasures. FDA is working with CDC to ensure that that regulated products that are a component of the NPS are safe and effective and will be appropriately labeled to treat the medical consequences of biological, chemical or radiation attacks. In addition, FDA is preparing guidance for industry on the development of products that can be used as medical countermeasures.

FDA is also continuing the contract between the Agency and New Mexico University for the evaluation of microbiological rapid testing methods to include additional foodborne pathogens and import risk assessment study.

Improving FDA's Business Practices

In order to keep FDA staff well informed and up-to-date on the latest technologies being used by our stakeholder partners in academia, health care, and industry, the Center for Devices and Radiological Health (CDRH) developed the "CDRH Medical Device Fellowship Program" to provide an opportunity for health professionals in the scientific community to participate in the FDA medical device regulatory process, share their knowledge and experience with medical devices with FDA, and increase the range and depth of collaborations

FDA has also worked to create the "Science Leadership Education Program", which is a joint educational venture between FDA, Georgetown University and Virginia Polytechnic Institute, designed to encourage continual learning and enhance professional skills.