

July 14, 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 FY 10 staffing level from budget authority appropriations is the same as it was in 1994.

As you know, FDA regulates products that represent nearly 25 percent of consumer spending in America. However, today's FDA faces severe resource constraints due to 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.

Of primary concern to members of the Association of Clinical Research Organization is the FDA's ability to oversee and inspect foreign clinical trials. In June, the HHS Office of the Inspector General released a report on this topic that included recommendations for the FDA to: require standardized electronic clinical trial data; monitor trends in foreign clinical trials not conducted under INDs; and continue to explore ways to expand the oversight of foreign clinical trials.

ACRO endorses all of these recommendations, particularly the third, and urges increased funding for the FDA's Office of International Programs, which we see as a crucial link to improved oversight of foreign clinical trials and coordination with other national regulatory agencies. ACRO member companies have invested billions of dollars building a global clinical research infrastructure to make the drug development process faster and more efficient while maintaining quality and patient safety. FDA oversight of these activities is critical to preserve confidence in the clinical trials process.

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.

Warmest Regards,



Douglas Peddicord, PhD
Executive Director