

July 15, 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 restoring the agency's capacity to handle a rapidly growing list of complex public health responsibilities.

The agency's public health responsibilities have exponentially increased – from the management of serious threats such as bioterrorism and the H1N1 Influenza Virus to the increasing internationalization of the products FDA regulates. And yet, the agency's funding levels so inadequately reflect the expansive nature of the agency's tasks at hand.

FasterCures is a nonprofit think tank and center of the Milken Institute that works across sectors and diseases to improve the effectiveness and efficiency of the medical research enterprise. We cannot accelerate medical progress if we do not have a robust, scientifically sound FDA. The real potential of scientific breakthroughs and cutting edge medical solutions to improve the lives of patients, even cure disease, will not be actualized without appropriately resourced review and regulatory processes. *FasterCures* is, and will continue to be, an advocate for the agency, but deficiencies in capital – human, scientific, and financial – are creating a widening gap between microscope and marketplace that curtails the FDA's ability to achieve its mission.

For an agency that regulates products that represent nearly 25 percent of consumer spending in America, its FY10 staffing level from budget authority appropriations is the same as it was in 1994. With the majority of its budget going to staff and operational costs, at the current rate of growth the agency will be unable to sustain, much less expand, its current scope. FDA needs excellent staff with scientific expertise, but it also needs strong, selective scientific research programs that are appropriately mission-driven in all of the areas of FDA responsibility (e.g. generic biologic review, adverse event tracking, drug import field exams, and foreign manufacturing facility review) in order to carry the baton of innovation from the research community over the regulatory "finish line" and into the hands of patients.

Continuing chronic underfunding of FDA affects our public health, hinders our economy, and compromises our national security. Together with the Alliance for a Stronger FDA, of which we are a member, **we are requesting at least a twenty percent increase over the FY11 budget.**

Thank you for your leadership on this important issue.

Sincerely,



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