

FDA: Advancing Medical Innovation

Recommendations for improving FDA scientific expertise and capacity

In order to accelerate the development of new, safe, and effective treatment and cures, the U.S. Food and Drug Administration (FDA) must have adequate scientific expertise, staffing, and other resources (including effective use of public-private partnerships) to successfully carry out provisions of medical innovation legislation.

Recommendations:

Assure adequate capacity, scientific expertise at FDA:

1. Require the FDA to conduct an organizational review process to identify gaps in scientific expertise, capacity to carry out FDA's mission, and opportunities for streamlining and using existing resources more efficiently.
2. Require FDA, working with HHS and the Office of Personnel Management, to modernize HR practices and systems to address expertise/capacity gaps, by performing and reporting to Congress within 12 months on:
 - a. Reviewing and improving recruiting, hiring, and retention strategies;
 - b. Implementing direct hiring authority;
 - c. Allowing the use of qualified blind trusts or other appropriate mechanisms to address conflict-of-interest concerns;
 - d. Exploring and improving personnel policies that support appropriate turnover; and
 - e. Implementing additional federal hiring policy exemptions (e.g., allowing more employees to exceed federal salary compensation caps).
3. Eliminate barriers that prevent FDA staff from attending scientific conferences and meetings, which are crucial to helping them keep up with the latest scientific developments.
4. Encourage FDA to expand its partnerships with academic institutions to raise awareness of the opportunities at the FDA and build a pipeline of talented graduates who can establish a career at the agency.
5. Encourage FDA to improve its IT infrastructure to support knowledge management and sharing, workflow management, and more effective communications across reviewers and centers, as well as with sponsors.
6. Waive certain OMB Paperwork Reduction Act requirements to further FDA's ability to more readily survey experts from industry, academia, patient groups, and other stakeholders to expand expertise.

Encourage effective use of public-private partnerships:

1. Reconfirm and encourage the FDA to use its existing authority to use partners and trusted intermediaries to augment FDA internal resources, particularly for novel or complex technologies that may be outside of the FDA's normal expertise.
2. Require the FDA to monitor, evaluate, and report on the outcomes and effectiveness of existing public-private partnerships to determine whether additional investment in these programs and/or further coordination and accountability associated with such programs is warranted, as well as whether outdated or ineffective public-private partnerships should be phased out.
3. Support the launch of a study to both assess current conflict of interest policies associated with advisory groups and develop recommendations that both effectively address conflict of interest concerns and enable FDA to gain input from a broad and representative set of individuals including patients, clinicians, and researchers.

Improve FDA's internal review processes:

1. Direct FDA to conduct and implement strategies in response to an organizational study of its review and approval processes which would: evaluate review times, identify root causes of delays, identify best practices, and recommend measurable goals/actions to support faster turnaround times. A best practices study of review divisions would also identify best practices that can be applied across divisions.
2. Direct FDA to develop an inter-agency education and training program to implement best practices across centers and divisions.
3. Direct FDA to establish a monitoring system to track and report progress against implementation goals and impact on drug and device review times.

For a full list of BPC recommendations on advancing medical innovation, see <http://bipartisanpolicy.org/library/advancing-medical-innovation-for-a-healthier-america/>