



U.S. Senate Committee on Appropriations

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U.S. Senate Appropriations Agriculture, Rural Development, FDA, and Related Agencies Subcommittee Testimony of FDA Commissioner Andrew Von Eschenbach

WASHINGTON, D.C. . The U.S. Senate Appropriations Agriculture Subcommittee on Tuesday held a hearing to examine the Fiscal 2008 budgets for the U.S. Department of Agriculture and the Food and Drug Administration. As part of that hearing, the subcommittee heard testimony from Dr. Andrew Von Eschenbach, Commissioner of the Food and Drug Administration. Dr. Von Eschenbach's prepared testimony is below.

Chairman Kohl and members of the Subcommittee, this year as a confirmed Commissioner I am honored to present for your consideration and approval the President's fiscal year 2008 budget request for FDA. I am joined by Mr. John Dyer, my recently appointed Deputy Commissioner and Chief Operating Officer and Mr. Richard Turman, Deputy Assistant Secretary for Budget at the Department of Health and Human Services. I also have members of FDA's senior leadership with me, who at your discretion can respond to any specific questions you may have.

We live in an era of rapid science, technology, and individualized medicine that is changing the products FDA regulates and the environment for FDA regulation. Congress and the Administration recognize the challenges we face and have responded with the resources in FY 2007 that will allow FDA to begin addressing these challenges.

As you consider our FY 2008 request, please do so mindful of the extraordinary gratitude of the FDA for your support in FY 2007. The budgets for these two fiscal years represent important steps in an ongoing effort to create a modern FDA capable of responding to the challenges and opportunities to protect and promote public health in the 21st century. We will be good stewards of the funds you provide and we will search for efficient and effective solutions to the problems we are working to solve.

The resources requested in the President's budget for fiscal year 2008 will allow FDA to respond to emerging challenges, advance the gold standard for regulating food and drugs, and strengthen America's confidence in the work of our important agency.

Our achievements during the past year reflect our service to the American public and our dedication to their health and safety. These achievements also justify the trust you placed in us with your support in FY 2007. Using funds that you appropriated, FDA:

" approved a new test to diagnose avian influenza virus in humans

- " issued guidelines to expedite seasonal and pandemic flu vaccine development
- " approved new vaccines for shingles and to prevent HPV infections
- " approved new treatments for cancer, HIV, diabetes, Parkinson's, schizophrenia, and macular degeneration
- " issued more than 510 generic drug approvals or tentative approvals
- " approved the first totally implanted artificial heart
- " embraced many of the Institute of Medicine findings on The Future of Drug

Safety

- " launched a program to achieve the optimum safety system for drugs and other medical products
- " developed proposals to renew prescription drug and medical device user fee programs
- " conducted drug reviews and issued approvals under the President's Emergency Plan for Aids Relief
- " conducted enforcement actions to protect consumers against unapproved drugs and devices, to safeguard the blood supply, and to protect consumers from dietary supplements containing ephedrine alkaloids
- " worked with Federal, state, and local partners to respond to Salmonella, E. coli O157:H7, and other foodborne threats
- " issued a final rule on health claims for barley products and issued guidance on whole grain content in food
- " protected consumers with food allergies by publishing guidance documents for industry on food allergen labeling and soy derived products
- " conducted a CARVER + vulnerability assessment in eight food products to distinguish between real and perceived food vulnerabilities.

FDA's 2008 President's Budget Request

For FY 2008, the President's budget request builds on success of FY 2007 to maintain the trajectory, by proposing a 5.3 percent increase above the FY 2007 President's budget. This will provide FDA with \$2.085 billion, which consists of \$1.641 billion in discretionary budget authority and \$428 million in current law user fees. Our budget also includes \$42.7 million for three proposed user fees related to reviewing generic drugs, reinspecting facilities, and issuing export certificates for food and animal feed.

Strengthening Food Safety

FDA is committed to ensuring that America's food supply continues to be among the safest in the world, but we face challenges. For example, consumption of produce, particularly ready-to-eat products, has increased dramatically during the past decade. Americans often consume these products in their raw state, harvested from the vine, stem, or soil without processing to reduce or eliminate pathogens that may be present. Consequently, the manner in which these products are grown, harvested, packed, processed, and distributed is crucial to ensuring that microbial contamination is minimized, thereby reducing the risk of illness to consumers. Even if a small amount of what is harvested is contaminated, it can result in severe illness. FDA is taking a %arm.

to. fork+systematic risk management approach to food safety to reduce the risk of food illness at all points in the food chain.

FDA's ability to prevent and respond to outbreaks of foodborne illness needs to be strengthened. For FY 2008, we propose a \$10.7 million increase for a food safety initiative focused on fresh produce. FDA will develop methods to prevent food outbreaks from occurring by rapidly detecting contamination that leads to illness, more quickly tracking contamination to its source, and more effectively conducting root cause analysis of contamination. We will also provide training to our state and local partners and develop a geographic information mapping system for faster emergency response. Finally, we will develop a decision-making system to detect high-risk imports before they enter U.S. commerce, so they can be evaluated by FDA.

Access to Safe and Effective Medical Products

On January 30, 2007, FDA released a report, *The Future of Drug Safety . Promoting and Protecting the Health of the Public*, that presents our comprehensive commitment to the safety of drugs and other medical products throughout their lifecycle. The report addresses issues referred to FDA by the 2006 Institute of Medicine report. The report details initiatives FDA will take to achieve the best possible safety systems for medical products, and ensures that FDA processes and scientific methods keep pace with, and harness the benefits of, the rapid evolution of science, technology, and health care.

At FDA, we use a systems approach to ensure drug quality and maintain the right balance between the benefits and risks of the drugs we approve. An \$11.2 million increase for modernizing drug safety allows FDA to advance a lifecycle approach to regulating drugs and managing drug risks. Using the FY 2008 increase and base resources in the drug program, FDA will revolutionize our ability to identify safety issues and rapidly and effectively communicate safety concerns to health professionals, patients, and the public. These efforts will improve drug safety both before FDA grants approval and after drugs reach the market. We will also strengthen our organizational culture to further foster an environment dedicated to the safety of drugs and biologics.

As the complexity and utility of medical devices increases by virtue of advances in electronics and engineering, FDA maintains the same commitment to the safety of medical devices. Our budget contains a \$7.2 million increase to strengthen medical device safety and improve FDA's ability to identify, analyze, and act on postmarket safety information and use this information to improve the quality of new devices coming to market.

Generic drugs are an important part of our health care system. The Congressional Budget Office estimates that generic drug use results in savings of \$10 billion per year. During the next few years, \$60 to \$70 billion in brand name drugs will lose their patent protection, and FDA must be poised to respond to the growing number of generic drug applications. To help ensure that consumers enjoy a wide selection of lower-cost generic drugs, FDA requests an additional \$5.6 million in budget authority and \$15.7

million in new user fees to accelerate the review and approval of generic drugs. With the \$5.6 million budget authority increase, FDA expects to approve an additional 50 applications during FY 2008. The new user fee program ensures that FDA can measurably improve generic drug review performance over the next 4 to 8 years. With this new program in place, by 2014 FDA expects to approve 90 percent of generic drug applications within 180 days. These investments will return many billions of dollars in savings to consumers and government-sponsored health plans.

Our budget includes long-standing user fee programs. These programs provide supplemental resources that not only allow FDA to provide services in response to manufacturers' product applications but also ensure that Americans have access to safe and effective medical products. Two of these programs, the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee Modernization Act (MDUFMA) expire on September 30, 2007. We have engaged with stakeholders to develop proposals to extend these programs for an additional five years. In the case of PDUFA, FDA published a draft proposal for PDUFA IV in the Federal Register and conducted a public meeting with stakeholders on February 16, 2007. In the case of MDUFMA, FDA is nearing the end of discussions on the reauthorization of MDUFMA. FDA will notify Congress of our results when we complete this process.

Ensure a Strong FDA

To successfully perform its broad mission, FDA must hire and retain a world-class workforce that can respond to complex and escalating public health challenges. Our workforce is FDA's most important asset, and securing the resources to support our workforce is a top priority in our FY 2008 budget. We have nearly 10,000 employees, consisting of medical officers, consumer safety officers, food and drug safety experts, medical product reviewers, and other scientists and professionals with specialized education, training, and experience to address complex public health challenges. Eighty percent of the FDA budget funds payroll or costs related to personnel, such as rent, utilities, and security. These are operational costs, and the amount we pay rises each year. For FY 2008, we propose a \$64.7 million initiative to ensure that increased costs for the pay raise, infrastructure costs, and the cost of relocating to our new White Oak, Maryland campus do not erode core FDA programs.

Closing

FDA's request of \$2.085 billion is essential to the success of our mission . established by Congress . to protect and promote the health and safety of the American public. These resources are an essential step in building a 21st century FDA that responds to the new opportunities and new challenges of science and technology. Our budget allows FDA to strengthen the tools we use to ensure the safety of foods, evaluate new products, and better predict . earlier and more accurately . the safety and efficacy of drugs, biologics and medical devices. With these resources, we will work to ensure that Americans enjoy the benefits of personalized medicine, a safe and wholesome food supply, and the promise of a better, healthier future. Our goal is to enable all Americans

to go to bed each night confident that the food they ate is safe, the medical devices they used are reliable, and the drugs that they gave to their children and grandchildren are safe and effective.

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