Hearing Summary

HEARING ON FDA'S CRITICAL MISSION AND CHALLENGES FOR THE FUTURE

Rep. Henry A. Waxman
Chairman, Committee on Oversight and Government Reform

The Food and Drug Administration (FDA) plays a crucial role in protecting the public health. FDA is responsible for ensuring that drugs and medical devices are safe and effective and that food is safe for consumption. In each of these areas, the FDA's regulatory challenges are growing rapidly. Rapid technological advances have increased the complexity of new medical products seeking approval. The consumption of "ready to eat" foods is also on the rise. Globalization of markets has led to rapid growth in the number of imported drug, device, and food products, dramatically increasing the FDA's regulatory workload. Congress has also added dozens of new responsibilities to FDA's mission. Yet FDA's budget has not kept pace with its workload, leaving the agency seriously underfunded.

In order to better understand the challenges the FDA faces and how it might address them going forward, on May 1, 2007, the Committee invited the current FDA Commissioner, as well as three former FDA Commissioners from Democratic and Republican Administrations, to share their views.

Donald Kennedy, Ph.D., served as FDA Commissioner from 1977 to 1979. He testified that despite its critical regulatory responsibilities, "FDA has for some time been chronically under-funded and under-staffed." He stated: "If we expect our pet foods to be safe and our spinach uncontaminated, Congress need to provide FDA with the resources and authorities it needs."

Frank Young, M.D., Ph.D., served as FDA Commissioner from 1984 to 1989. He identified nine major challenges that the FDA faces, including "neglect due to short-term Commissioners; a workload that greatly outstrips its resources; accelerating technological challenges coupled with insufficient resources to remain at the forefront of the science it regulates; a crush of imported goods with an insufficient number of enforcement personnel; and an ever-increasing degree of political influence in what should be a scientifically based agency."

David Kessler, M.D., J.D., served as FDA Commissioner from 1990 until 1997. He testified that the FDA needed a "substantial" increase in funding. He also urged a rethinking of the FDA's food safety mission: "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 … 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."

Andrew C. von Eschenbach, M.D., the current FDA Commissioner, described his vision for the future of FDA, noting that for over 100 years, FDA has been recognized throughout the world as "the gold standard for regulation." He discussed the steps the FDA is taking to ensure the safety of fresh produce and the Agency's response to the 2006 Institute of Medicine report

on the future of drug safety. He called for enactment of user fee reauthorization bills "without delay."

Additional information, including Chairman Waxman's statement, copies of testimony, and a transcript of the hearing, is available online at www.oversight.house.gov.