ONE HUNDRED TENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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January 29, 2008

The Honorable David M. Walker
Comptroller General of the United States
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Walker:

The Food and Drug Administration (FDA) is the federal agency responsible for ensuring the safety and effectiveness of a wide range of consumer products, including 80% of the nation's food supply, and human and veterinary drugs, biological products, medical devices, cosmetics, and products that emit radiation. These enormous responsibilities have major implications for the health, safety, and well-being of all Americans.

Each year Congress adds to the list of duties assigned to FDA. At the same time, market forces are requiring the agency to refocus its efforts and change the way it does business. Our growing reliance on imported foods and drugs, the changing nature of the foods Americans choose to eat, the pressing need for new medicines, and constant changes in medical device technology are just a few of the factors influencing the way that FDA must shift and expand to accomplish its mission.

Despite its growing list of responsibilities and accompanying needs, FDA's budget has declined in real terms. In recent years, its annual budget requests have not covered its own needs, its annual appropriations have not kept pace with inflation, and the agency has become increasingly dependent on user fees. Federal funding for other public health agencies, such as the Centers for Disease Control and Prevention and the National Institutes of Health, has increased, but FDA's federal funding is dwindling. The effects of this situation are now being felt acutely by the agency and those it serves. According to a just-released report of FDA's Science Board on deficiencies in FDA's scientific capacity:

> We found that FDA's resource shortfalls have resulted in a plethora of inadequacies that threaten our society — including, but not limited to, inadequate inspections of manufacturers, a dearth of scientists who understand emerging new

> technologies, inability to speed the development of new therapies, an import system that is badly broken, a food supply that grows riskier each year, and an information infrastructure that was identified as a source of risk in every Center and program reviewed by the Subcommittee. We conclude that FDA can no longer fulfill its mission without substantial and sustained additional appropriations.[1]

The staffing needs of the agency are of particular concern. FDA appears to lack enough personnel that possess the sets of skills necessary to meet the increasing demands on the agency. There simply are not enough staff available and prepared to perform important tasks such as inspecting the imported foods and drugs now entering our country, evaluating medical devices that use new technologies such as robotics and nanotechnology, and managing the rapidly increasing number of adverse event reports related to all of these products.

We are concerned about the dilemma that FDA faces in its oversight of foods and critical medical products. Although our government always faces financial constraints, we cannot afford to put FDA, which performs tasks vital to the public health, in a situation in which it cannot succeed. We know that we are not alone in our concern. Public confidence in FDA, and the foods and medical products it regulates, is waning. Therefore, we are requesting that you examine the staffing and other resources necessary for FDA to successfully carry out its oversight of foods, drugs, biologics, and medical devices.

We believe this examination could reasonably be divided into three components: (1) focusing on FDA's oversight of food; (2) focusing on its regulation of drugs, biologics, and devices; and (3) focusing on its information technology needs.

* * *

Americans depend on the FDA's oversight of domestic and imported foods to protect them from a wide range of disease-causing organisms and contaminants in food. Yet recent food safety crises, from repeated *E. coli* outbreaks in fresh produce to salmonella in peanut butter and melamine contamination in imported wheat gluten, suggest that FDA is increasingly unable to fulfill all of its food safety responsibilities.

We are very concerned that the agency no longer has the tools or the resources to ensure the safety of our food supply. FDA documents indicate a significant decline in resources, staffing, and inspections at the agency. For example:

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[1] *FDA Science and Mission at Risk, Report of the Subcommittee on Science and Technology*, 7 (Nov. 2007) (online at: www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA Report on Science and Technology.pdf).

- Funding for domestic food investigations is down by a fifth since 2002, even without adjusting for inflation or increased workload.
- Food safety field, laboratory, and center staff have fallen by 10 to 30%. Staffing levels are now at some of the lowest levels in years.
- Inspections for high risk food facilities, including fresh produce firms, have declined by a quarter since 2004.
- Laboratory sampling is down by a quarter since 2003. Even sampling of high risk foods has declined during this time period.

The dramatic increase in imported foods poses one of the most significant threats to the safety of our food supply. According to FDA, "the volume of FDA-regulated imports has doubled in the last five years, and 60 percent of these imported shipments are food. Currently, the FDA is overseeing over nine million line entries of imported food annually and most of these entries are large volume commercial shipments. It is estimated that approximately 15 percent of the U.S. food supply is imported, but for some products such as fresh fruits and seafood, imports account for 50 to 60 percent of the supply."[2]

FDA appears to have grossly inadequate resources to ensure the safety of imported foods as they come across the border. The agency is able to inspect less than 1% of food imports. Even as food imports increase, the number of FDA inspectors has fallen since 2003.

The FDA Science Board report paints a detailed and bleak picture of the growing gap between FDA's food safety responsibilities and the resources available to carry them out.[3] The authors conclude that FDA's food safety programs have been so starved of resources that its ability to carry out basic food safety inspection, enforcement and rulemaking functions, as well as its ability to respond to, and prevent, outbreaks have been "severely eroded."[4]

Deficiencies in FDA's food safety capacity can be very costly for consumers, the health care system, and the food industry. FDA has estimated that illnesses from just 13 food-borne pathogens result in over 13 million illnesses and $57 billion in costs annually. This is only a fraction of the total cost from all food-borne pathogens, because these 13 pathogens account for less than 20% of the 76 million food-borne illnesses in the US each year. Repeated outbreaks of food-borne illness also impose devastating costs on individual food producers and have a

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[2] Statement of David Acheson, MD, Assistant Commissioner for Food Protection and Margaret Glavin, Associate Commissioner for Regulatory Affairs, before the U.S. House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations (Oct. 11, 2007).

[3] *FDA Science and Mission at Risk, supra* note 1, at 21-24, App. C.

[4] *Id.* at 21.

significant impact on the food industry as a whole. Public confidence in the food supply has been so undermined that, for the first time, food industry trade associations are supporting resource increases for FDA and even new regulatory authorities.

Therefore, we are requesting that you examine the tools, staffing and other resources necessary for FDA to successfully carry out its food safety responsibilities. This examination could include, but not be limited to:

- An evaluation of whether FDA's food budget over the past 10 years has kept pace with inflation and with new responsibilities;
- An assessment of staffing by key component or function;
- An analysis of the impact of user fees for drugs, biologics, and devices on the funds available for food oversight; and
- An evaluation of FDA management's approach to overseeing its work, given the dynamic environment in which it now finds itself.

* * *

Although FDA's drug and device review programs are supported by user fees, several key components of FDA's oversight of drugs and devices are not, or are clearly insufficiently, supported by user fees, including generic drug review, the scientific base of the agency; inspections and general enforcement; and oversight of clinical trials and enforcement of human subject protections. Therefore, we are requesting that you examine the tools, staffing, and other resources necessary for FDA to successfully carry out its responsibilities related to drugs and medical devices. This examination could include, but not be limited to:

- An evaluation of whether FDA's drug and device budget over the past 10 years has kept pace with inflation and with new responsibilities;
- A review of the extent to which the agency has been able to meet its medical product responsibilities not funded by user fees, such as inspections;
- An assessment of staffing by key component or function;
- A determination of whether the agency needs to refine or establish new management tools to help it track its accomplishments; and
- An evaluation of FDA management's approach to overseeing its work, given the dynamic environment in which it now finds itself.

* * *

FDA accomplishes its mission through its five centers — the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, the Center for Food Safety and Applied Nutrition, and the Center for

Veterinary Medicine. These centers rely on various information technology (IT) systems to support their principle functions. As such, having reliable and useful systems is important to the agency meeting its mission. Information management deficiencies could weaken FDA's regulatory programs, lead to inefficient uses of resources, or result in uninformed or misinformed decisions.

We are concerned that FDA has not been able to effectively modernize and use its IT systems to fulfill its mission needs. The FDA Science Board report concluded that "an information crisis is putting the FDA's mission at risk."[5] While the authors of the recent report believe that FDA is making some progress towards improving its IT systems, they conclude that there are "critical capability gaps" in FDA's information technology and science.[6] The report included the following findings:

- "The FDA lacks the information science capability and information infrastructure to fulfill its regulatory mandate;"[7]
- "The FDA cannot provide the information infrastructure support to regulate products based on new science;"[8]
- "The FDA IT infrastructure is obsolete, unstable, and lacks sufficient controls to ensure continuity of operations or to provide effective disaster recovery services;"[9] and
- "The IT workforce is insufficient and suboptimally organized."[10]

Other reports have pointed out information deficiencies in specific programs. A past report by GAO (GAO-06-402) noted that FDA faced data constraints in making post-market drug safety decisions. In addition, a recent report from the Department of Health and Human Services' Office of Inspector General (OEI-01-06-00160) found that even though FDA maintains six databases to track Bioresearch Monitoring Program inspections, none includes complete information needed to track all such inspections. According to the report, these weaknesses in

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[5] *FDA Science and Mission at Risk, supra* note 1, at 46.

[6] *Id.* at 47.

[7] *Id.*

[8] *Id.* at 49.

[9] *Id.* at 50.

[10] *Id.* at 51.

FDA's IT systems obstruct its ability to oversee clinical trial inspections and ensure the protection of trial participants.

In order to fully understand the extent to which deficiencies in FDA's IT systems impair the agency's ability to execute its mission, and the actions and resources necessary to correct those deficiencies, we request that GAO conduct a review of FDA's IT systems, focusing on the following questions:

1. What are the mission-critical IT systems and infrastructure that FDA centers rely on to conduct their missions?
2. What studies or other efforts have been made to identify shortcomings, such as data limitations and inadequacies in the agency's IT infrastructure, in FDA's IT systems?
3. What IT system modernizations efforts are underway and planned by FDA and to what extent do they address identified shortcomings? What is the status of these efforts?
4. Does FDA have established processes to guide the implementation and management of its planned and ongoing IT modernization projects, and what challenges, including funding shortfalls, does it face in ensuring the success of these projects?

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Although our government faces financial constraints, we cannot afford to put FDA in a situation in which it cannot succeed. Your assistance in this matter is greatly appreciated. If you or your staff has any questions, please do not hesitate to contact Stephen Cha of Rep. Waxman's staff at (202) 225-5056 or David Dorsey of Sen. Kennedy's staff at (202) 224-7675.

Sincerely,

Henry A. Waxman
Chairman
House Committee on Oversight
and Government Reform

Edward Kennedy
Chairman
Senate Committee on Health, Education,
Labor, and Pensions