Lester Crawford, D.V.M., Ph.D.

Deputy Commissioner

Food and Drug Administration

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Good afternoon Mr. Chairman and Members of the Subcommittee. My name is Lester M. Crawford, D.V.M, Ph.D. I am the new Deputy Commissioner for the Food and Drug Administration. Some of my previous positions include Director of the Center for Food and Nutrition Policy at Virginia Tech, Administrator of the U.S. Department of Agriculture Food Safety and Inspection Service, and Director of the Center for Veterinary Medicine at the Food and Drug Administration. I am honored to be with you here today to discuss public health and the President's FY 2003 budget for the Food and Drug Administration.

As we lay the groundwork to address the challenges of this new century, we need to understand where we have been, what has been accomplished, how much has changed and how much still remains to be done. For FDA, the events of September 11, 2001, and subsequent incidents involving anthrax contamination underscored the importance of our role in protecting the public health, and reinforce the fundamental principles required for public health protection. The events of the past year have highlighted to all of us that the products FDA regulates --- human and animal foods, drugs, biologicals and medical devices -- could be used intentionally to cause widespread harm. This situation has raised our awareness of the challenges being faced in the public health sector, including:

- Increasing consumer anxiety about the safety and security of FDA-regulated products;
- Increasing expectations of consumers with changing demographics and consumption habits to easily obtain medical, research and risk-related information;
- Continuing rapid transformation and complexity of the science and technology that generates the products FDA must regulate; and
- Expanding and evolving composition of global trade and production.

Let me assure you, FDA is deeply committed to our 100 year public health mandate ---to provide the U.S. citizen with the world's best public health promotion and protection. Today, more than ever, in order for FDA to continue to fulfill the public's expectations of safe and effective medical products and a safe food supply, FDA needs a strong science foundation.

Science will always play a defining role in our Agency's work. The U.S. continues to lead the world in an era of extraordinary scientific achievements in research, product development, and collaboration --- all of which can yield unprecedented advancements for health and nourishment. We continue to marvel at scientific achievements in fields as diverse as cell and gene therapy; genomics-based drugs; state-of-the-art surgical robotics; medical devices that reduce trauma to patients; and bioengineered plants and animals. These achievements represent an enormous potential for saving lives, improving the quality of life and stimulating economic growth. I caution that along with the potential benefits, there exists the possibility for harm if these new technologies and products are not appropriately monitored by well trained investigators who understand the risks involved as well as the potential rewards.

It is important to mention that for many of these innovative products, the most significant hurdle to their acceptance is not the technology itself, but consumers' distrust of unfamiliar features, and the newness itself. The public expects that food, from farm-to-fork, will be safe and wholesome; that new medical products will be accessible and available in a timely manner; will have scientifically demonstrated real benefits that outweigh their known risks; and that product information and labeling will be accurate, and understandable.

As an Agency, FDA has always been proud of its commitment to maintain high standards which helps us maintain consumer trust and confidence. Maintaining that trust requires constant vigilance. Responding to the new dangers we face is a job that requires time, resources, and careful planning. We will not rest on the accomplishments of the past and we realize the enormity of the job that lies ahead of us.

With that in mind let me discuss some of our recent accomplishments and summarize our budget request which speaks to the immediate and long-term challenges that we face.

Accomplishments - Counter Terrorism

Public health agencies have long assumed that a terrorist attack targeting the U.S. food supply was possible. Given the September 11, 2001, events, and the supplemental funding of $151 million in FY 2002, it is gratifying to know that we have the resources to better equip ourselves to prepare for, and respond to, a terrorism attack. I want to thank you for the additional resources provided to FDA in the FY 2002 Emergency Supplemental Appropriation.

Responding to emergencies is not new to the FDA. Our Office of Emergency Operations responds to all types of emergencies and is routinely working behind the scenes on a day-to-day and hour-by-hour basis on public health crises. FDA staff has well-established experience on a wide range of emergencies, from outbreaks of foodborne illness to product tamperings and now, to deliberate exposure to anthrax.

Counter Terrorism resources recently provided by Congress will allow our Agency to hire 218 staff to pursue the work required to fully support the regulation of the development and licensure of new drugs, vaccines, medical devices, and radiological products for protection and treatment against terrorism-related diseases. Toward that end, we are working to develop new bioterrorism tools by accelerating the availability of medical products necessary to ensure public health preparedness. One such element is the expeditious development and licensing of products to diagnose, treat or prevent outbreaks from exposure to the pathogens that have been identified as bioterrorist agents. This process is extremely complex and early involvement by staff is crucial to the success of the expedited review process. These products must be reviewed and approved prior to the large-scale productions necessary to create and maintain a stockpile. Staff must guide the products throughout the regulatory process, including the manufacturing process, pre-clinical testing, clinical trials, and the licensing and approval process. Experts in these areas are needed to expedite the availability of these products.

The supplemental funding also will support our efforts to enter into various research contracts and Interagency Agreements (IAGs) with other federal agencies, such as the Department of Defense (DOD), the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC), to develop protocols, conduct animal studies, and define reference databases on treatment and alternative therapies for infectious diseases caused by the intentional use of biological agents. In addition we plan to use a portion of the resources to improve internal scientific knowledge and capabilities, conduct research to assess in vitro diagnostic technology used to detect biothreat agents, conduct a market assessment to identify potential device shortages, and educate health professionals and consumers on the use of medical biowarfare products. We have high expectations that our efforts to target Agency resources

simultaneously toward research and risk assessment; an expanded science base; and education, outreach, and consultations to customers will help maximize and leverage our work efforts effectively.

Thus far FDA has developed strategies to strengthen the protection of all regulated products against willful contamination, and to improve the availability of medical products for the prevention or treatment of injuries caused by biological, chemical or nuclear agents. For example, FDA took the initiative to issue a notice which clarified that the antibiotics doxycycline and penicillin G-procaine are effective and approved for use in treating all forms of anthrax infections. This notice included explicit dosing based on FDA's review of scientific literature and data that had been used to support the August 2000 approval of ciprofloxacin for anthrax. The assurance that the three drugs are effective against all forms of anthrax infection eased the public's concerns about a potential shortage of medication for victims of the mailed anthrax powder. Further we stepped up work on measures to encourage the development of new drugs to counter the toxic effects of chemical, biological, radiological and nuclear weapons.

FDA is working closely with industry and other government agencies in an effort to assure an adequate supply of products for immunization against anthrax, smallpox and other substances that might be used by terrorists, and to evaluate adverse experiences reported after administration of anthrax vaccine in order to optimize its safe use.

FDA contributed to the development of methodology for the detection of biological agents for potential use by terrorists, and cooperated with the National Institutes of Health in developing a guidance on the use of potassium iodide to reduce the risk of thyroid cancer in radiation emergencies.

FDA is increasing its emergency response capability by reassessing and strengthening its emergency response plans. For example, we targeted certain FDA activities to better support the protection of regulated products (food and animal feed, radiologic devices, the blood supply, drugs, and vaccines) from contamination and tampering and shifted resources to ensure the availability of medical products necessary for public health preparedness and for use against anthrax and other biological, chemical, or nuclear agents. We revisited how best to communicate with manufacturers to ensure the availability of products needed to treat biological agents. We have expedited our efforts to develop strategies to seize illicit or contaminated products and to provide regulatory and scientific guidance to government agencies responsible for the use of medical products in a public health emergency. We have met with key staff from the medical device and electrical manufacturers associations to identify potential device shortages and to ensure an adequate and safe supply of medical products nationwide. We have had numerous discussions with industry representatives, manufacturers, and innovative technology developers to discuss product design for devices that can detect biological and chemical weapons and agents.

The supplemental funding also will enable FDA to enhance its surveillance of imported and domestic foods thus allowing us to strengthen our deterrence and prevention capability. These resources will allow the Agency to hire 673 investigators, laboratory analysts, compliance officers and support staff. The additional import investigators will increase our ability to monitor food as it enters the U.S. We plan to increase physical examination of imported foods four fold from 12,000 to 48,000 line-entries per year. In addition, we will increase the number of investigators to survey critical product safety points in the domestic food production and

distribution system, and the added laboratory support will increase the number of food samples tested for possible contamination. A portion of the supplemental funding will enhance the capability of the Operational and Administrative System for Import Support, (OASIS), system to better identify those imports warranting closer scrutiny with both initial and follow-up inspections and other surveillance activities and provide better access to data in other Agency systems. We need to continue to improve the OASIS system, which has an impressive track record for detecting the admission of contaminated food.

In conjunction with our Counter terrorism Initiative, we intend to take a comprehensive approach that addresses all food safety hazards -- including dietary supplements microbiological, chemical, and physical - for products under FDA's jurisdiction. We also expect to continue to provide guidance on food security and preparedness to industry and other Federal agencies.

Food Safety

The American food supply continues to be among the safest in the world. Great strides have been made in recent years that have strengthened the Federal food safety system. The Federal food safety program includes new surveillance systems, stronger prevention programs and faster outbreak response. These programs are supported by a new risk-based inspection strategy, better coordinated and focused research and risk assessment activities, and enhanced education. Food safety agencies are working together more closely than ever before. Thanks to the budgetary support provided by Congress, this multi-agency effort has successfully built a strong foundation for a state-of-the-art, science-based food safety system and has promoted partnering among the key Federal agencies, States, academia, industry, and consumers. We now

have in place newer surveillance systems such as Foodnet, Pulsenet, NARMS and pilots for eLexnet. Stronger preventive controls implemented by the Federal agencies, such as good agricultural practices for produce and HACCP systems for seafood, meat and poultry and juice, have already shown results. The numerous interagency and Federal/State partnerships have demonstrably improved the efficiency of our outbreak response systems.

Recent accomplishments in research and risk assessment include the establishment of a microbiology laboratory especially designed for rapid throughput of imported food samples collected for microbiological analysis at FDA's Northeast Regional Laboratory in New York. Using specialized methods and equipment, this laboratory was able to cut analysis time from over 20 hours to less than 8 hours per sample. We intend to expand this concept to other field microbiology laboratories. We also installed new mass spectrometry equipment in our field pesticide laboratories, and trained analysts in the use of a method developed by one of our scientists which can detect over 100 pesticides, previously undetectable by older methods.

The diversity and types of scientific expertise and knowledge are ever-expanding. Consequently, we recognize that we must leverage both academia and industry expertise through cooperative agreements or consortia. The National Center for Food Safety and Technology (NCFST) at the Illinois Institute of Technology is devoted to research and evaluation of better food processing and packaging technology. The Joint Institute for Food Safety and Nutrition at the University of Maryland is devoted to risk assessment, agricultural practices and education, such as international Good Agricultural Practices training programs, and establishment of the Center for Risk Analysis and clearinghouse for risk assessment.

The University of Mississippi and FDA are collaborating in the area of the safety of dietary supplements. The University's Center for National Products Research will help strengthen our science base in this emerging field. At the same time, the New Mexico State University's Physical Science Laboratory and FDA continue their second year of collaboration to conduct method evaluation of rapid testing methods of fresh fruits and vegetables for microbial contamination. In addition, we continue to work with the Interstate Shellfish Sanitary Commission (ISSC) to promote educational and research activities related to shellfish safety in general, *and Vibrio vulnificus* in particular. We are committed to assuring the safety and quality of shellfish and development of shellfish regulation. FDA will work to strengthen these existing collaborations and will develop additional partnerships with other universities that have strong food safety and security research programs.

In the extramural area, we have strengthened our scientific foundation by providing over $24 million dollars through extramural research grants. These grants have gone to over 30 States to support research in the areas of Bovine Spongiform Encephalopathy, produce safety, egg safety, HACCP system validation, food service or retail practices, antimicrobial research and consumer practices. Our association and reliance on these grants have continued to provide our Agency a tremendous resource to improve our scientific expertise.

Food safety education programs have also been greatly enhanced. In fact, the National Academy of Television Arts and Sciences Mid-Atlantic Region awarded an Emmy to FDA and the National Science Teachers Association's for their video "Dr. X and the Quest for Food

Safety." The video, part of the curriculum in "Science and Our Food Supply", competed in the Outstanding Children's Program category.

Bovine Spongiform Encephalopathy (BSE)

We must continue to carry out effective steps to keep the agent of BSE out of the American food supply. The cost of not doing so is far greater than we realize. Let us not forget the European and Japanese experiences and the costs they have incurred. In 2001 "Mad Cow Disease", more properly known as Bovine Spongiform Encephalophy (BSE), cases continued to occur in a number of Western European countries, e.g. Finland recently discovered its first case followed by a similar announcement by Austria. Outside Western Europe, in September 2001, Japan announced its first confirmed case of BSE. First identified in the U.K. in 1986, the brain-wasting disease is fatal to animals and is believed to be transmissible to people who consume infected beef products. World-wide, there are just over 100 people known to suffer this disease, with no cases documented in the U.S. There is a great deal that is not known or understood well about BSE and other Transmissible Spongiform Encephalopathies, TSEs, hence the important emphasis on the science/research aspect of this disease. With this in mind, inspection of feed and import monitoring for BSE continues to be a top priority for our Agency.

The Department of Health and Human Services, (HHS), the U.S. Department of Agriculture, USDA, and other partners have spearheaded comprehensive efforts to safeguard the nation's food supply and strengthen protections already in place. We continue to try to ensure that the feed comply with the bans on the use of sheep and cattle proteins in feeds, and that contaminated material is not imported. We have begun to accelerate oversight of bovine derived

products used in drugs, vaccines, medical devices, food products, dietary supplements, and cosmetics. Resources provided in this year's budget have helped intensify these efforts.

The Department BSE/TSE action plan outlines steps to improve scientific understanding of BSE and other TSEs. The DHHS action plan outlines four areas of responsibility-surveillance, protection, research and oversight. This effort will be coordinated with other government agencies, the private sector, and the international community to contain this epidemic and assist those affected by it. The plan incorporates a comprehensive approach to further strengthen surveillance, increase research resources within the FDA budget level, and expand existing inspection efforts to prevent BSE from entering or taking hold in the U.S. This plan lays out a course of action to expand our understanding of the underlying science of TSE and their potential for transmission to humans.

Protecting our borders against banned import products is a full time enforcement and compliance activity. To meet this challenge, we reinforced the existing import ban, in collaboration with USDA/APHIS, with more specific product information on FDA-regulated products, including food products, dietary supplements and cosmetics that contain bovine materials from BSE-identified countries, so that we an better identify and detain prohibited potentially harmful products. As the result of funding received in FY 2002 from Congress we are also hiring additional investigators to reinforce our responsibilities in this area.

With regard to the U.S. animal feeding industry, we designed a new database and data entry procedures for BSE inspections as well as a new BSE inspection checklist to better target

firms for re-inspections and for collection of better data from both FDA & FDA State-Contract inspectors. By the end of FY 2001 we had inspected over 12,000 firms since 1997 for compliance with our BSE related feed regulations.

In terms of our outreach and education efforts, we conducted two training sessions for Federal and State investigators on BSE to enhance the conduct and quality of domestic inspections, ensure timely and accurate reporting of inspectional findings, and provide updates on the science of BSE and animal protein detection methods. And, we held a public meeting in Kansas city to get public input regarding ways to further improve the feed ban regulation and compliance with the rule.

Regarding some strides made in the research area, we are in the final stages of developing a test which will provide a quick yes/no answer on whether there is a potential animal derived material of concern in a sample of ruminant feed.

Antibiotic Resistance

The prevention of antimicrobial resistance is another longstanding effort by FDA to promote stronger and better public health within our food chain from farm-to-fork. The link between antibiotic resistance in human foodborne bacterial pathogens and the use of antimicrobials in food-producing animals continues to be documented by an increasing amount of scientific evidence. The focus between the use of antimicrobial products in food-producing animals and human food safety is necessary because foods of animal origin are frequently identified as the source of foodborne disease in humans.

Due to concerns that people are acquiring resistant infections from foods because of the use of these drugs in livestock and poultry, we continue to monitor this work very carefully and scrutinize the most up-to-date scientific findings available. For example, FDA recently published a notice of opportunity for a hearing (NOOH) to withdraw approvals of new animal drug applications (NADAs) for use of the fluoroquinolone antimicrobial enrofloxacin in poultry due to new evidence that the product has not been shown to be safe. This is an excellent example of how FDA has addressed the dangers of antibiotic resistance in response to refined and updated scientific research and findings.

We are committed fully to leveraging with other agencies in our battle to tackle public health concerns regarding antimicrobial resistance. For example, the recently completed work on our annual interagency agreements with the U.S. Department of Agriculture's Animal Research Service (USDA/ARS) and Centers for Disease Control and Prevention's National Center for Infectious Diseases (CDC/NCID) continues to provide funding for conduct of animal and human isolate testing. The two arms of the National Antimicrobial Resistance Monitoring System (NARMS), human and animal, are an integral component of this monitoring system. FDA used the data to track the changes in susceptibility among isolates from both sources. We have also expanded NARMS to include monitoring resistance emergence in retail food and animal feed.

We continue to rely on FoodNet, a data gathering tool to expedite our access to large amounts of information that assist our work on antimicrobial resistance. We added a third testing site for NARMS at FDA to test samples from retail meats to determine the prevalence and antimicrobial resistance patterns of foodborne bacteria in commonly consumed meats.

Biotechnology – Medical Products

Biotechnology is fundamentally transforming the practice of medicine. For example in February of this year, scientists from FDA and the National Cancer Institute, (NCI) reported research findings that may lead to a new way to determine the presence of ovarian cancer through a simple finger stick blood screening.

The research behind this advance depends on two disciplines - proteomics and computer intelligence. The diagnostic test relies on software that can detect patterns of key proteins in the blood. Using a sophisticated artificial intelligence computer program, scientists were able to "train" the computer to tell the difference between patterns of small proteins found in the blood of cancer patients versus control samples. Also, we are actively engaged in exploring the use of the new technologies of genomics, proteomics, and information technology to provide better biomarkers to help us track and avert adverse health effects, to rapidly identify micro-organisms that may reach FDA products via intentional or adventitious routes, and to provide better and more rapid diagnostic tests.

In July of last year, FDA approved two new medical tests which use biotechnology techniques to diagnose infection of the hepatitis C virus. The hepatitis C virus chronically infects several million Americans and causes hepatitis C and other liver diseases in many people. The devices, the Amplicor and COBAS Hepatitis C Virus tests, are the first tests approved to use nucleic acid amplification to diagnose hepatitis C infection and monitor therapy. These highly

accurate tests use genetic material from the patient's blood along with enzymes to produce the information needed for a reliable laboratory diagnosis.

Generic Drugs

Generic drugs provide Americans with safe and effective lower-cost alternatives to brand name prescription drugs. The American public can be confident that when a generic drug product is approved by the Agency, it has met the rigorous standards established by FDA with respect to identity, strength, quality, purity, and potency.

Over the years, FDA has approved several thousand generic drugs that have been used successfully by millions of patients. The Congressional Budget Office reported in a study completed in 1998 that the purchase of generic drugs reduced the cost to the public of prescriptions drugs (at retail prices) by roughly $8 to $10 billion dollars. The most recently approved generic drugs are for anxiety, heartburn, depression, and pain management. Given that the cost of prescription drugs has continued to rise over the last decade, many retired Americans, living on fixed incomes, have continued to face affordability issues for medications on which they depend.

Congress has continued its support and increased funding for the generic drug program. We have continued to make improvements in the process itself and to educate the public in the safe and effective use of generic drugs. We have started to recruit and hire additional medical officers and scientists to help reduce the approval time for abbreviated new drug applications (ANDAs) and increase the efficiency of bioequivalence assessments.

Patient Safety/Medical Errors

This past year the media paid a great deal of attention to human clinical trials – both favorable and not so favorable. Thus, an important focus of the Department's activities in 2001, was the strengthening of patient protections through programs and measures designed to enhance the ethical standards of clinical trials and the safety and effectiveness of approved health care products. We acknowledge that the Agency has a very important oversight role to protect patients involved in clinical trials. We must ensure the accuracy, safety and effectiveness of the data gathered from these trials and submitted in product applications. We have made important strides to address some of these limitations. FDA's Office for Good Clinical Practice (OGCP) is responsible for improving the conduct and oversight of clinical research and ensuring the protection of participants in FDA-regulated clinical research. We are committed to ensuring that the data and reported results are credible and accurate and that the rights, safety and well being of trial subjects are protected. We require that the biomedical research that we regulate conform to Good Clinical Practice, (GCP) standards as articulated the FDA regulations. GCP standards address all aspects of clinical research submitted to the Agency in support of product applications and serve to enhance the integrity of such applications. We also published draft guidance for clinical trial sponsors on the operation of data safety monitoring committees. In addition to promoting the protection of human research participants, and supporting the quality and integrity of clinical trials and applications submitted to FDA, OGCP works with our international colleagues in support of global harmonization.

FDA issued an interim rule to provide additional safeguards for children participating in clinical studies. The new rule provides specific criteria, such as an assurance of informed consent by the children and their parents, which have to be maintained by the Institutional Review Boards that oversee the trials. In addition, FDA proposed a regulation covering the methods, facilities and controls used to manufacture human cellular and tissue-based products. Another new measure, which is of particular significance for people with AIDS, is an agreement between FDA and the Department of Veterans Affairs (VA) to improve clinical knowledge of adverse effects of drugs used to treat HIV infections. Recipients of blood products will be better protected thanks to FDA's licensing of the first nucleic acid test systems intended for screening of plasma donors by permitting earlier detection of HIV and HCV infections in donors.

The safety of hospital patients has been improved by two new measures. One of them is FDA's requirement of evidence that all but the lowest-risk reprocessed single-use medical devices – such instruments as laparoscopy scissors and balloon angioplasty catheters – are as safe and effective as the original products. The other new measure is an FDA guidance for the safe use of bed rails, which have been involved in nearly 400 reported accidents in hospitals, nursing homes and home use.

In addition, FDA awarded several contracts that will enable FDA to access commercial data bases on the actual use of marketed prescription drugs in adults and children. The information, which does not reveal the identity of patients, helps FDA determine the public health significance of reports it receives through its Adverse Event Reporting System (AERS).

Last year, FDA announced the creation of a new Drug Safety and Risk Management Subcommittee to the Advisory Committee for Pharmaceutical Science. The new subcommittee, which consists of nationally-recognized experts in areas related to risk perception and management, pharmacology and other related disciplines, will advise FDA on general and product-specific safety issues.

In 2001, FDA and the Department's Office of Women's Health awarded two contracts to study labetalol and atenolol, medications that are used by pregnant women to treat high blood pressure despite scant clinical data on the use of these products in this patient population. The studies are to determine appropriate dosages of greatest benefit and least risk for pregnant women and their babies.

Correct and appropriate guidance on drug usage is critical to our efforts to decrease the number of medical errors. To support these efforts, we have proposed a new prescription drug labeling rule. The proposed new labeling will reduce practitioners' time spent looking for information, decrease the number of preventable medical errors, and improve treatment effectiveness.

An example of FDA's strong commitment to department-wide coordination and information sharing is FDA's active participation in the Patient Safety Task Force established within DHHS. FDA helps integrate medical error data collection efforts; coordinates research and analysis efforts, and develop strategies to implement patient safety programs. We also worked to develop plans to utilize existing vaccine and blood event reporting systems to reduce medical errors and improvement of patient safety.

Safe Blood

Safe and accessible blood is essential to our American health care system. Recent terrorist attacks have shed light on the need to increase our efforts to protect, maintain, and ensure access to a safe blood supply. The Blood Safety Action Plan begun in 1997, is currently being implemented among other agencies of the Department, CDC, NIH, and the Centers for Medicare and Medicaid Services, (CMS). Our goal is to strike a careful balance between increasing the safety of the blood supply while ensuring that life-saving blood and blood products remain available.

FDA's Blood Safety Action Plan specifically addresses issues of how to increase speed, efficiency, and coordination of an FDA response to an emergency affecting the blood safety. To that end, we have continued to work with the Department to enlist national philanthropic and other private sector organizations to take a lead role in promoting blood donations during times of shortage. These and other similar efforts are designed to improve the ability to predict and respond to blood shortages and increase the availability and elasticity of the blood supply. We have also made strides to reduce the number of exemptions to outdated regulations as well as the number of guidance documents lacking enforceability through regulations. Further, we have targeted our efforts to increase industry's compliance with published standards, improved execution of GMPs and quality assurance. A current database of potential threats to the blood supply has been developed and includes appropriate teams to address each threat which has allowed us to make improvements to streamline coordination among the Department's agencies and to address emerging infectious diseases and the prevention of transfusion of transmitted diseases.

Gene Therapy

FDA, with primary lead role being performed by its Center for Biologics, Evaluation and Research, (CBER) is developing a Gene Therapy Patient Tracking System, (GTPTS), to supplement and/or replace current systems for assessing and promoting the safety of gene therapy human subjects/patients. The system is designed to provide oversight with regard to what information should be collected, how best to collect that information, how to store the data, how to analyze the data, and how to report and use the data. The system will consist of many components including databases, procedures, policies, and guidance. Additionally, FDA and the National Institutes of Health (NIH), Office of Biotechnology Activities (OBA), are jointly developing a database application, the Genetic Modification Clinical Research Information System (GeMCRIS), to facilitate the evaluation and analysis of human gene therapy clinical information. This joint database application is a component of the GTPTS.

New Products Approved

As part of its public health mission, FDA last year evaluated and approved many new pharmaceutical products and medical devices that advanced the frontiers of modern medicine. FDA's Center for Drug, Evaluation and Research, (CDER) approved 66 new drugs, 24 of which were new molecular entities (NMEs) which are drugs containing active ingredients never before marketed in the U.S. Ten of the 66 new drugs (7 of the NMEs) received priority review status and were reviewed and approved in the median time of 6 months. CBER reviewed a total of 16 complex biological license applications (BLAs) in the median time of 13.8 months and approved them in the median time of 20.3 months. Two of the BLAs, which were classified as priority products, were reviewed in the median time of 11.5 months and approved in the median approval

of 13.2 months. Most of the products approved by CBER were designed to detect or treat infectious diseases. The Center for Devices and Radiological Health, (CDRH) was no different, they approved 54 premarket approvals (PMAs), of which 24 were for devices with novel technologies or new uses. The median total approval time for the 54 products was 11.3 months.

These major product approvals are expected to benefit a large number of different groups of clients and include breakthrough medicines for patients with cancer, heart disease, diabetes and certain infectious diseases.

Cancer Patients

Again this year, several newly approved products contribute to the prevention, early diagnosis or treatment of cancer – the second deadliest disease in the United States. One of FDA's most important approvals last year was Gleevec (Imatinib Mesylate), a new oral treatment for patients with chronic myeloid leukemia, a rare life-threatening form of cancer. Gleevec was developed for use in a U.S. patient population below 200,000, and was therefore designated by FDA as an "orphan drug." Sponsors of such products receive inducements that include seven-year marketing exclusivity, tax credit for the product-associated clinical research, research design assistance by FDA, and grants of up to $200,000 per year. FDA reviewed the drug in two- and-a-half months and approved it under a special procedure that permits the marketing of important therapies on the basis of their effect on surrogate markers. In addition FDA approved a new biological product, Campath (alemtuzumab), for the treatment of patients with B-cell chronic lymphocytic leukemia.

For women, FDA approved two breast cancer products. One is a combination of two drugs, Xeloda (capecitabine) and Taxotere (docetaxel). The other approval was a new indication for Femara (letrozole) as a first-line treatment for advanced or metastatic breast cancer in postmenopausal women with hormone receptor positive or unknown disease.

FDA also cleared a new device that can facilitate early detection of cancer of the small intestine. The Given Diagnostic Imaging System is a swallowable capsule containing a tiny camera that snaps pictures twice a second as it is moved by natural muscular waves of the digestive track trough the small intestine. The device enables the physician to see areas that are not reachable by endoscope.

Heart Patients

FDA approved five highly advanced medical devices for heart patients. One important device was for children. The Heartstream FR2 AED is the first automatic external defibrillator system for use on infants and young children who experience cardiac arrest. The device is designed to restore normal heart rhythm by using conductive adhesive pads to administer an electric shock through the chest wall.

Two of the devices are new, one-of –a-kind pacemakers. The Biotronik Home Monitoring System, the first implanted pacemaker that includes a tiny transmitter capable of automatic, remote data transmission. The device can be programmed to collect data on the patient's heart condition and at certain intervals automatically send them to the patient's physician. The second pacemaker, is the InSync Biventricular Cardiac Pacing System, is a new type of pacemaker that sends specially timed electrical impulses to the heart's lower chambers to

treat the symptoms of moderate to severe congestive heart failure. The impulses are generated by an implanted pulse generator and delivered to the heart by three wires.

Another first-of-a-kind product is the WCD System, a vest like device that is worn under clothing to monitor and treat abnormal heart rhythms in people at risk of dying from sudden cardiac arrest.

FDA also approved PercuSurge, a device consisting of balloon and aspiration catheters. The device is used to collect and remove blood clots and other debris created by angioplasty and stenting of a blocked bypass vein graft.

One important new drug approved last year for cardiac patients is Natrecor (nesiritide) injection for the treatment of acute congestive heart failure. The medication, which was developed with the use of recombinant DNA technology, is a synthetic version of a human hormone that dilates veins and arteries.

Infectious diseases

Five new products to fight infectious diseases were approved by FDA last year. The first, biologic treatment Xigris, was approved for the most serious forms of life-threatening sepsis, which claims 225,000 lives in the U.S. each year. The new treatment is a genetically engineered version of a naturally occurring human protein, Activated Protein C, which interferes with some of the body's harmful responses to severe infection. PEG-Intron (peginteferon alfa 2b) injection was approved for the treatment of patients with chronic hepatitis C, an infectious disease responsible for as many as 10,000 deaths per year in the U.S. A new combination vaccine was approved that protects adults against diseases caused by the hepatitis A virus (HAV) and the

hepatitis B virus (HBV). The vaccine, called Twinrix, combines two already approved vaccines, Havrix (Hepatitis A Vaccine, Inactivated) and Engerix-B [Hepatitis B Vaccine (Recombinant)] so that people at high risk for exposure to both viruses can be immunized against both at the same time. Twinrix is recommended for travelers who are at high risk for HBV, and who are visiting countries where there is a substantial incidence of both HAV and HBV disease. A new anti-fungal medication Cancidas (caspofungin acetate) intravenous infusion was approved for patients not responsive to or unable to tolerate standard therapies for the invasive form of aspergillosis. This is the first approval in a new class of drugs called echinocandins, which are believed to work by disrupting the formation of fungal cell walls. Another novel product approved last year is Viread (tenofovir disoproxil fumarate), a new anti-viral drug for the treatment of HIV-1 infection in combination with other antiretroviral medicines. Viread is the first nucleotide analog approved for HIV-1 treatment.

Diabetes

The number of people diagnosed annually with diabetes has increased more than sixfold from 1.6 million in 1958 to 10 million in 1997, according to the CDC. Today, some 16 million people have the disease--making it a leading cause of death in the United States. About 2,200 people are diagnosed with diabetes every day, and that close to 800,000 will be diagnosed with the disease this year, according to the American Diabetes Association (ADA). Many people don't know they have diabetes until they develop a serious complication such as blindness, kidney disease, nerve disease requiring amputation, heart disease, or stroke.

The FDA's Office of Women's Health, the ADA, the National Association of Chain Drug Stores, and 80 other organizations nationwide are planning a campaign that will focus on the

early identification and control of diabetes. The campaign will highlight the fact that about 8.1 million women in the United States have diabetes. Diabetes is a unique condition for women. When compared with men, women have a 50 percent greater risk of diabetic coma, a condition brought on by poorly controlled diabetes and lack of insulin. Women with diabetes have heart disease rates similar to men, but more women with diabetes die from a first heart attack than do men with diabetes.

Diabetes-related brochures, wallet-sized calendars, and recipe cards for nutritious meals will be distributed at grocery stores and pharmacies in several cities: Atlanta, Baltimore, Chicago, Dallas, Detroit, Indianapolis, Los Angeles, Miami, New Orleans, Philadelphia and Phoenix.

FDA also is funding ongoing diabetes outreach through the Indian Health Service (IHS). "Portion control is an important message to get out to women in order to impact the escalating diabetes and obesity rates among American Indians and Alaska Natives," says Sandra Dodge, an IHS women's health coordinator. IHS is developing culturally-appropriate handouts to help American Indian women with diabetes manage portion sizes for meals. The project will target certain urban areas, as well as American Indian reservations. The overall prevalence of Type 2 diabetes is just over 12 percent in Native Americans versus 5 percent of the general population. In some tribes, half of the population has diabetes.

In addition, new technology for monitoring glucose levels in people with diabetes is moving ahead rapidly, and FDA has been working with a number of companies to help bring it to market. A novel device approved last year is the GlucoWatch, a wristwatch-like device that provides adult diabetics with more information for managing their disease. This device is one of

the first steps in developing new products that may one day completely eliminate the need for daily finger-prick tests. The Gluco-Watch extracts the wearer's fluid every 20 minutes by sending out tiny electric currents, and sounds an alarm if the glucose level reaches dangerous levels.

FDA also approved a new device to aid diabetics with foot ulcers. The Dermagraft is a skin substitute made from human cells, which helps replace and rebuild damaged tissue in diabetic foot ulcers that have been present for more than six weeks and extend deep into the skin. The Dermagraft can remain on a shelf for up to six months, a major advantage over similar types.

Global Trade and Global Production - International Standards and Harmonization

Working closely with international organizations to harmonize technical requirements and standards for products regulated by our Agency remains an important priority. This work recognizes the international nature of our regulated industries. Equally important is the recognition of our collective need to share expertise concerning new products throughout an entire life cycle. We cannot allow international borders to stem the flow of information as foodborne pathogens, adverse events, and terrorist activities have no boundaries.

For example, our Agency, along with USDA, and Mexico's Secretary of Agriculture signed a cooperative agreement in September 2001 to enhance existing food safety measures through expanding programs, sharing information and coordinating specific activities. The agreement will allow us to share information on the sources of fresh produce and to investigate the causes of any contamination of these imported food products. These efforts are expected to ensure that borders remain open and that safe products continue to flow freely between the countries. The arrangement, in conjunction with other cooperative measures, will help reduce

the incidence of foodborne illnesses on both sides of the border. The agencies will also collaborate on other specific projects to achieve common understanding on issues of mutual concern.

We have also continued a project with Mexico on a monitoring system for antimicrobial resistance in *Salmonella camphylobacter and E. coli.* The increase in international trade in food has increased the risk from cross-border transmission of foodborne pathogens and underscores the need to use international surveillance systems to monitor the prevalence of resistance to antimicrobials of importance to human medical therapy. A cooperative agreement was signed in the Fall of 2001 with human hospitals and veterinary medical schools in four agricultural states in Mexico to develop a monitoring system compatible with NARMS.

FDA has established itself as a preeminent leader in international food safety harmonization efforts as exemplified via our association and work with Codex Alimentarious. Codex is sponsored jointly by the United Nations World Health Organization (WHO), and the United Nations Food and Agricultural Organization (FAO). We helped plan and participated in the Global Forum of Food Safety Regulators, a conference designed to enhance communication among food safety regulators worldwide that was held in Morocco in January. The intent is to increase the level of food safety as well as food security, which will result in safer products being exported to the U.S.

Other Federal agencies look to FDA for guidance and input that promote public health policies consistent with our mission. In particular, we provided advice and analysis to the Office of the U.S. Trade Representative, the Department of Commerce, and the USDA Foreign Agriculture Service on a broad range of trade negotiations and issues, pursuant to the Food and

Drug Administration Modernization Act (FDAMA) to further U.S. trade objectives in ways that would not compromise FDA's health and consumer protection mandate. We continued efforts to eliminate potential barriers in the global marketing of products that are approved for use in the U.S. These efforts facilitate the Agency's efforts to promote mutual recognition and international harmonization aimed at approval systems as well as product surveillance. Our leadership on the Global Harmonization Task Force provides oversight and technical expertise in the development of international guidance of the premarket review and post market patient safety of medical products. We have also worked with the European Union to train qualified auditors to conduct FDA quality inspections for products purchased by the U.S. consumer.

Challenges

Each year we find ourselves confronted with more challenges to the way we do our business. As we have seen, some of these challenges present a higher degree of risk and harm to the general public if not addressed. Issues are increasingly complex and the breadth of FDA's responsibility ever expanding. Whereas, many of our constituents primarily focus on the product marketing application review process, it has become clear FDA attention must oversee and regulate the full life cycle of all the products that we regulate. We continue to see the changes and challenges that are outgrowths of the successful mapping of the human genome. We continue to explore a new and unchartered scientific frontier that promises to deliver the hope that we will be in a position to transform the diagnosis, treatment, and even prevention of diseases that afflict groups within our society. The pipeline of new genetic information remains immense. Genome research is only in its infancy and of the hundreds of genetic tests in development and available in the U.S., still only a few have been submitted to and approved by our Agency. We continue to refine how we coordinate drug and genetic diagnostic development

together. Products will need to evolve from the research laboratory to the well-characterized therapeutics with established safety and effectiveness. To make these critical decisions, we need to ensure that our scientists remain on the leading edge in their specific scientific disciplines.

The FY 2003 Budget lays out proposed funding levels for the President's initiatives, identifies resources that can be redirected to higher priority activities, and highlights some potential opportunities for management and financial reform and streamlining. The President is proposing a total budget for the FDA of $1.7 billion that includes $1.4 billion in budget authority and $286.7 million in user fees. Counter terrorism funding includes $159.048 million of the total funding and annualizes the generous supplemental funds received from Congress in FY 2002. The request also includes increases of $28.552 million for pay related inflationary costs; $5.0 million for patient safety/medical errors; $4.582 million for generic drug review; and $5.2 million for continued development of the Department's Unified Financial Management System.

Our Most Valuable Resource

Our Agency work is a blending of science and law directed at protecting consumers by focusing on patient, food and consumer safety. The public trusts us to ensure that food on the family table will be safe and wholesome; new medical products, drugs, biological products, and medical devices are available in a timely manner with demonstrated benefits that outweigh risks; and, product information is useful and understandable. FDA's ability to maintain the public's trust is dependent on having a high performing science-based professionals carry out its mission. FDA is always challenged to make sure we have the personnel in the scientific disciplines needed. The aftermath of the September 11 tragedy is a perfect example of changing needs and increased human resource levels needed in specific scientific disciplines. Approximately 45

percent of FDA's workforce are dedicated to "front line" efforts, such as import monitoring and inspections, coordination with states' efforts, and cooperative education programs with industry, states and consumers.

The $28.5 million requested will fund the mandatory pay increase. This increase for base resources focuses on pay adjustments because personnel are so essential to accomplishing the Agency's mission. These resources will enable FDA to maintain current levels of performance, and to continue to improve the drug review process. Payroll increases are needed to cover about half of the staff involved in the drug application review process not supported by PDUFA user fees; to improve the ability to assure the safety of regulated products; to inspect and investigate domestic and foreign manufacturers; and, to participate in harmonization efforts with countries to establish global standards for foods, pharmaceuticals and devices. We need now, more than ever, your continued support to assure FDA is ready to respond to the challenges of counter terrorism as well as a new medical age.

Counter Terrorism

The Counter Terrorism request of $159 million reflects the President's commitment to promote and protect the public health by ensuring that safe and effective products reach the market in a timely way, and to monitor products for continued safety after they are in use. Funding will continue the activities begun in FY 2002 for the safety of imported foods through expanded inspection and surveillance of imports; and activities related to medical products, including measures to help patients exposed to terrorist agents such as anthrax, smallpox and plague. In some cases, we expect to reframe existing Agency strategies to anticipate possible terrorist threats that may translate into risk situations that FDA has not yet addressed.

The tragedy of the attacks of September 11 and subsequent national events resulted in an accelerated and intensified need for attention to activities related to Counter Terrorism. A combination of public health and law enforcement responsibilities requires FDA involvement in preparedness for and response to a terrorist act. FDA's responsibilities encompass both the civilian and military sectors of the population. FDA activities include surveillance, investigation and laboratory support for detection and management of product contamination; provision of regulatory guidance to manufacturers and other government agencies to assure the availability of medical products, including blood; and establishment of a communications network that optimizes emergency preparedness within FDA and across the federal government.

Our Counter Terrorism initiative prescribes a strategic blueprint for protecting the U.S. citizens in the event of future terrorist attacks. The Initiative will be supported by a Counter Terrorist Action Plan that will more specifically outline the blueprint. We have structured the Agency's Counter Terrorism Initiative with the following four goals:

- Protection of regulated products
- Medical counter measures
- Preparedness and response
- Radiation safety

Today our world is faced with new and more complicated challenges. In our endeavors to address Counter Terrorism issues, our time and resources will be thoroughly engaged on threat and vulnerability assessment to guide and target our risk-based strategies; integrated intelligence and how to identify, gather, assess, and react to the data; effective collaboration and the ability of

multiple organizations to share information in a timely and accessible manner; and appropriate intervention to reduce threats as well as a validation and performance assessment tool to determine output measures and success rates.

Counter Terrorism – Food Safety

In the aftermath of September 11, we realize how our role to ensure a safe U.S. food supply has become exponentially more important and complex. It is important to state that we have no credible information identifying food as a target of terrorist activity. But we know that it is possible, and that food could be a vector making people sick shaking public confidence.

Thus our efforts to address emerging public health threats must now include not only unintentional agents but intentional as well. We have heightened our awareness to the repercussions and impact of the latter and our workforce and resources are being reframed accordingly. We will be challenged to make sure that our role is appropriate for the anticipated and unforeseen possibilities.

FDA's Counter Terrorism strategy for foods is three-fold. First we must try to anticipate threats by collecting better information. Second, we must be prepared to respond should an outbreak occur. Most importantly, we must expand our inspectional presence particularly at the border so we can deter terrorist activity. Prevention will be our best long-term solution.

FDA's food security responsibilities extend throughout the food chain, and employ research and risk assessment and prevention strategies through a nation-wide inspection and surveillance partnership program with the States. To protect the nation's food supply, we address aspects of food production, manufacture, and transport in the country of origin, at the

U.S. port of entry, and in domestic commerce. We must continue to enhance the frequency and quality of imported food inspections, and modernize our import data system to enable better detection and detention of contaminated food.

We know that further food safety successes require us to work hand-in-hand with our partners to ensure the quality and safety of our nation's food supply. The main results of this cooperation -- more effective prevention programs, new surveillance systems, and faster foodborne illness outbreak response capabilities -- have already enabled FDA to protect the safety of our food supply against natural and accidental threats. Every significant element of our Counter Terrorism Initiative will require successful collaborative efforts between our staff and other organizations, including other health, scientific, and law enforcement agencies operating at international, Federal, and State levels.

Although investigators will continue their role in protecting the public health, the Agency's relatively small number of personnel will limit the effectiveness of efforts that rely only on people. Key to the Agency's Counter Terrorism Initiative will be FDA's ability to gather and assimilate pertinent information about products, hazards, establishments, suspect individuals, distribution and consumption patterns and then bring the right combination of information and resources to crucial decision points.

Counter Terrorism - Medical Product Safety

Those of us in the field of science know too well that this discipline does not fit neatly into a square box with four well-defined walls. If one factors into the science equation suspect actors with terrorism on the agenda, then the ability to predict outcomes becomes more difficult. Preparedness for and response to an attack involving biological agents are complicated by the

large number of potential agents (some of which are rarely encountered naturally), their sometimes long incubation periods and consequent delayed onset of disease, and their potential for secondary transmission. In addition to naturally occurring pathogens, agents used by bioterrorists may be genetically engineered to resist current therapies and evade vaccine-induced immunity. Pathogens that have been identified as potential biological warfare agents include those that cause smallpox, anthrax, plague, botulism, tularemia, and hemorrhagic fevers.

We must ensure sufficient availability of safe and effective medical products and a safe blood supply to support the development, maintenance; and deployment of stockpiles of medical countermeasures, as well as support post-event follow-up and data collection initiatives for these products, some of which may be investigational. The challenge will be to identify all of the respective threats and vulnerabilities assessments and then use intelligence and collaboration to fully understand the most dangerous intersections of the two and how best to respond. All of this entails a great deal of planning, dedication, and execution on our part to reframe our fundamental principles used to protect the public health mandate. As I have mentioned before, we are committed to our public health mandate and will continue to play a pivotal role in counter terrorism preparedness and response via a combination of regulatory and law enforcement responsibilities.

Counter Terrorism - Physical Security

Congress also provided us critical resources to enhance and tighten our Agency's physical security by expanding existing service contracts for facility guards and augmenting equipment to safeguard building access, laboratory equipment, and protect proprietary research and information. FDA personnel and facility locations are dispersed throughout the U.S. We

must ensure that our employees have access to secure and safe locations and that they are able to pursue their work responsibilities under an ideal work environment without fear for their well being.

Patient Safety/Medical Errors

Our FY 2003 increase request of $5 million builds on the growing momentum from last year's work to further enhance the identification of risks associated with the use of medical products and to reduce the occurrence of adverse events. This initiative, which also provides for the enhancement of the adverse events data system and linkages with other health care systems, is a growing initiative that requires ongoing support to tap into the volume of information within a large and extremely diverse public health community.

As an Agency, we have to achieve better ways to communicate with the growing universe of people impacted by FDA regulated products - education, outreach, information technology, or what is most likely a heightened combination of all elements. Many patient deaths and injuries are associated with the use of FDA-regulated products. We believe that as many as half of these could be avoided by fully implementing its strategies to prevent Medical Errors.

In light of the rapid scientific advancements and the increasing volumes of sheer medical information, our ability to effectively oversee these products must be maintained. The rapid transformation of the science and technology that generate the products we must regulate has a direct correlation on the growing workload in our Agency—both on the premarket as well as postmarket oversight. Systems have to be arranged to capture, track, monitor, and process the growing pockets of information. All of these issues must be weighed against the increasing

expectations of consumers with changing demographics and consumption habits, and then these issues must be factored into the expanding and evolving composition of global trade and production which will further necessitate greater coordination and sharing of information.

FDA sees firsthand the technological advances in healthcare as new medical devices are reviewed and cleared for marketing. FDA must have quality information about post market problems with devices, especially how they are used in the clinical setting. FDA has planned designed, and is implementing a pilot program that will lead to a national surveillance network, called the Medical Product Surveillance Network (MedSun), composed of well-trained clinical facilities, to provide high quality data on medical devices in clinical use. There are currently 50 hospitals enrolled in the program. Recruitment will continue over the next two years, with a target final complement of 225 facilities enrolled in the pilot program.

Generic Drugs

The costs and availability of affordable pharmaceuticals will always be a concern for the consumer. The safety and effectiveness of the drugs, as well as costs issues, will always be a concern for our Agency. We recognize that bridging of these concerns for all stakeholders is a complicated and delicate process and consumer expectations are difficult to easily measure.

Advancements in the Generic Drug Program are a product of Congressional support, additional resources, and high quality FDA staff. The requested increase of $4.6 million will provide for improvements to the generic drug review program and allow FDA to review and act upon 75% of fileable original generic drug applications within 6 months.

President's Management Agendas

The President's Management Agenda provides an outline for our Agency to pursue the five presidential initiatives. The challenges for us will be to tailor these initiatives to FDA's unique public health mandate with the goal to further enhance our citizen focus and bring us closer to the consumer on a day-by-day basis. Given that our Agency is overwhelmingly labor intensive, the ability to successfully connect 100 percent of the time with our external customers will be daunting.

FDA's first step to helping the Department improve program performance and service delivery is to manage more strategically human capital and to ensure that resources are directed toward national priorities. To this end, FDA is realigning functions to achieve efficiencies. For example, during FY 2003, 25 administrative/management positions will be eliminated resulting in $2.6 million in efficiencies. Additionally, the FY 2003 budget shows the consolidation of staff associated with public affairs and legislative affairs functions at the Department level, for $7.3 million in efficiencies. FDA has also begun a study of the current organizational structure to identify opportunities to consolidate and streamline other administrative functions.

As a part of the FDA Revitalization Act, we have embarked on a multi-year plan to relocate the major portion of its headquarters personnel to White Oak, Maryland. This project, coupled with on-going efforts to reduce supervisory ratios, consolidate administrative functions and delayer headquarters staff, will afford FDA maximum flexibility to move resources closer to the day-to-day "front line" programmatic work of the Agency. In the meantime, we recognize that there will be temporary work interruptions during transition periods.

The Agency is integrating information systems and databases, where possible, with related DHHS systems, and external stakeholders, such as health providers, academia, other government agencies, regulated industry, and consumers. This is an ambitious but necessary schedule that requires a great deal of coordination and planning.

Maintaining a high standard of excellence and then trying to improve upon that during a time of change requires patience. We are aiming high in terms of expediting FDA's product review processes by ensuring sponsors know what is required, eliminating unnecessary requirements, and soliciting proposals and nominations for consensus standards from manufacturers to use to satisfy some review requirements.

PDUFA III

FDA has collected significantly less in PDUFA fees than estimated due to a reduced number of new drug applications and an increased proportion of submissions whose fees were waived. The Agency has been able to meet nearly all of the PDUFA performance goals so far. The Agency's efforts to meet the PDUFA II goals may have had an unintended impact on approval times of standard new drug and biologics applications. Preliminary data indicates that approval times have begun to increase because more applications require multiple review cycles to reach approval. The Agency is watching this situation closely. However, for PDUFA to continue its strong record of success it must be on a sound financial footing.

FDA is also concerned about the safety of new drugs and biologics following approval and marketing. In recent years fully 50% of all new drugs world-wide have been launched in the

U.S., and American patients have had access to 78% of the world's new drugs within the first year of their introduction. More rigorous safety monitoring of newly approved drugs in the first few years after a product is on the market could help to detect unanticipated problems earlier.

To protect American patients, FDA needs to strengthen its ability to carry out post-market drug surveillance and other non-user fee functions it carries out in conjunction with PDUFA. The Agency will continue to work with industry, the Congress, and all other stakeholders on a reauthorization of the PDUFA program that will continue to bring benefits to American consumers by bringing important new therapies to market quickly without compromising scientific review standards.

Closing

I thank you for the opportunity to share with you the breadth of FDA's responsibilities. FDA touches the life of every citizen through the medicines we take or feed for our animals, the blood products we may need one day, through the food we eat, the cosmetics we use, and, the medical devices in use today. Americans expect FDA to remain vigilant, to promote their health and well being, and to protect them from unacceptable hazards to our population at large, and to assure that they are adequately informed about the myriad hazards about which they will have to decide as individuals whether or not they are willing to accept. Significant investments must be made to keep this Agency strong and at the forefront of the science upon which its regulatory mandate is based. The returns on that investment will be an Agency that is equal to the challenges it faces and able to keep the confidence and trust of the American public. A strong FDA is clearly good for the consumer and industry alike, which in turn is good for the economy and health of our great nation. Thank you once again for the opportunity to express our views

and for your interest in the Food and Drug Administration and its mission of protecting the public health. I appreciate your interest and continued support of the Agency and its public health mission. I expect this year to be another exciting one for the Agency and I look forward to working with you as we face the challenges ahead. I welcome any questions you may have.