STATEMENT
OF
THE HONORABLE BART STUPAK
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS
"SCIENCE AND MISSION AT RISK: FDA'S SELF-ASSESSMENT"

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Since the Federal Food, Drug, and Cosmetic Act was first enacted in 1938, FDA's role in protecting the American consumer has expanded considerably. FDA is now responsible for ensuring the safety of medical devices, human food, animal feed additives, new human and animal drugs, human biological products, and the list goes on. Today, no new pharmaceutical product or medical technology can be used in the U.S. without FDA first determining that it is safe and effective for its intended use. By some estimates, the agency now regulates more than $1 trillion in consumer products or close to 25 cents of every U.S. consumer dollar spent.

Unfortunately, as this Committee under both Republican and Democratic leadership has documented, FDA's resources have become woefully inadequate given the agency's expansive mission. Accordingly, the agency's ability to protect American families from unsafe foods, drugs, medical devices, and other products has radically deteriorated. Last year's slew of tainted consumer goods and related recalls was the proverbial canary-in-the-coal-mine illustrating the strain under which the FDA now functions.

To his credit, in December 2006, FDA Commissioner Andrew von Eschenbach requested that the FDA Science Board—which is his primary advisory group—form a special subcommittee to assess whether "science and technology" at the agency is capable of supporting existing and future regulatory operations.

The subcommittee had extensive input from 30 world class external advisors representing industry, academia, and other government agencies. These experts were selected based on their extensive knowledge of cutting-edge research, budget, science, and management operations. Their assessments were compiled in a report entitled, "FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology." All 33 advisors and subcommittee members signed off on the findings of this report, which was presented to FDA last month and unanimously accepted by the Science Advisory Board.

Today, we have the honor and privilege to hear directly from the Chair of the Science Board's Subcommittee as well as from a number of its expert advisors. They will raise a number of concerns regarding FDA's current capability. More directly, they will raise their concern that **the FDA's overall mission of protecting the public's health is at risk**. **The report's findings are shocking and extensive.** Some key concerns include the following:

- The FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak;

- The FDA does not have the capacity to ensure the safety of the Nation's food supply;

- The FDA's ability to provide basic inspections, conduct key rulemakings, and carry out enforcement actions are severely eroded, as is its ability to respond to food-related outbreaks in a timely manner;

- During the past 35 years, the decrease in FDA funding has forced the agency to impose a 78 percent reduction in food inspections;

- The FDA cannot fulfill many of its core regulatory functions because its IT infrastructure is obsolete, unstable, and inefficient;

- The agency faces substantial employee recruitment and retention challenges;

- The agency has insufficient access to critical data needed for various core missions and thus cannot effectively regulate products based on new science;

And the list goes on.

Alone, each of these issues would be a daunting task to resolve. Taken together, they suggest much of FDA's core regulatory mission is at risk. When coupled with the recent findings by the Government Accountability Office (GAO) regarding the agency's effort to inspect food, foreign-made drugs, and medical devices, the situation is truly alarming. As pointed out in the GAOreport, "American lives are now at risk."

The findings of this report, however, should come as little surprise to Members of this Subcommittee. The work we conducted last year provides ample evidence that FDA is increasingly struggling to perform its most rudimentary regulatory missions.

For example, the Subcommittee held four hearings related to how FDA protects Americans against substandard foods. These were prompted because of incidents involving tainted human and pet food and other commodities. FDA's failed regulation of domestic food producers, its ill-conceived plan to close laboratories and reorganize field staff, and its inability to ensure the safety of imported foods from China and other foreign markets, painted a bleak picture of FDA's ability to protect the Nation's food supply.

In addition to our food safety investigations, the Subcommittee examined FDA's foreign drug inspection program. That investigation found FDA's IT system for managing drug imports and related inspections was antiquated and disturbingly incapable of providing timely and basic data.

Because of resource constraints on field inspectors and related travel, FDA could only inspect about 7 percent of all foreign establishments in any given year. Experts told the

Subcommittee that foreign drug firms should be inspected at least once every few years, but at that rate it would take FDA 13 years to inspect each foreign establishment a single time. Today, GAO will report similar findings relating to FDA's ability to inspect foreign medical device manufacturers.

One of the key findings in the Science Advisory Board's report is that "In contrast to previous reviews that warned crises would arise if funding issues were not addressed, recent events and our findings indicate that some of those crises are now realities and American lives are at risk." These observations are troubling and they fit a pattern: FDA is increasingly being asked to do more and more with less and less and many of the agency's tools and resources are stretched to the breaking point and incapable of supporting the agency's mission.

I would like to thank the witnesses who will be testifying today. Your work has assisted this Committee greatly, and we look forward to your continued help and leadership. The Committee takes the report's findings very seriously.

The deterioration of the FDA's ability to protect the American people did not happen over night. This deterioration is a cancer that has developed over many years, under the watch of both Republican and Democratic Administrations. This deterioration is also not something that will be changed over night, but there are many recommendations in the Science Advisory Board's report that can be addressed immediately.

The FDA - and Congress – have an opportunity for great leadership. It is my sincere hope that Commissioner von Eschenbach will commit to us that he will not just accept the startling findings and the positive recommendations made by the Science Advisory Board, but he will develop and implement the Science Board and GAO's recommendations to put the agency back on track as the world's premier agency to safeguard food and drugs. The Commissioner should know, that Congress is not willing to just throw more money at the problem. We will require a realistic plan with vision and measurable results to ensure the promises made are commitments kept.

The Commissioner has taken the first step in developing a plan by asking for this report. He has also shown a willingness to listen and learn from our hearings. Just last week he announced that he will implement one of our key recommendations from last fall's hearing on drug imports. The FDA plans to open offices in foreign countries such as China and India, where so much of our food and drugs now come from. This is an important small step – with required follow through – and oversight.

I look forward to working with the Commissioner on how we can forge ahead to give the FDA the tools necessary to protect the American public. Our Nation deserves nothing less.