



P O Box 7508, Silver Spring, MD 20907-7508 • Tel: 202-887-4211 or 301-539-9660

A STRONG FDA IS GOOD FOR AMERICA*

The U.S. Food and Drug Administration (FDA) does not have the resources it needs to meet its existing responsibilities, prepare for the avalanche of new science in medicine and food, and assure U.S. defensive ability against bioterrorism. Those who know the agency best—particularly regulatory professionals—are well-aware that it needs more resources to do its job properly. When the FDA is strong, America benefits.

Until 2006, there had been no organization committed to increasing public awareness of, and generating support for, the FDA ... and no year-round source of information and advocacy on behalf of the agency's resource needs. To remedy this, the Alliance for a Stronger FDA was created to provide "education and advocacy to increase the appropriated resources available to FDA." The Alliance is a coalition of patient and consumer groups; health professional organizations; trade associations; food, drug, medical device, and biotechnology companies; and consultants and individuals.

The Alliance builds on a well-established model. Many parts of the government (notably NIH and its Institutes) benefit from independent, private organizations that educate and advocate on their behalf. This model has led to high levels of public awareness, favorable media coverage, grassroots involvement, and Congressional support for the mission and budget of the government agency involved.

FDA needs this type of outside advocacy. Before the existence of the Alliance, FDA received minimal new dollars annually. Yet, the agency's costs increase, its mission evolves, science expands, and inflation erodes budgets. The Alliance wants to ensure an FDA that is sized and modernized to meet its mandate in the 21st century.

Americans are often surprised that FDA does not have more resources. The agency's budget was \$1.57 billion in FY 06 (before the Alliance was formed) and has now grown to \$2.35 billion for FY 10. However, it is not nearly enough to cover activities and products that involve foods, human drugs, biologics, animal drug and feeds, medical devices, toxicological research, cosmetics, dietary supplements, and more.

FDA's budget is largely spent on people and their support. Monies cover salaries and benefits for the agency's 9,100 full time employees, building leases, travel, supplies, laboratory equipment, computers, etc. By comparison, the Centers for Disease Control and Prevention (CDC) received about \$6.5 billion in FY 10, not quite three times that of the FDA. Also for FY 10, the NIH received \$31.3 billion, more than 13 times what FDA has received for FY 10. Some U.S. school districts get as much or more money than FDA.

Yet, FDA oversees products that represent one-quarter of the US economy. Its responsibilities are global in scope and form the backbone of the world's economy. And it does all of that on a budget that costs Americans only \$8 per year.

As of January 2010, the Alliance for a Stronger FDA has more than 180 members and continues to grow. It is proud that three former HHS Secretaries and seven former FDA commissioners have chosen to become honorary members. The Alliance is already working with the Obama Administration to push for increases in the president's FY 11 budget request, to be released at the beginning of February 2010.

Throughout 2010, the Alliance will be active—in the halls of Congress and as a grassroots force in every state and Congressional district—delivering the message that FDA needs more resources.

**This commentary is revised from an article originally published in the January 2007 edition of Regulatory Affairs Focus.*