

Testimony of Catherine E. Woteki, Ph.D., R.D.
Science and Mission at Risk: FDA's Self-Assessment
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
January 29, 2008

Mr. Chairman and members of the Committee, thank you for the opportunity to appear today to present the findings of the FDA Science Board's review of the Center for Veterinary Medicine and the Center for Food Safety and Applied Nutrition. Between them, these two centers are responsible for assuring the safety of the nation's food and feed supply, cosmetics, veterinary drugs, and dietary supplements and for assuring that information on labels is truthful and not misleading. All together, this segment of the US economy amounts annually to \$466 billion in domestic and imported foods sales; \$18 billion in dietary supplements, \$60 billion in cosmetics, \$5 billion in veterinary drugs, \$35 billion in animal feed and \$15 billion in pet food sales.

Our committee's key finding is that "FDA does not have the capacity to ensure the safety of food for the nation. Crisis management in FDA's two food safety centers, Center for Food Safety and Applied Nutrition(CFSAN) and Center for Veterinary Medicine (CVM), has drawn attention and resources away from FDA's ability to develop the science base and infrastructure needed to efficiently support innovation in the food industry, provide effective routine surveillance, and conduct emergency outbreak investigation activities to protect the food supply" (Report of the Subcommittee on Science and Technology, FDA Science and Mission at Risk, November, 2007, p. 3).

This crisis is the result of decades of neglect and erosion of CVM and CFSAN's resource needs. In contrast to drug discovery and development, FDA's food evaluation methods have not kept pace with evolving risks, and evolving science These centers are

strapped for resources and can accomplish little beyond addressing the top priority of the moment. Major issues of public health concern are not being addressed such as cosmetic safety and the many regulatory responsibilities FDA has for human nutrition

The current situation is not a reflection on the outstanding staff who do a commendable job under enormous pressure. They set priorities, they focus on the most important public health issues, and they develop innovative ways to leverage what they have.

Rather, our review (which was conducted in winter and spring of 2007 against a backdrop of cascading product recalls) led us to conclude that CVM and CFSAN's basic functions of inspection, enforcement and rulemaking are severely eroded. Over 35 years, there has been a 78% reduction in inspections with food establishments now inspected, on average, once every 10 years.

The CVM workforce consists of 375 FTE, 4% of FDA total, but it faces unique challenges in the number and diversity of species it must address as well as maintaining a human health orientation. The pet food industry is a \$15 billion a year business and largely falls under FDA's regulatory purview. The recent pet food crisis strained the already overtaxed system. CVM received more than 18,000 telephone calls concerning melamine pet food contamination. Estimates are that about 1 percent of the total volume of pet food was involved with a potential economic impact of \$200 million. However, CVM is able to devote only two people working full time on pet food issues.

Since 2003, CFSAN's workforce declined from 950 FTE to 771 FTE. CFSAN no longer generates the science needed to fulfil its human nutrition regulatory responsibilities. The dietary supplement industry has grown to more than \$20 billion in

annual sales, and millions of Americans use those products every day. But the legislation authorizing FDA regulation of those products has never been funded, the practical effect being that the products and their health claims are essentially unregulated. The same can be said of the cosmetics industry, which has more than \$60 billion in annual sales, but is overseen by an FDA staff of less than 20 people supported by \$3.5 million budget.

Why has this happened? Most importantly, CVM and CFSAN have experienced a dramatic increase and diversification of their responsibilities. Since 2003, a half dozen new laws have been enacted that require significant investment of personnel and resources to implement. The new laws include FDAMA provisions related to food contact substances, the Bioterrorism Act, FALCPA-food allergen labeling, trans fat labeling, egg safety food cGMP, pandemic flu planning, and minor use and minor species health. These new responsibilities increase the complexity of the Centers' tasks and increase scientific demands, but do not provide funding to enable the Centers to implement their new responsibilities.

Our finding is not a new one. In 1991, a previous committee reported to the Secretary of HHS its "deep concerns about the viability of the foods program and the lack of Agency priority for food issues. Decline in resources and program initiatives during the past 10-15 years indicate a lack of Agency management attention and interest in this area, although public interest in, and concern for, an effective food program remain high" (Report of the Advisory Committee on the Food and Drug Administration to the Secretary of HHS, May, 1991).

Center for Veterinary Medicine – specific findings and recommendations

CVM faces a spectrum of regulatory issues requiring high levels of science. These include methods to identify residues (synthetic and natural chemicals) and emerging infectious diseases; antimicrobial resistance monitoring (science and informatics base of NARMS); biotechnology (genetic engineering, cloning, use of phages, biopharma); and new technologies in drug manufacturing and delivery (nanotech, genetics, biomarkers, new approaches to characterizing microbial resistance). The key stressors that CVM faces are: the convergence of massive data volume and complexity with newly developed products from the “omics revolution”; developing and maintaining unique databases with respect to species, endpoints, human health; and under staffing (375 FTE), vacancies in key scientific positions, and lack of funds (>80% of budget in salary). Our committee’s recommendations are to: bolster CVM’s in-house scientific capability in emerging areas relevant to veterinary medicine; improve IT capability, and integrate within FDA and with CVM partners (CDC, USDA), eliminate paper storage; and foster integration with cutting edge science activities across FDA and with external partners; and to expand the FDA Fellow Program.

Center for Food Safety and Applied Nutrition – specific findings and recommendations

CFSAN’s regulatory responsibilities require high levels in diverse sciences: food production sciences; risk mitigation at the source; consumer understanding of nutrition and food safety information; better labeling for public health; immunology; detection and prevention of foodborne viral diseases; safety of cosmetics; and adverse event reporting and analysis. The key stressors on the Center include: lack of resources (950 FTE in 2003 vs. 771 FTE in 2007; new mandates; elimination of research programs);

globalization of the food supply; new food processing technologies; new threats to public health; ongoing response to emergencies; outmoded IT systems and laboratory instruments; and the fact that they are addressing only the highest priorities. Our committee's recommendations pertaining to CFSAN are to: add resources to attract, retain and leverage scientific expertise and regulatory research in priority areas; invest in 21st century regulatory science that could anticipate future food safety issues; and develop a cadre of professionals capable of applying the new science to emerging challenges; leverage research programs sponsored by NCTR, ARS, CSREES, CDC, NIH and DHS and conduct this activity with the Chief Scientific Officer; and not neglect cosmetics and nutrition.

Thank you, Mr. Chairman, I will be happy to answer questions.