Testimony of Dr. David Kessler

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Committee on Oversight and Government Reform

"FDA's Critical Mission and Challenges for the Future"

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Mr. Chairman and members of the Committee, thank you for the opportunity to participate in today's hearing. I am Dr. David Kessler, Dean of the School of Medicine at the University of California, San Francisco.

The opportunity and challenge this Congress has before it now, to equip the Food and Drug Administration (FDA) to meet the public health challenges of the 21st century, are as pivotal as those that Congress faced in 1938 and 1962 when it gave the Agency the fundamental responsibility of ensuring drug safety and efficacy.

I know of no other regulatory Agency that touches the lives of so many people so directly. The safety and efficacy of our drug products, vaccines, blood supply and medical devices, and the safety of our food should be at the top of our nation's priorities. I am concerned that this is not the case.

We are seeing a confluence of factors - chronic under-funding, a lack of enforcement authority, severely outdated scientific and regulatory frameworks - that are creating a lack of confidence in the Agency. At the same time, there are considerable challenges the Agency must be able to address if it is to remain the world's standard for public health protection. These challenges include the globalization of markets, particularly in food and drugs, and the imminent and profound shift toward a new era in medicine in which treatments are geared to individuals rather than mass markets.

As just one symptom of the Agency's condition, there has been a dramatic drop in the number of FDA enforcement actions. The number of inspections went down in recent years, and the number of warning letters issued by the agency dropped dramatically since 2000. It is difficult, if not impossible, to believe that this is driven by industry reform and true absence of violations. In fact, the number of recalls during this period increased significantly, suggesting that there are <u>more</u> serious problems, not fewer.

This would be a grim assessment but for the fact that the history of the Agency is such that it is precisely in times of crisis that the great leaps forward have been made. But this is not to make light of the task that Congress and the Agency face.

While there are important questions about the adequacy of the FDA's authorities and the need for sustained leadership, perhaps the most fundamental issue is ensuring that the Agency has the resources necessary to effectively meet its obligation to protect the public health. That means the resources to reclaim its scientific leadership in the fields it regulates, to implement enforcement programs that have a reasonable prospect of assuring compliance with essential public health protections, to expand the scope of its reach to encompass the global marketplace, and to earn and retain the confidence of the American people that the

food they eat is safe and the drugs and medical devices they use are safe and effective, and available to patients as quickly as possible.

There is a paradox here that needs to be addressed. We have funded the Agency responsible for the safety of products that comprise a quarter of all consumer spending at a level wholly inadequate by any measure - and then asked it to do even more with less. In just the past several years, the FDA has had to contend with a 16-fold increase in reports of adverse drug events, a doubling of direct to consumer television advertisements, a 65% increase in food imports, and an increased role in battling bioterrorism - all with a budget that has essentially been flatlined.

While Congress has attempted to provide resources for burgeoning public health needs on other fronts, support for the FDA has faltered in comparison. In 1986, FDA's budget was comparable to 97% of the budget for the Centers for Disease Control and Prevention (CDC) and 8% of the National Institutes of Health's (NIH) budget. By last year, it had dropped to 28% of the CDC's budget and 5% of NIH's. Significantly, while the NIH's budget to fund the research that leads to discoveries that ultimately fill the FDA's drug pipeline has doubled over the last five years, FDA's budget has not grown.

We can debate the merits of the model of industry paying fees to supplement the Agency's budget for drug approvals. But the truth is, at least as it relates to funding, the reality has never matched the program's design. The Prescription Drug User Fee Act (PDUFA) was never intended to be the predominant source of funding for drug approvals. It was intended to serve as a commitment from both drug manufacturers and the federal government to adequately fund the Agency. The drug industry lived up to its part of the bargain, but I submit that the federal government has not. In that sense, PDUFA has failed, and it has had the unintended consequence of shifting resources away from post-market drug safety and other important public health protection functions.

However, we also need to remember that PDUFA did succeed in helping to shorten review times. I saw how it gave hope to patients with cancer, HIV/AIDS and other illnesses for whom a significant reduction in review time was a matter of life and death.

Against a backdrop of essentially level appropriations and rising responsibilities, the need to meet PDUFA funding requirements has exacerbated the funding shortfalls not only in drug safety, but also in other Agency functions, with food safety being a glaring example. The minor increases in funding for food safety that FDA has received in recent years have been eclipsed by rising costs and additional responsibilities.

The FDA regulates 80% of the nation's food supply and products that involve more than 50,000 different manufacturers, processors and warehouses, yet it receives only 24% of the

federal food safety budget, the majority of which is directed to the US Department of Agriculture, which is not a public health agency. As a consequence, FDA has an insufficient number of inspectors to handle the workload and must increasingly rely on the industry to police itself. During my last year as Commissioner, there were around 3 million FDA-regulated products imported. This year, there will be about 20 million imports. Yet there has been no increase in staff for inspections.

Moreover, FDA scientists are ill-resourced to do the research necessary to turn scientific findings about foodborne illness into practical guidance that food companies can implement to make our food supply safer. This lack of scientific leadership does not make the headlines, but there is no question that one of the greatest losses from lack of resources is the Agency's ability to serve as a leading voice on sound scientific decision-making.

The erosion of funding has struck hard at the Agency's ability to support its proud tradition of groundbreaking research in regulatory science. While in the past, the Agency led the way in developing new scientific paradigms for approving biologics and assessing food contaminants - to the benefit of both industry and consumers - resources for FDA to lend its intellectual firepower to addressing key regulatory questions are increasingly scarce. Historically, other nations in Europe, the Far East and worldwide have looked to the FDA for its scientific leadership and as a model for public health protection, I am concerned that the Agency is losing its leadership role.

While lack of money is a significant obstacle, the FDA is also severely hampered by archaic authorities, outdated science and outmoded regulatory paradigms. As the public has come to learn, the FDA has virtually no authority to compel drug manufacturers to continue to study the safety of products after approval, require timely changes to drug labels, ensure that direct-to-consumer advertising serves a public health interest, or require that the results of clinical trials be shared with the patients who make them possible. Where it does have the authority to act, it is forced to work within the century-old regulatory concept of determining a product to be "adulterated" or "misbranded" - two terms that made sense in the days when snake-oil salesmen hawked their tonics on the street but have little relevance to today's mass-marketing. And, when it does determine that a product is adulterated or misbranded, it is constrained by inflexible enforcement tools that too often leave the Agency with the untenable option of doing nothing or pulling a drug from the market that may still hold some benefit for certain patients. Once a drug has been approved, the FDA is virtually powerless and cannot compel a manufacturer to change the drug's label, even if there is new, important information about the drug that physicians or patients need.

In particular, the FDA's authority to protect children's health lags even further behind. We have made great strides in the past decade with bipartisan legislation that created a "carrot and stick" approach to prompting the testing of drugs for children. This approach has been extraordinarily successful, yielding hundreds of pediatric studies and over 170 new or

improved labels for children. Yet, we're still denying children the same protections we demand as adults. While adults have had the right to safe medicines since 1938 and to effective medicines since 1962, the idea of permanently granting children those same assurances is still under debate in 2007.

When it comes to protecting consumers from unsafe food products, the problems are even more dramatic. Currently, FDA has no mandate for leadership on prevention of food safety problems, no funding to do important research to find ways to prevent food-borne illness, and no tools to hold companies accountable for implementing food safety measures and taking quick action when a problem is discovered. The fact is that the federal government has more authority to halt the distribution of dangerous toys than it has over unsafe food products. Because the process is entirely voluntary, FDA has no ability to verify that the manufacturer has in fact removed an unsafe product from the marketplace promptly and thoroughly. And, in contrast to the federal government's authority over recalls of toys, cars or medical devices, FDA has no ability to impose fines on a company that is slow to act.

The ultimate consequence of our failure to provide the Agency with sufficient resources and authority is that FDA's regulatory presence is diminished, to the detriment of the public health. Without the real potential for the Agency to act against unsafe drugs or contaminated foods, the likelihood of compliance diminishes. Without a strong agency, incidents like those recently covered in the Washington Post on food safety are inevitable. According to the Post, FDA inspectors had concerns about salmonella in a Georgia peanut butter factory in 2005. But because they relied on voluntary compliance, there was no follow-up action when company officials refused to provide requested food safety documentation. That factory was linked to more than 400 cases of food-borne illness in 44 states.

Over the past 20 years, there has been robust debate about the FDA's role in drug approval and safety. This focus on drugs also has been reflected in Agency funding and management attention. Now, it is time, indeed overdue, to address the same attention and concern to the Agency's food safety mission. In 1938 when the statute was written, people were not thinking about food safety in terms of global markets and worldwide supply and distribution networks. Spending weeks or months tracing back cases of food borne illness to their origin, although important, is too much like chasing the horse after it has left the barn - and too often with devastating results in illness and death.

Our focus today needs to be on prevention, not just reaction, if we are to have any hope of averting a future failure in the food safety system. FDA must have the scientific capability to do the research to develop the right processes and controls, producers and suppliers must be required to take steps to protect their link in the food chain, and the Agency must have the authority to hold producers and suppliers accountable for the failure to establish the necessary protections.

I believe we also need to look very seriously at the structure and leadership of the food safety system. Under the current structure, no FDA commissioner can be a strong leader on blood safety, vaccines, drugs and medical devices and also on food safety all at the same time. The American public should not have to choose between safe food and safe drugs, but when those two missions compete for the same scarce resources and leadership attention, that choice is being made for them. Shortchanging food safety to advance or address other aspects of the Agency's mission is dangerously shortsighted, and it has seriously compromised the effectiveness of the Agency's food safety program.

Congress and the Administration should act urgently to strengthen FDA by meeting its resources needs and by unifying and elevating food safety leadership within FDA and the Department of Health and Human Services (HHS). Food safety must not compete with drug or device safety for resources and leadership. Food safety can't be delegated to second-tier management within the agency, and the fact is that food is a second-tier priority within the FDA. In addition, the current structure is fragmented in FDA. Responsibilities for food are spread across the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and the Office of Regulatory Affairs. There must be a clear recognition within HHS that food safety is an essential part of protecting the public health. And it cannot be housed in the Department of Agriculture, because the Secretary of Agriculture does not speak for public health. We need a commissioner of foods at FDA who is responsible and accountable for all that FDA does on food safety, in headquarters and the field, and who reports directly to the Secretary.

A first step toward correcting these problems must be for Congress and the Administration to commit to a substantial increase in funding for the Agency. To bring the FDA's framework for drug regulation up to date, legislation proposed by the Chairman and by Senators Kennedy and Enzi are strong steps in the right direction. In my view, individualized plans for managing drug risk, backed by increased and more flexible enforcement authority, are a sensible solution and should be enacted.

When it comes to the mission to protect the public health, FDA must lead. There should be, in my view, no reasonable debate on that question. It is our responsibility - Congress, the Administration, and the public - to give the Agency what it needs to do that.

Mr. Chairman, I appreciate your long-standing interest in these issues and your willingness to devote your time and energy to finding a solution to the challenges confronting the Agency. I offer to you whatever help I can provide as you work toward strengthening the ability of the FDA and the federal government to continue to protect the public health.