Pillar 1 — 2011 Accomplishments

Pillar 1: Enhance FDA's product review and approval processes for the highest priority MCMs and related technologies

- Established ***MCMi Action Teams.*** FDA is fully engaged with its Enterprise partners — including ASPR, BARDA, CDC, and DoD — to stay abreast of MCM priorities and requirements. FDA is establishing Action Teams based on those priorities and in alignment with investments in medical countermeasure programs:
  - Action Team on multiplex in vitro diagnostic tests: The goal of this Action Team is to identify and help resolve scientific, legal, regulatory, and policy gaps inhibiting the development of multiplex in vitro diagnostic tests. Such diagnostics could be used to test for multiple pathogens simultaneously, providing invaluable information when responding to a public health emergency.
  - Action Team on therapies for radiation sickness: Acute radiation syndrome occurs when the entire body — or the majority of it — receives a high dose of radiation as would be expected to occur after a radiological or nuclear event. The goal of this Action Team is to support the development and approval of candidate MCMs to treat acute radiation syndrome. The scope of the Action Team is also being expanded to address radiation biodosimetry, which is a high-priority for facilitating an effective response to a radiological or nuclear event.
- Developing a ***memorandum of understanding (MOU)*** to facilitate information sharing with Enterprise partners. Action Teams must collaborate extensively with Federal partners in the Enterprise (e.g., DoD, DHS, other HHS agencies), including the sharing privileged information.
- Scheduled and planning ***three workshops*** to obtain scientific and public input on the regulation of complex in vitro diagnostic tests (September 2011), on development and evaluation of next-generation smallpox vaccines (September 2011), and on MCMs for pediatric populations (winter 2012).
- Established ***CDC/FDA Strategic Leadership*** group, which holds quarterly meetings for threat-based prioritization of regulatory and preparedness issues.
- Working to identify ***regulatory gaps to support effective use*** of stockpiled MCMs, with a focus on at-risk populations, especially the pediatric population.
- Continuing and expanding FDA's MCMi professional development program to include ***threat briefings by relevant experts*** to make sure FDA reviewers are fully aware of the threats (and therefore the risks) as they conduct risk–benefit analyses on MCM products.