



**For Immediate Release**  
**September 28, 2015**

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## **Alliance Praises New FDA Science Board Report, Says It Reinforces Need for More FDA Resources**

### **Blueprint for Meeting Patient/Consumer Needs Through a Modernized, Well-Resourced FDA**

Silver Spring, MD, September 28, 2015 –The Alliance for a Stronger FDA today urged that special attention be paid to a new report from the FDA Science Board, entitled [“Mission Possible: How FDA Can Move at the Speed of Science.”](#)

Intended as a follow-up to the Science Board’s 2007 report, entitled “FDA Science and Mission at Risk,” the new report describes significant progress since 2007. However, the report also notes that FDA’s mission continues to be “at risk.” This is “due to an expanding and extraordinary range of increasingly complex responsibilities and insufficient resources with which to address them.”

The report identifies specific areas that FDA needs to address. For example, the report urged FDA to facilitate the qualification of biomarkers, including surrogate endpoints, for new therapies, and “use new data-mining and analytical tools to evaluate the efficacy and safety of new medical products, including full deployment of FDA’s Sentinel Initiative and its expansion to medical devices.”

The report expressed concern “about the weaknesses in FDA’s food program” and urges additional resources as part of its recommendations. Specifically, it recommends that FDA undertake a series of actions, including “conduct of targeted regulatory science research to develop hazard mitigation strategies or preventive controls” and expand FDA’s “under-resourced nutrition initiatives to empower the consumer to make the best nutritional choices.”

“The new Science Board report provides a clear-eyed assessment of what needs to be done for FDA to keep pace with rapidly advancing science and remain the cutting-edge public health agency that our nation needs. As such, the report is warmly welcomed by the FDA stakeholder community. This is a must read for all of us concerned about the agency’s resource needs to execute future priorities and build the scientific capacity of

the FDA,” said Jeff Allen, PhD, President of the Alliance and Executive Director of Friends of Cancer Research.

He added: “We believe FDA has the perseverance and the foresight that will be needed to make the report’s recommendations into reality. We also know that significant additional funding is needed and the Alliance will continue our work with Congress to make this happen.”

The FDA Science Board, which released the report at its September 15 meeting, advises the Commissioner by evaluating the agency’s scientific efforts and projecting future needs. Its seminal 2007 report is widely credited with stimulating public and policymaker concern that FDA’s scientific mission was “at risk” without additional focus and additional resources. Over the past eight years, the agency has created the Office of Chief Scientist, boosted training and research, stimulated regulatory science and received additional monies.

“The Science Board also pointed to the additional challenges since the 2007 report: substantial new responsibilities in every area of FDA jurisdiction; massive expansion of globalization; and dramatic breakthroughs increasing scientific complexity,” said Cynthia Bens, Vice President of the Alliance and Vice President for Public Policy of the Alliance for Aging Research. “No other Federal, state or private agency provides a fallback if FDA can’t fulfill its ever-growing mission.”

“The Alliance urges Congress, OMB and HHS to review this latest report from the FDA Science Board. It tells a compelling story of FDA’s agenda for self-improvement and the multiple areas in which it needs support for future progress,” said Troy Zimmerman, Alliance Board Member and Vice President, Government Relations at the National Kidney Foundation.

He added: “If the budget cap for FY 16 non-defense discretionary spending is increased, we expect that FDA will be given serious consideration for additional funding.”

**The Alliance for a Stronger FDA’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](http://www.StrengthenFDA.org).

**The FDA Science Board** provides advice to the Commissioner and other appropriate officials on specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice that supports the Agency in keeping pace with technical and scientific developments, including in regulatory science; and input into the Agency’s research agenda; and on upgrading its scientific and research facilities and training opportunities.

The FDA Science Board's latest report "Mission Possible: How FDA Can Move at the Speed of Science" is attached and can also be found at:  
<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM463328.pdf>.

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