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ONE HUNDRED TENTH CONGRESS

# Congress of the United States

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December 3, 2007

The Honorable Michael O. Leavitt  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Mr. Secretary:

I am writing to express my profound concern about the findings of the FDA Science Board's Subcommittee on Science and Technology, which were released last week. According to the Subcommittee's report, funding shortages at FDA have endangered public health. As the Subcommittee reported:

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.<sup>1</sup>

In recognition of the critical role that FDA plays in the overall health and well-being of Americans, Commissioner Andrew C. von Eschenbach requested that the Science Board examine whether FDA's science and technology capacity is adequate to support the agency's current and future regulatory needs. The Subcommittee's report paints a dire picture of a chronically underfunded public health agency. The Subcommittee found that the FDA's scientific capacity has been so eroded that it can no longer fulfill a frightening number of critical regulatory and public health responsibilities:

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

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<sup>1</sup> Subcommittee on Science and Technology, *FDA Science and Mission at Risk*, 6 (Nov. 2007) (online at [http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007\\_4329b\\_02\\_01\\_FDA %20Report%20on%20Science%20and%20Technology.pdf](http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007_4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf)).

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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. ... [I]f these gaps are not addressed immediately, FDA is in jeopardy of losing its remaining dedicated staff. The extraordinary efforts of these committed FDA staff members are the very reason further catastrophic food and drug events have been averted.<sup>2</sup>

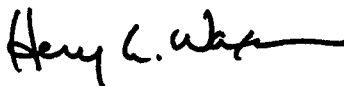
The Subcommittee further recognized that the severe loss of scientific capacity at FDA threatens not only the health of our citizens, but the viability of the industries FDA regulates, the speed of medical innovation, and the security of our nation.<sup>3</sup>

The report cited two primary causes for the grave deficiencies it identified: the ever-increasing number of demands on the agency combined with resource levels that are wholly inadequate to allow the agency to keep pace with those demands. Consequently, according to the report, the agency has been reduced to "management by crisis."<sup>4</sup>

These are urgent and compelling findings. I would like to know what steps you intend to take to restore FDA's capacity to ensure the safety of food and drugs and protect the public health.

There is much that you can do to strengthen FDA so that it is prepared to meet these challenges, starting with requesting adequate funds and resources for FDA. I have asked Commissioner von Eschenbach to ensure that his budget request to the Department of Health and Human Services reflects the urgency of this report. I urge you to ensure that the budget request that you submit to the White House also includes sufficient resources for FDA.

Sincerely,



Henry A. Waxman  
Chairman

cc: Tom Davis  
Ranking Minority Member

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<sup>2</sup> *Id.* at 7.

<sup>3</sup> *Id.* at 1-2, 26.

<sup>4</sup> *Id.* at 24.