Statement of Donald Kennedy, Ph.D., former commissioner, FDA (1977-78)

President, emeritus, Stanford University and Editor-in-Chief, *Science*.

Mr. Chairman - It is a pleasure to appear before the Committee on Oversight and Government Reform, and to make your acquaintance once again. You have asked that I provide information that might be helpful in examining the critical mission of the Food and Drug Administration as it faces new challenges. If I may, I'd like to begin by citing a few of those contemporary challenges, and then move to a consideration of FDA's needs to guarantee the future quality of its work. Among the current problems are food safety, as evidenced by recent recalls owing to bacterial contamination; preparations for pandemic influenza; difficult questions surrounding the safety of already marketed drugs – an old problem that owes much to the unavailability of a sound adverse-reaction reporting system in this country; and problems in maintaining inspection and analytic capabilities to deal with a wider range of problems and production sites.

These problems, of course, all lie within the orbit of FDA's statutory and regulatory responsibility. Others, however, lie outside the agency itself. For example, in only a fraction of the past 6 years has FDA had at its head a commissioner confirmed by the Senate. I think we all knew that FDA could function well for periods with a competent, highly graded technical civil service staff. But FDA enjoys frequent external challenges that must be met by leadership that is fully authorized and credible.

A second problem, Mr. Chairman, is that FDA has for some time been chronically under funded and under staffed. A comparison of FDA's budget comparing 2003 with the current fiscal year tells a disheartening story. To conserve its purchasing power from

one year to the next – that is, buying the same bundle of goods and services – would require an increase of about 5.8% in that-year dollars. FDA is, after all, a payroll-intensive agency, and at that rate of increase FDA's 2007 budget would have been 1 billion 924 thousand but its actual appropriation was only 1 billion 558 thousand – nearly 20% below what it needed to be. I think my fellow ex-commissioners would agree that an appropriated budget of 2 billion in FY'08 would restore FDA's capabilities to the level they were in FY'03. It might be asked whether increases in user fees could not substitute for appropriated funds. I think not. FDA's user fees are restricted to activities related to the new drug approval process. They are thus not equivalent to appropriated funds, which must cover the full spectrum of FDA activities. With respect to present needs, the recent report from the Institute of Medicine of the National Academies makes a useful point: there is a large disparity between the resources available for the new drug review and approval process at FDA and those available for drug safety. You may remember, Mr. Chairman, that FDA had to explain repeatedly to the Congress in the late 1970s that it was very difficult for the agency to pursue a comprehensive program for evaluating the safety of already-marketed products. The reason is that in order to calculate an adverse reaction rate, you need to know the numerator – the number of observed problems – and the denominator – the number of prescriptions that are out there. FDA's numerator depends upon a largely voluntary reporting system involving doctors and firms; the denominator might ideally depend on a triplicate prescription system in which one copy is made centrally available for data storage, but that is not available. The ironic result, in the case of the Vioxx problem, is that FDA had to make use of the nation's largest health maintenance organization, Kaiser Permanente, which had so many prescriptions recorded

in such an extensive medical records data base that a careful assessment of the risks associated with Vioxx could be made. From this topic, I hope the Congress will examine with special care the recommendations of the Institute of Medicine report with respect to clinical trial reports and the capacity of FDA to undertake risk assessment and risk management with respect to already-marketed drugs. IOM, in agreement with several major medical journals, is urging the requirement that industry sponsors must register at clinicaltrials.gov all phase through four clinical trials. In section 5.1, the report asks Congress to give FDA authorities that might be applied to conditions for distribution. These would include the capacity to make FDA initiated changes in drug labels, a moratorium on direct consumer advertising, and various other kinds of conditions.

Let me summarize a few of these thoughts. Public confidence in the Food and Drug Administration is a vital asset for an agency that regulates about 25 cents out of every consumer dollar spent in the United States. If we expect our pet foods to be safe and our spinach uncontaminated, Congress needs to provide FDA with the resources and the authorities it needs. Americans won't tolerate, nor should they be asked to tolerate, an undermined sense of confidence in the safety of products it needs every day. The additional resources FDA needs to fulfill its responsibility is pretty moderate by federal budget standards, but is essential. Congress provided a system for industry to subsidize the drug and device approval program through user fees – but the rest of the FDA is broken. It has apparently escaped the Congress that FDA – like other medium-sized businesses – has suffered because health and other benefits costs for its employees have risen much faster than salaries. As a consequence, FDA not only has less money in '07 than it had in '03 – it has many fewer employees!

Mr. Chairman, I hope you and your staff will be diligent about pursuing FDA resource needs. But you may have to rely on grizzled veterans like me, because budget authorities at HHS and OMB specifically prohibit present officials in the agency from speaking out publicly about the need for more funding. I used to squirm about this in my day but it's a fact of life. So I hope that plainly you know all about that prohibition, but it is important that Americans know, when they hear FDA officials say they are satisfied with their budget allocations, that they have their fingers crossed underneath the witness table.

I have enjoyed being here, and it is a real pleasure to speak out with enthusiasm and even some love from an agency I continue to care about very much.