Testimony of
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Before the

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United States Senate

"Restoring FDA's Ability to Keep America's Families Safe"
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Mr. Chairman, members of the Committee: it is a pleasure to have the opportunity to provide you with information which may be of help in developing a common vision for the FDA role in food safety during the next decade. In particular, I would note the importance of the following issues:

Food safety remains an important area of concern to the U.S. public. For the public, problems have been underscored by ongoing reports of foodborne disease outbreaks and major product recalls. However, from an epidemiologic perspective, it is perhaps more concerning that reported incidence rates for the major foodborne pathogens (based on 2007 FoodNet data) have remained relatively constant during the past several years, with some actual increases. This is in the context of initial declines in incidence rates in the early part of this decade, as compared with a 1996-98 baseline. I was instrumental in the establishment of FoodNet in the mid-1990's, to serve as a means of assessing the public health impact of the new HACCP rules at USDA. While there are constraints on the interpretation of available CDC data, it is concerning that the initial declines in incidence rates seen in the years following the implementation of the USDA HACCP rule may have "leveled off," suggesting the urgent need for new and innovative approaches to protect the health of the American people.

FDA, with responsibility for overseeing an estimated 80% of the nation's food supply, must take the major leadership role in the development and implementation of such new approaches. As has been noted by multiple national committees (and by the FDA itself, in its Food Protection Plan), the FDA tends to be primarily reactive in issues of food safety: they spend most of their time putting out fires, rather than focusing on how to keep the fires from starting in the first place. There is a broad consensus that the agency must develop a pro-active, risk-based (and science-based) preventive approach to food safety. Initial steps in this direction have been taken by the agency, with the announcement of their Food Protection Plan. However, some key issues remain:

Development of a risk- and science-based approach to prevention requires science. More specifically, there is a need for high quality surveillance, both microbiologic and epidemiologic, to clearly identify and delineate problem areas. This, in turn, must be combined with a strong analytic capacity, both to guide the original data collection and to "make sense" of the data when it is collected. In this regard, many of the European countries (such as the Netherlands and Denmark) are well ahead of us, having in place well-designed surveillance systems that are used to regularly "tweak" the approaches and

focus areas of the associated food safety regulatory agencies. Development of public health-based performance standards, which, long-term, are a critical element of a risk-based prevention system, requires an even higher level of sophistication in surveillance and analysis. Unfortunately, the capacity at FDA for such analysis is limited, and there is at best a clouded vision of what is needed for development of such systems.

As is true for many things in government, **development of risk-based systems will require money** – including substantial "up front" funding to get new systems in place. Long-term, there is little question that implementation of risk-based approaches will be cost-effective, both in terms of the agency budget and the reduction in costs associated with foodborne disease, but it will cost money to get there. I had the privilege of serving on the FDA Science Board Subcommittee on Science and Technology, which was responsible for the November, 2007, report, "FDA Science and Mission at Risk." I strongly concur with the findings of the report. As the report has been widely circulated, I will not repeat the conclusions, other than to emphasis the critical need for adequate funding if the FDA is to continue to do its current job appropriately, let alone move forward with a vision for the future.

While there is unquestionably a need for science, and the funding to support that science, we, unfortunately, find ourselves in a situation where there are even more basic steps that must be taken to move the agency to a point where science can be applied. In this context, **I strongly applaud the efforts of this committee to provide the necessary legislative mandate for the agency to begin to move toward a preventive, risk-based future.** At a very simplistic level, there is a need for legislation that will require inspections at consistent intervals, and give FDA the tools necessary to recall products that may contain pathogenic microorganisms or toxin materials. Moving up from there, there is a need to bring companies into the creation of a vision for improved food safety, with a willingness to assume responsibility for identifying potential foodborne hazards within their products. Ultimately, a smoothly functioning risk-based system will include key components of HACCP, with strong industry buy-in and performance monitored by public health-based performance standards.

We have a long way to go to reach this point, both in terms of science and regulatory structure. However, there is a need to get started – to depart from the *status quo*, and to begin to apply innovation and creativity to an inadequate and antiquated system. I applaud this committee for beginning to move in this direction.

* Dr. Morris is Director of the newly established Emerging Pathogens Institute (EPI) at the University of Florida, Gainesville, where he is also a Professor of Medicine (Infectious Diseases). From 1994-96, Dr. Morris worked with the Food Safety Inspection Service, USDA, on development of the new HACCP regulations, and was instrumental in the establishment of FoodNet, the national surveillance system for foodborne illness. He has served on four National Academy of Sciences expert committees dealing with food safety, and currently serves on the Institute of Medicine's Food and Nutrition Board. Most recently, Dr. Morris served as a member of the FDA Science Board's Subcommittee on Science and Technology, which was responsible for the February, 2008 report "FDA Science and Mission at Risk."