Charge to the CBER Research Review Subcommittee

The Center for Biologics Evaluation and Research regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug and Cosmetic Act. CBER protects and advances the public health by ensuring that biological products are safe and effective and available to those who need them. CBER also provides the public with information to promote the safe and appropriate use of biological products. CBER regulates a wide range of products from vaccines to cell and gene therapy, blood and blood products and related devices.

CBER Vision for Regulatory Science: To conduct scientific research of the highest quality and relevance, that is integral to the Center's regulatory mission and public health portfolio, proactive and anticipates regulatory and public health needs, and in direct support of CBER's regulatory decision-making and policy development responsibilities.

In 2015, CBER hired McKinsey Consulting Company to review how CBER manages and supports regulatory science. The outcome of that engagement has been to augment management processes with new governance, new tools for communication, and some changes to the way funding is provided to support research programs. CBER performs external peer review of all laboratory programs every four years, and periodically has done broader Center or Office-wide reviews of the scientific program. As we move into our second full year of using the new approaches to manage and govern research at CBER, we now want to evaluate the ongoing overall research portfolio and look strategically to the future research agenda.

Charge to the FDA Science Board: The FDA Science Board is charged with conducting a review to assess how CBER's regulatory science portfolio can best anticipate and address biological products that are emerging or on the horizon, as reflected in ongoing scientific research, as well as new public health concerns from currently marketed biologic products. The subcommittee should consider the broad scientific disciplines and technologies that CBER needs to support its regulatory functions and decision making.

Specifically, the Board is asked to address the following question:

- Given the existing breadth of CBER's current and anticipated future regulatory portfolio and responsibilities, are there changes CBER should make to its regulatory science research portfolio to best accomplish our regulatory and public health mission?
  - Assess any gaps in regulatory science capabilities or expertise.
  - Identify scientific areas where CBER should make programmatic and resource changes.
  - Identify opportunities for collaboration to better leverage CBER's regulatory science programs.