

AIMBE POSITION STATEMENT

AIMBE's Support of the Regulatory Mission of the Food and Drug Administration

ISSUE

Increases in oversight responsibilities within the Food and Drug Administration (FDA) have occurred without the necessary increases in funding to sustain the high quality efforts expected of the FDA.

BACKGROUND

In a recent report, the FDA Science Board's independent Subcommittee on Science and Technology stated in Congressional testimony that the "scientific demands on the FDA far exceed its capacity to respond. This imbalance is imposing a significant risk to the integrity of the food, drug, cosmetic and device regulatory system, and hence the safety of the public."

The FDA's budgets have not adequately reflected the critical role it plays in our nation's food safety system or its increasing responsibilities. For example, the number of Program Level Full-Time Employees (FTE) in FDA's Foods Program has declined from 3,082 in FY2004 to 2,613 in FY2007. This decline has coincided with a period of time in which the value of agricultural imports has increased dramatically from \$45.6B in FY03 to \$64B in FY06.

Other FDA programs, such as the Center for Devices and Radiological Health (CDRH), which is charged with ensuring safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation, faces similar declines in funding for research and staff. Bringing a medical product from the research stage to the patient requires a lengthy process, several years in the best cases — longer in most. Timely FDA regulation is critical to the innovation process. Currently for medical devices, a new version of a device could be created before the initial version is even approved by the FDA for marketing. These delays not only hinder the ability of practitioners and patients to choose and use new innovative technologies, but make the innovation process more expensive and cumbersome.

RECOMMENDATIONS

AIMBE supports the budget increases called for by the Alliance for a Stronger FDA, which include a \$330M increase over the President's FY08 budget request. Additionally, AIMBE supports legislation aimed at streamlining the approval process for medical devices, shrinking the time it takes for technology to go from the laboratory to the patient's bedside.

