

**Testimony**  
**of**  
**Gail H. Cassell, Ph.D.**  
**before the**  
**Subcommittee on Oversight and Investigations**  
**of the**  
**Committee on Energy and Commerce**  
**House of Representatives**

**On**

**“American Lives Still at Risk: When Will FDA’s Food  
Protection Plan be Fully Funded and Implemented?”**

**June 12, 2008**

Mr. Chairman and Members of the Subcommittee, I am Gail H. Cassell, Vice President for Scientific Affairs and a Distinguished Research Scholar for Infectious Diseases of Eli Lilly and Company and Professor. I am also Professor and Chairman Emeritus of the Department of Microbiology of the University of Alabama Schools of Medicine and Dentistry. I am a member of the Institute of Medicine of the National Academy of Sciences and am currently serving a second term on the governing board of the IOM. Of relevance to my testimony today, I have previously been a member of the Advisory Committees of the Directors of both the Centers for Disease Control and the National Institutes of Health. I also co-chaired the Congressionally mandated review of the NIH intramural program. I appear before you today as a member of the FDA Science Board, Advisory Committee to the FDA Commissioner as I have done so twice before this year. As you know I served as Chair of the Subcommittee on Science and Technology of the Science Board, which authored the report "FDA Science and Mission at Risk".

In December 2006, the Commissioner charged the Science Board with establishing a subcommittee to assess whether FDA's current science and technology can support the agency's statutory mandate to protect the nation's food and drug supply. The subcommittee was comprised of three Science Board members and 30 other experts. The subcommittee formally presented its report to the Science Board and FDA on December 3.

The report was unanimously endorsed by each of the 33 members of the Subcommittee and the full Science Board. On December 3, the Science Board accepted the report as

final and dissolved the subcommittee. The record of the proceedings of that meeting will show that due to the seriousness of the deficiencies found and the urgency of the situation, the Science Board was adamant that the report be broadly disseminated among the public and policy makers. The level of concern by all members of the Subcommittee and the Science Board members was, and remains, high...and thus the intensity of their commitment to this review. On behalf of our Subcommittee, I again want to thank you Mr. Chairman and members of your Committee for your attention to our report.

The subcommittee review was unique in many respects. First, it is only the second time in over a century that the agency has been reviewed by an external committee as a whole entity. Second, the committee was composed of leaders, not from a single sector, but from industry, academia, and other government agencies. The expertise and level of accomplishments of the members are almost unprecedented in a single committee, especially considering their breadth and knowledge in regulatory science and understanding of the mission of the agency.

The subcommittee included expertise ranging from a Nobel laureate in pharmacology, 14 members of the National Academy of sciences (including two engineers), a renowned economist and specialist in workforce issues, a leader in health care policy and technology assessment, a former CEO of a large pharmaceutical company, a former Assistant Secretary for Health and Human Services who also headed global regulatory affairs within a large company for over 20 years, a former Chief Counsel for the FDA, and the first under Secretary for Food Safety at the U.S. Department of Agriculture

overseeing the Food Safety and Inspection Service and coordinating U.S. government food safety policy.

For over a year, this group of experts worked intensively for thousands of hours, including many nights, week-ends, and holidays conducting their review. It was the norm, not the exception, that when we met, even by teleconference, we would have as many as 30 members actively engaged in discussion for over two hours. Let me assure you, this level of engagement by so many very busy people with diverse expertise is rare in such a committee let alone that there would be such rapid consensus about its findings. How then do you explain the consensus and commitment to this exercise?

It became rapidly apparent that the FDA suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities. It is agency wide, i.e. not limited to a single program or Center. Since every regulatory decision must be based upon the best available scientific evidence in order to protect the public's health, we concluded that American lives are at risk and that there is an urgent need to address the deficiencies. Quite simply we concluded that FDA can no longer fulfill its mission without substantial and sustained additional appropriations.

On February 25, in response to your request, we submitted a summary of the estimated resources required to implement the recommendations made by our Subcommittee which included \$375M in FY 2009. This was in great contrast to the \$50.7M requested by the Administration for FY 2009. We are encouraged that the Administration's FY 2009

budget amendment acknowledges the FDA's need for \$275M to address serious safety issues. Unfortunately, we do not believe this amount is sufficient and most importantly, even if it were, it would not be available until March or April of 2009 at the very earliest.

Just within the past two months there have been 81 deaths in this country from contaminated heparin. Just this past week, the Centers for Disease Control has reported there have been 23 hospitalizations and 145 people sickened from salmonella contamination of fresh tomatoes. The latter alone has cost the food industry over \$51M in the last few days. Mr. Chairman, if we do not act now to address the deficiencies at FDA, we will see more lives lost and greater economic losses. We therefore urge you to include \$275M for FDA in the Supplemental appropriations bill currently being considered by the House and Senate in order to get the critically needed funds flowing rapidly.

You will recall in the hearing held by your Committee on January 29, we summarized the overall findings of our Subcommittee. In the hearing you held, April 22, findings concerning drug safety and foreign inspections were extensively discussed. However, our Subcommittee found the most serious deficiencies to be in the area of food safety. Today you will hear from Dr. Glenn Morris, a member of our review group about our specific concerns and recommendations about food safety. In addition, you will hear about our concern that the agency's current Food Protection Plan lacks specificity regarding the actions to be taken, technologies to be utilized, and mechanisms of

implementation. I will now defer to him and the other panel members to discuss these issues in greater detail.