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July 28, 2010

The Honorable Kathleen Sebelius
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Sebelius:

As you work to develop the President's budget for Fiscal Year 2012, we respectfully urge you to make the Food and Drug Administration (FDA) a major priority.

Consistent funding increases over a sustained period of time are essential to ensuring that the agency is able to effectively evaluate new and emerging treatments. However, while FDA regulates products that represent nearly 25 percent of consumer spending, their FY10 staffing level from budget authority appropriations is the same as it was in 1994.

As such, the agency faces severe resource constraints, stretched thin by years of chronic underfunding and an exponential increase in the agency's public health responsibilities, including serious threats such as bioterrorism, the H1N1 Influenza Virus, and the increasing globalization of the products FDA regulates. It is critical that this trend of chronic underfunding be reversed.

In order to be effective, the FDA needs to employ a sufficient number of reviewers to evaluate new treatments. In the past five years, the Cystic Fibrosis Foundation has invested hundreds of millions of dollars in basic research and drug development, and due to this investment our drug pipeline now contains thirty therapies to treat CF. Inadequate resources at FDA slow the approval process for such treatments, hindering the distribution of therapies that could help CF patients live longer, healthier lives.

In addition to securing enough reviewers, FDA must also possess the funding it needs to employ those with the particular expertise to evaluate treatments for rare diseases like CF, ensuring that enough attention is paid to ailments that affect small populations. They can only do this if they have adequate resources.

Continuing chronic underfunding of FDA affects our public health, hinders our economy, and compromises our national security. We are requesting at least a twenty percent increase over the FY11 budget.

Thank you for your leadership on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert J. Beall". The signature is fluid and cursive, with a prominent initial "R" and a long, sweeping underline.

Robert J. Beall, Ph.D.
President and Chief Executive Officer