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# Congress of the United States

## House of Representatives

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### Statement of Chairman Henry A. Waxman Chairman, Committee on Oversight and Government Reform FDA's Critical Mission and Challenges for the Future May 1, 2007

Before I make any specific comments on today's hearing and FDA, I want to say a few words about an important initiative this Committee is undertaking.

One of the most important debates in modern politics is the role of government.

Some believe in having the smallest government possible and live by the old joke that the scariest words in the English language are "I'm from the government and I'm here to help."

I and others have a fundamentally different view. I think government can be a tremendous instrument of good and I've seen it help Americans in countless ways. The Social Security system transformed our country. Landmark health and environmental laws have improved the quality of life for millions of Americans. Regulatory and consumer agencies have made financial stability and basic safety precautions a part of everyday life.

In this regard, FDA has had a remarkable record of accomplishment. It has been, and by and large remains, an agency with highly qualified and dedicated staff doing a big job under difficult circumstances. But it is our job to ensure that it has the resources to continue to perform with competence.

We have reason to be concerned — to examine the strengths and weaknesses of this agency in the light of ever increasing demands — and to ensure that it remains strong.

Because we know from other areas, that without proper support — or with deliberate weakening of agency leadership or unwarranted outside interference — things can change.

We need only look at the example of FEMA. Once it was the gold standard for government. But something has gone very wrong in recent years.

We saw government at its worst during the Hurricane Katrina disaster. FEMA completely failed America's citizens. We saw it break down again at Walter Reed Hospital, in the deplorable conditions provided to our bravest Americans. And we've seen profound

problems in the Iraq War, from flawed basic intelligence to a failure to supply our troops with the right armor and equipment.

In all those cases we know incompetent government can have deadly consequences.

One of the most important responsibilities for our Committee is to understand what's gone wrong. How did some of the best government agencies become so weak? And we need to work together in a bipartisan way to get government back on track.

I know my friend, Tom Davis, shares my view on this. We don't want government programs to be ineffective; we want them to be models of excellence. So, over the next year, our Committee is going to hold a series of hearings on making government effective again, by looking at the performance of a number of agencies. By the end of those hearings, we will have a better idea of the impact of budget cuts and cronyism on the current problems. And I expect we will have legislative suggestions that would ensure taxpayers get the government they deserve.

Today, we start this effort. We are in the fortunate position of looking first at an agency that has not yet been decimated by the pressures placed upon it or the lack of resources made available to it. But a series of public health crises, from the belated withdrawal of Vioxx, to deadly bacteria in spinach, to contaminated pet food, have revealed alarming cracks in the foundation of FDA's ability to protect the American public. The warning signs are clear: FDA is an agency in crisis. We need to act now, and to learn from the vast experience of those who have managed the agency through the years.

Today, we are fortunate to have an unprecedented assembly of experts, including three former FDA commissioners and the current commissioner, Dr. Andrew von Eschenbach. In addition, two former commissioners, whose schedules did not allow them to be here in person, will submit written testimony.

I especially want to thank the Commissioner for accommodating the Committee's request that he testify on the same panel as the other witnesses. I recognize that it is the Administration's policy for governmental officials to testify on panels without non-governmental witnesses, and today's arrangement is not intended to nullify that policy. Since this hearing presents a highly unusual circumstance, gathering together the former and current heads of a single agency, we appreciate the Commissioner's departure from general agency practice.

The Food and Drug Administration protects the lives and health of every American, every day. FDA oversees thousands of products so routine that we don't even notice them — oatmeal, aspirin, even microwaves and cell phones. FDA also oversees products for the times in our lives that are anything but routine — days when we need emergency surgery, chemotherapy, or a blood transfusion.

FDA's mission is vast and daunting, but not impossible. The Agency's history is full of success stories, whether it was protecting consumers from rotten meat in the early 1900s; saving

lives by refusing to let thalidomide on the market in the 1950s; or speeding AIDS drugs to patients in the 1990s.

It is no exaggeration to say that FDA has touched the lives of every person in this room. Some of us are alive today because of its actions, and none of us wants to see a day without a strong and effective FDA.

But, as I have said, recent years have brought signs of trouble at FDA. At this hearing, we hope to learn about the causes of these problems. We'll hear about four major areas of concern.

The first and most critical issue facing FDA is simple: resources. The agency is vastly under-funded, relying on a steadily shrinking budget to tackle a rapidly expanding list of responsibilities. In fact, FDA's entire budget for Fiscal Year 2007 is less than the budget for the Montgomery County school system in the same year.

A second major concern is scientific integrity at the agency. In recent years, key decisions at FDA have been made under the cloud of real or perceived political interference, undermining FDA's most basic foundation.

A third area of concern is enforcement. Investigations by my staff and other analysts have found that, across the agency—from post-market drug trials to drug advertising to the handling of fresh produce—FDA's enforcement activity has declined. Strong enforcement is a critical component of FDA's work, and I am concerned to see how it has atrophied in recent years.

Finally, we must look closely at FDA's legal authorities to examine where its governing provisions are outdated or inadequate. One prominent example is in the area of food regulation, where our standards are literally a century old.

On the topic of food safety, I want to acknowledge this morning's announcement that FDA will create a new position for food protection at the agency. This idea of a food safety czar seems like a reasonable idea, and I support FDA in taking steps to increase the priority of food safety at the agency. However, as the agency begins to undertake long-term strategic planning, I think the need remains for an immediate response to the current crisis, and I hope that today's announcement will be followed by concrete and effective action.

For all its challenges, FDA remains one of our nation's greatest assets. I called this hearing because I believe in this Agency, and I want to see it work. As the primary oversight committee of the House, it is this Committee's responsibility to identify and begin to address the urgent challenges facing FDA. I hope that this series of hearings will lead to real solutions for FDA, restoring it to its full capacity and preparing it to serve its critical mission many years into the future.

I thank the witnesses for coming today and I look forward to your testimony.