New FDASIA Legislation Will Help Biotechs

The need to invest in the regulatory environment to support biotechnology innovation is urgent, says Jim Greenwood, president and CEO, Biotechnology Industry Organization

In a recent discussion with BIOTECHNOLOGY HEALTHCARE, Biotechnology Industry Organization (BIO) president and CEO Jim Greenwood underscored the need for change in the U.S. Food and Drug Administration's drug approval process and the reimbursement landscape. "Regulatory uncertainty," Greenwood says, "can have a major negative impact on the private funding of biomedical innovation and can hinder the ability of biotechs to deliver new medicines."

FDASIA highlights

- Adds new user fee categories for biosimilars and medical devices
- Creates a new risk-benefit assessment framework for drug approvals
- Calls for optimization of global clinical trials
- Provides for modified Risk Evaluation and Mitigation Strategies (REMS)
- Speeds up approval process for breakthrough drugs and therapies that treat life-threatening conditions
- Encourages the FDA to build its expertise in nanomaterials to assist diagnostic and biotech companies
- Calls for a strategic integrated management plan for the Center for Biologics Evaluation and Research

Source: PwC Health Research Institute

Greenwood says that the Prescription Drug User Fee Act (PDUFA), reauthorized in July under the FDA Safety and Innovation Act of 2012 (FDASIA), is a significant step in this direction. The FDASIA, he says, will help to promote a "21st century" FDA that can speed breakthrough products to the patients who need them while helping the agency retain its position as the global "gold standard" for the review and approval of safe and effective medications.

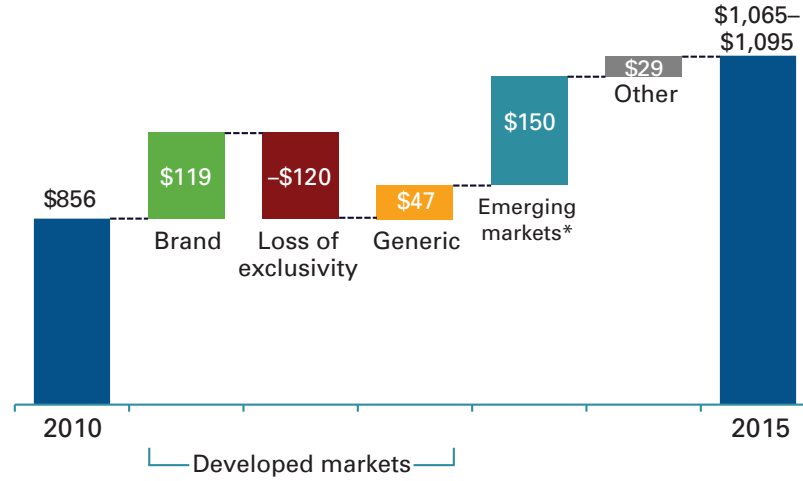
Jim Greenwood

"The FDASIA will improve transparency and communication between the FDA and drug sponsors, thereby leading to greater accountability and predictability in the drug evaluation process." BIO and Pharmaceutical Research and Manufacturers of America intend to work with the FDA to ensure that implementation of the FDASIA helps PDUFA live up to its potential. "If FDASIA is

New global pharmaceutical markets and generics will drive growth in the next 5 years

- The largest segment of growth will be emerging pharmaceutical markets* driven by reforms and economic growth. Reforms include the passage of the Affordable Care Act in the U.S., new guidelines for the approval of biosimilars, and spending priorities in major European countries and Japan.

Components of change in total spending (US dollars, in billions)



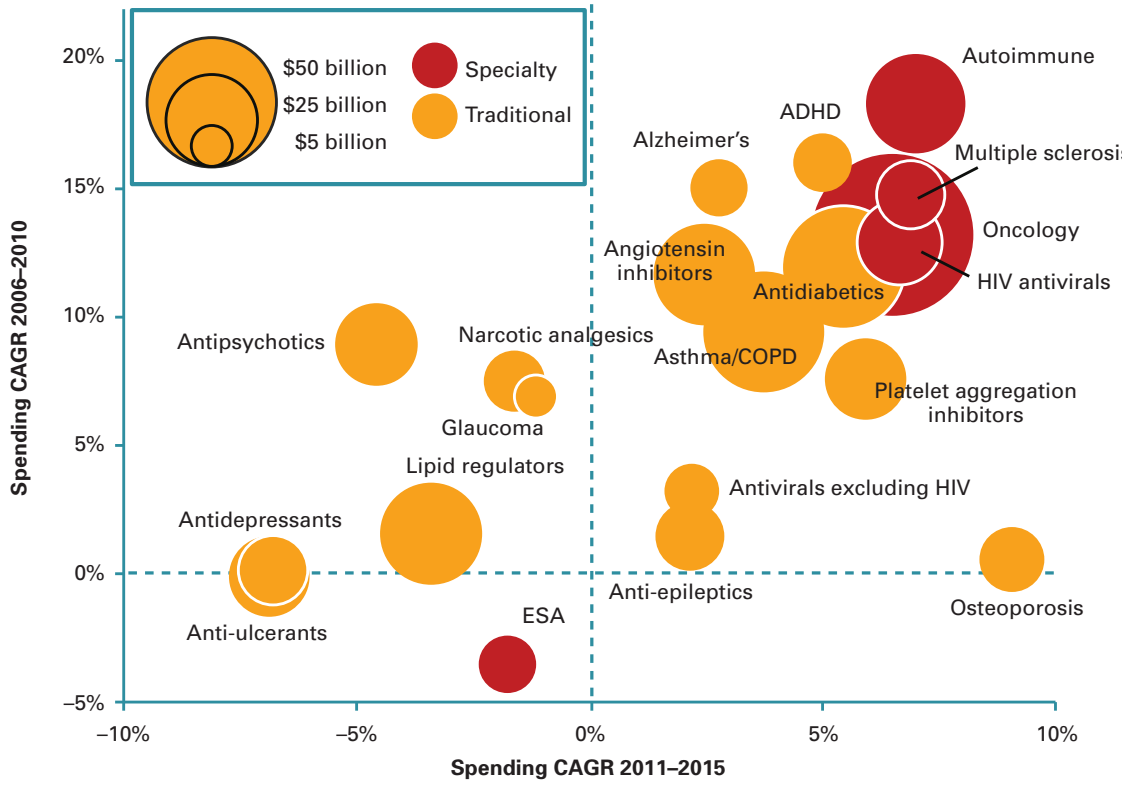
*Emerging markets = U.S., Japan, Germany, France, Italy, Spain, Canada, U.K., and South Korea

Source: IMS Market Prognosis, April 2011

Specialty drug spend will increase through 2015

- Utilization of specialty medications will experience continued growth driven by novel mechanisms of action, improved efficacy, and relatively large patient populations.
- Growth is decelerating in most other therapy areas due to patent expirations and the lack of significant new treatment options.

Spending figures are in U.S. dollars. Bubble size reflects 2015 spending estimates. Specialty therapies include products that are injectable and high-cost and that require patient follow-up or monitoring.



ADHD=attention deficit hyperactivity disorder, CAGR=compound annual growth rate, COPD=chronic obstructive pulmonary disease, ESA=erythropoiesis-stimulating agents, HIV=human immunodeficiency virus.
Source: Adapted from IMS Institute for Healthcare Informatics, Therapy Forecaster, May 2011

implemented correctly," Greenwood says, "a more streamlined and forward-thinking regulatory review process will ensure that innovative biotech firms can focus resources where they belong — on R&D that leads to scientific breakthrough medicines and cures."

Greenwood believes that access to quality patient care and outcomes must be the cornerstone of any conversation about reimbursement reform. "There will be 10,000 baby boomers entering Medicare every day for the next 20 years. If fewer of them are sick from cardiovascular disease, cancer, Alzheimer's disease, diabetes, and other diseases, Medicare costs will be driven down astronomically."

Greenwood also points to the High Technology Small Business Research Incentives Act, recently introduced in both the House and Senate, which is meant to stimulate capital formation for small biotech companies. This legislation, says Greenwood, provides incentives for innovation to help the U.S. biopharma industry compete. "BIO will be conducting grassroots advocacy efforts and working with Congress and our member companies to support and encourage passage of this legislation."

— Susan Worley