

For Immediate Release May 20, 2014

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Alliance on House FY 15 Funding for FDA: "FDA's Responsibilities Require Significantly More Funding"

House Marks Up Appropriation of \$2.583 Billion--A \$23 Million (<1%) Increase

Silver Spring, MD, May 20, 2014 – The Alliance for a Stronger FDA said today that the House Appropriations Committee's FY 15 budget level for FDA would leave the agency without enough funds to carry out its many responsibilities and functions, particularly those assigned to it by recent legislation.

At \$2.583 billion for FY 15, the agency's appropriation would increase by only \$23 million over FY 14, less than a 1% increase. The Alliance, whose almost 200 members represent a cross-section of FDA stakeholders, emphasized that "substantially greater increases are needed for FDA to maintain the level of activities in which it will be engaged on behalf of the American public next year."

"In this time of continuing deficit reduction pressures, we understand the difficult fiscal environment under which the Congress is operating," said Kasey K. Thompson, Pharm.D., M.S., President of the Alliance and Vice President, Office of Policy, Planning and Communications at the American Society of Health-System Pharmacists (ASHP).

He continued: "This budget proposal would leave FDA short-handed in many areas, which we think the American people will regard as unacceptable. FDA's funding needs to be increased further—well above the FY 14 level--to reflect the agency's vast public health responsibilities and continually increasing workload. If the FDA does not have the resources to fulfill its mission, there are no other Federal, state or private agencies that provide a fallback."

Under the House numbers, food programs (CFSAN + CVM) would grow \$23 million (slightly more than 2%), despite the substantial and immediate demands of implementing the Food Safety Modernization Act, estimated at \$200 million. The remainder of FDA (including medical products programs) is essentially flatfunded (no growth). As a result, FDA will be receiving no new net funding to implement a wide variety of global and scientific initiatives plus legislative mandates for a biosimilars approval pathway, drug and device safety and promotion of innovation, and the recently enacted Drug Quality and Security Act.

"Alliance members remain committed to assuring that FDA is adequately funded," said Jeff Allen, PhD, Vice President of the Alliance and Executive Director of the Friends of Cancer Research (FOCR). "It is a national priority for FDA to have the resources it needs to meet the challenges of a changing global economy, food safety and medical advances."

The importance of FDA and its regulated industry to the American economy is detailed in the Alliance's white paper: FDA: A Cornerstone of America's Economic Future.

The Alliance's nearly 200 members are comprised of consumer, patient, professional and research groups, companies, trade associations, and individuals who support increased appropriated funding for FDA. The Alliance is the only multi-stakeholder group that advocates for increasing resources at FDA to match the agency's responsibilities. More information about the Alliance can be found at www.strengthenFDA.org.

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May 20, 2014—PRELIMINARY ANALYSIS

Administration and House FY 15 Proposed FDA Funding

Vs. FY 12, FY 13 Post-Sequester, and FY 14 Budget Authority Appropriations for FDA (does not include user fees)

--Not all numbers add due to rounding--

Function	FY 12	FY 13 Actual	FY 14 Final	FY 15 Administration Reques
Budget Authority (BA) only,		Post-rescission,		AND
by center; no user fees		post-sequester		House Proposal5/20/14
Food	\$ 867 million	\$ 797 million	\$ 883 million	\$ 903 million
Human Drugs	\$ 478 million	\$ 438 million	\$ 466 million	\$ 471 million (House) (vs. \$480M Administration)
Biologics	\$ 212 million	\$ 195 million	\$ 211 million	\$ 211 million (House) (vs. \$210M Administration)
Animal Drugs/Feed	\$ 138 million	\$ 126 million	\$ 142 million	\$ 145 million
Devices & Radiological Health	\$ 323 million	\$ 296 million	\$ 321 million	\$ 321 million (House) (vs. \$318M Administration)
Natl. Ctr. For Toxicological Research	\$ 60 million	\$ 55 million	\$ 62 million	\$ 62 million (House) (vs. \$59M Administration)
HQ, Officer. of Commissioner & Other	\$ 154 million	\$ 160 million	\$ 172 million	\$ 175 million
Rent & Facilities Cost	\$ 266 million	\$ 269 million	\$ 295 million	\$ 285 million
SUBTOTAL, Salaries & Expenses	\$ 2.497 billion	\$ 2.335 billion	\$2.552 billion	\$2.574 billion (House) (vs. \$2.575B Administration)
Building and Facilities Repair	\$ 9 million	\$ 5 million	\$ 9 million	\$ 9 million
Food and Drug Safety Supplemental—No-Year		\$ 46 million		
All BA appropriations Total (no user fees)	\$ 2.506 billion	\$ 2.386 billion	\$2.561 billion	\$2.583 billion (House) (vs. \$2.584B Administration)

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