



U.S. Pharmacopeia
The Standard of Quality™

July 29, 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, the United States Pharmacopeial Convention (USP) respectfully urges 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. For example, the agency's FY '10 staffing level from budget authority appropriations was the same as it was in 1994.

Continuing chronic underfunding of FDA affects our public health, hinders our economy and compromises our national security. We therefore join the 180+ - member Alliance for a Stronger FDA, <http://strengthenfda.org/> (of which we are a member organization), in requesting at least a twenty percent increase over the FY '11 budget.

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.

As a scientific, independent, volunteer-based, not-for-profit organization established in 1820, USP supports FDA's essential standard-setting mission, and we appreciate the work of the Agency. For more than 100 years, we have worked closely with FDA, developing and revising drug quality standards that are recognized in law and enforced by FDA. We also contribute to the Department of Health and Human Services (HHS) and its efforts to promote public health through our drug and dietary supplement standards, food ingredient standards, verification programs, and activities around the globe – including our laboratories in India, China, Brazil, and Rockville, Maryland. HHS is represented through the USP Convention, the leadership body of our organization; Dr. Donald Wright, Principal Deputy Assistant Secretary for Healthcare Quality, is the senior HHS delegate.

The USP-FDA partnership results in quick monograph revision to meet public health emergencies (e.g., heparin), and USP helps FDA save resources. As part of USP Expert Committee Process, FDA liaisons communicate regularly with USP, and FDA participates in USP workshops and meetings. FDA standards-setting committees also have links with USP. USP works with each FDA center and with FDA's overseas offices. FDA and USP have also worked on increasing and improving communications. We note all that FDA does to help protect the safety net and the public, and we urge you to strongly support this important work.

Thank you for your leadership on this important issue. Please let me know if we can provide additional information.

Sincerely,

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Chief Executive Officer

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