

**FISCAL YEAR 2012 BUDGET:
SUMMARY OF LIFE SCIENCE PROVISIONS**

By Agency

Department of Health and Human Services

- **Comparative Effectiveness Research (CER)**
Comparative effectiveness research is designed to inform health-care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options. *The President's FY '12 Request: \$46 million for the Agency for Healthcare Research and Quality (AHRQ) to support CER -- an increase of \$25 million over the FY '10 Budget.*

- **National Institute of Health (NIH)**
The NIH strives to maintain a diverse portfolio of biomedical research founded on both public health need and scientific opportunity. Additionally, the NIH is proposing to establish a new National Center for Advancing Translational Sciences (NCATS) on October 1, 2011. *The President's proposal provides an increase of \$745 million, or 2.4 percent, over the FY '10 level. FY '12 NIH Budget: \$32 billion.*
 - The Cures Acceleration Network (CAN) accelerates the development of "high need cures" through the reduction of barriers between research discovery and clinical trials. NIH aims to increase its focus on bridging the translational divide between basic science and therapeutic applications. *FY '12 Budget Request: \$100 million.*

- **Food and Drug Administration (FDA)**
The President's budget provides for FDA to enhance the safety and oversight of medical products and to establish a pathway for the approval of generic biologics, thus allowing greater access to life saving biological products that are safe and effective. The budget calls for \$2.7 billion in funding for FDA -- \$872 million is related to human and animal drugs and biologics and \$329 million to devices and radiological products. User fee changes include new fees related to food safety and a new generic drug user fee (\$40 million) and re-inspection fees (\$14 million) for medical products. This new user fee requires manufacturers to pay the full costs of re-inspections "if they fail to meet FDA health and safety standards during an initial inspection." *The President's proposal provides a net program level increase (including user fees) of \$1 billion, or 33 percent, over FY '10. FY '12 Budget Request: \$4.4 billion.*

- Biosimilars: the President’s budget requests an additional *\$15 million* to allow FDA to begin to establish a regulatory pathway for the approval of generic biologic products as authorized by the Healthcare Reform Law. The Administration is proposing a five-year reduction (from 12 years to 7 years) in the new law’s data exclusivity period along with prohibition on “evergreening.”
- **Centers for Disease Control and Prevention (CDC)**
The mission of the Centers for Disease Control and Prevention (CDC) is to collaborate to create the expertise, information, and tools that people and communities need to protect their health. *FY ‘12 Budget Request (for CDC and ATSDR): \$11.3 billion. \$371 million increase above FY ‘10.*
 - CDC’s Healthcare Associated Infection (HAI) activities promote healthcare quality through the prevention of HAIs, including those caused by pathogens such as Methicillin-resistant Staphylococcus aureus (MRSA) and multi-drug resistant gram-negative bacteria. *FY ‘12 Budget Request: \$47 million. \$32 million above FY ‘10.*
 - Biodefense: Great progress in preparing for public health emergencies has been made with the federal investment at the state and local levels. However the President’s request provides a \$70 million decrease below FY ‘10. *FY ‘12 Budget Request: \$1.45 billion.*

Research and Experimentation Tax Credit

- The President proposes to make the **R&E Credit** permanent (*costing \$106 billion over 10 years*) to give businesses greater confidence to invest in innovation and create jobs here in the United States. Additionally, the President calls for increasing the rate of the alternative simplified research credit from 14% to 17%, effective after December 31, 2011.

Department of Commerce

- **National Institute of Standards and Technology (NIST)**
NIST promotes U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology. Funding NIST will accelerate the discovery, development and deployment of a wide variety of new, innovative technologies. *FY ‘12 Budget Request: \$764 million, an 8.9 percent increase from FY ‘10.*
- **Technology Innovation Program (TIP)**
TIP is designed to foster the development of high-risk, transformative research targeted to address key societal challenges. TIP was originally created by the COMPETES Act of 2007, which was recently reauthorized. TIP has supported research in industry and academia in a variety of fields including, biomanufacturing. *FY ‘12 Budget Request: \$75 million.*
- **U.S. Patent and Trademark Office (USPTO)**
Intellectual property is essential to the life sciences industry’s ability to attract capital, so the USPTO plays a pivotal role. The 2012 Budget reforms the patent process and strengthens the fee structure by requesting the USPTO have full access to its fee collections. Legislation restructuring and increasing patent fees was enacted for 2005 and 2006 and subsequently extended. An additional request has been made for an extension of these provisions in 2012,

along with a surcharge on patent fees to provide additional resources to decrease the current backlog of patent applications. *The President's proposal is a \$2.1 billion increase from 2010 actuals. FY '12 Budget Request: \$2.7 billion.*

- **Regional Innovation Program/Economic Development Administration (EDA)**
Regional Innovation Clusters are collections of businesses and organizations in the same field with open channels of communication between them. Clusters include: science and research parks, broadband/smart grid technology, and business incubators. The Regional Innovation Program was authorized in the recent America COMPETES Reauthorization Act. *FY '12 Budget Request: \$325 million (to the EDA for planning support).*

Department of Education

- **Preparing Science, Technology, Engineering & Math (STEM) Teachers**
The industry's continued growth and vitality depends largely on well-educated and talented scientists and engineers. The Budget proposes to overhaul the "TEACH Grant" program, as of the end of the 2011–2012 academic year, and replace it with a targeted teacher recruitment and retention program called the Presidential Teaching Fellows. This includes helping to train effective STEM teachers. The President has the goal of preparing 100,000 STEM teachers over the next decade. *FY '12 Budget Request: \$80 million.*
- **Education Improvement Programs**
Looking forward to the reauthorization of the Elementary and Secondary Education Act (ESEA), education proposals look to restructure K-12 funding and to encourage states to adopt standards which would prepare all students for college and a career thereafter. Funds would support competitive grants to states to implement comprehensive strategies to improve the teaching and learning of STEM subjects. *FY '12 Budget Request: \$835 million (to support a well-rounded education, including STEM subjects).*

National Science Foundation

- **Participation in the Science, Technology, Engineering & Math (STEM) fields**
Science and technology skills are critical to getting high-skills, high-paying jobs. The President's proposal is a comprehensive approach to engaging K-12 and college students in these subjects. K-12 programs would provide new instructional materials for students and teachers that incorporate the latest advances in teaching, learning, and educational technologies. Undergraduate programs would improve curricula, strengthen laboratory course offerings, enhance faculty, and lead reform efforts specifically in the STEM disciplines. *FY '12 Budget Request: \$20 million.*
- **Preparing STEM teachers (teaming w/ Dept. of Education)**
The President proposes to begin a new teacher-training research and development program for K-12 teachers and undergraduate instructors by enhancing teacher education opportunities that support the full continuum of STEM teacher education from pre-service and in-service, through life-long learning. *FY '12 Budget Request: \$20 million K-12 STEM; \$20 million Undergraduate STEM; Total: \$40 million.*