Written Testimony of Diane E. Dorman, President, Alliance for a Stronger FDA,

Before the U.S. House Appropriations Committee

Subcommittee on Agriculture, Rural Development, FDA and Related Agencies

March 20, 2013

Re: FY 14 Appropriations for the U.S. Food and Drug Administration

Chairman Alderholt and Ranking Member Farr:

The Alliance for a Stronger FDA respectfully requests that the Subcommittee **recognize the critical role and expanding public health mission of the U.S. Food and Drug Administration and provide appropriations funding in FY 14 that fully restores the agency's base lost in the FY 13 sequester. Additional funding above this level is also needed and can be fully justified.**

The Alliance is a 200-member coalition of all FDA's stakeholders—consumers, patients, health professionals, trade groups and industry. Our sole purpose is to advocate for increased appropriated resources for the FDA, an agency that oversees 100% of drugs, vaccines, medical devices, and personal care products and 80% of our nation's food supply. Altogether, the products and industries regulated by FDA account for nearly 25% of all consumer spending in the United States.

FDA's pre-sequestration budget authority (BA) appropriation of $2.5 billion is dramatically less than the amount the agency needs. The sequestration and FDA's growing public health and safety responsibilities puts the agency's mission "at risk."

Recognizing that FDA's public health mission is vital and growing, Congress continues to pass FDA legislation

New laws take enormous resources to implement. Once implemented, they permanently increase agency responsibilities. Since 2009, Congress has identified a number of additional public health needs that fall within FDA's jurisdiction, resulting in at least six new laws:

- Family Smoking Prevention and Tobacco Control Act (2009)
- Biologics Price Competition and Innovation Act (2010)
- Secure and Responsible Drug Disposal Act (2010)
- Combat Methamphetamine Enhancement Act (2010)
- Food Safety Modernization Act (2011), and
- FDA Safety and Innovation Act (2012), including re-authorization of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act

This year's legislative requirement--renewal of two Animal Drug User Fees--is a possible vehicle for other FDA mandates. Free-standing legislation is also being considered for: compounding; counterfeit/track and trace; drug shortages; and incentives for innovation.

In sum, the current appropriations level is totally inadequate to make up for decades of underfunding AND all of the new laws enacted since 2009 and also under consideration.

Globalization and Scientific Complexity Require FDA to Expand its Activities Each Year to Protect and Expand Public and Individual Health

Even were Congress not active in legislating new mandates for FDA, the agency's mission and responsibilities would grow enormously each year for reasons unrelated to new laws. Our remarks will concentrate on two: globalization and increasing scientific complexity.

One of FDA's highest priorities over the last 6 years has been to adjust for the accelerating globalization in all product categories overseen by the agency. For example:

- **Food Imports are growing 10% annually.** Altogether, 10-15% of all food consumed in the U.S. is imported. This includes nearly 2/3 of fruits and vegetables and 80% of seafood.
- **Device Imports are also growing about 10% annually.** Currently, about 50% of all medical devices used in the US are imported.
- **Drug Imports are growing even more quickly, about 13% annually.** About 80% of active pharmaceutical ingredients (API) are manufactured abroad, as are 40% of finished drugs.

Inspections at U.S. ports-of-entry are critical, but ultimately less than 2% of shipments can be inspected. Instead, FDA is following Congressional direction by increasing foreign inspections and establishing foreign offices to work globally to improve the standards and quality of products entering the U.S.

The value of this approach cannot really be quantified. The cost of illness, death and lost markets--from just a single bad actor in a single food category--can cost as much or more than the entire investment we put into FDA's food safety activities. Drugs and devices are harder to track for a variety of reasons, but there is no reason to doubt a similar effect.

Greater scientific complexity is diffused into every part of the agency and its mission. FDA has adopted a number of initiatives, including creation of a commissioner-level science office, investment in regulatory science, expanded and more intensive training, changes in time and manpower allotments for complex assignments, and significant reworking of the drug and medical device approval pathways.

Specifically, we have identified five areas in which FDA is improving product reviews to respond to more complex science. Each comes at a cost in additional dollars/manpower:

- Sponsors Need More Meeting Time and Other Feedback from FDA
- Applications Require More Patients, Study Sites and Analysis
- Enhanced Timeliness and Consistency of Product Review
- Expansion of Pre-and Post-Market Safety
- Enhance Innovation, Speed Approvals

Further, safety inspections have also become more complex—requiring more scientific training, more preparation and, often, more time during the inspection itself.

FDA's vital, complex world-wide public health responsibilities cannot be accomplished with its existing budget, particularly post-sequestration. The agency's mission is "at risk."

FDA is a staff-intensive organization. More than 80% of its budget is devoted to staff-related costs. If the agency budget fails to grow over the next few years:

- food will be less safe and consumers put at risk,
- drug and device reviews will be slower, conflicting with promises made to consumers and companies,
- problems with imports and globalization will become more numerous, and
- critical efforts to modernize the agency and improve its support for innovation will stall.

FOR MORE INFORMATION: www.StrengthenFDA.org or contact Ladd Wiley, Executive Director of the Alliance at (202) 549-3595 email: lwiley@strengthenfda.org