

# The FDA: In need of an innovation overhaul

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August 18, 2011

The mission is clear. The Food and Drug Administration must advance public health by helping to speed product innovation in addition to protecting the public by assuring the safety and effectiveness of drugs and devices, FDA Commissioner Dr. Margaret Hamburg states on the agency's website. Hamburg says that she is committed to strengthening programs that "find novel ways to prevent illness and promote health." But the new-product approval rate by the FDA has been decreasing for several years. This reduction in approvals threatens the future of America's life science industry and its promise to improve patient outcomes, reduce health care costs and maintain a global lead in biomedical research.

In 1992, Congress passed the Prescription Drug User Fee Act to expedite new-drug review by charging the industry "user fees." Under PDUFA, the FDA agreed to meet certain deadlines for new-product review. It seemed PDUFA's intended goal was being achieved by 1996 when 53 new products were approved.

By 2010, the number of new drug approvals had shrunk to 21 – down from 25 in 2009. In fact, from 1997 to 2007, the FDA's approval rate of new drugs dropped from 45 percent to 30 percent. Meanwhile, the user fees paid by drugmakers in support of PDUFA increased steadily, while the review time required for a new drug application increased.

Today, user fees account for a whopping 70 percent of the overall budget for the FDA's Center for Drug Evaluation and Research.

Since 1996, Congress has more than doubled the FDA budget, from \$1 billion annually to about \$2.4 billion in 2010. All the while, the cost and time needed to bring a new drug to market increased. Less than a decade ago, it cost \$800 million to develop a new drug and about 12 years to bring it to market. Today the cost is more than \$1.3 billion dollars, with a development time of 15 years. While these figures account for failures of candidate products as well as successes, much of the added cost and time is due to regulatory considerations, including ever-increasing clinical trial requirements.

The medical device industry has seen similar increases in regulatory cost and development time, although an independent study by the University of Minnesota shows that 99.8 percent of devices given the most common form of market approval by the FDA are safe.

A recent life-sciences industry survey, "Improving America's Health," conducted by PwC and BIOCOM, with input from FDA, identifies growing concern that the FDA is not equipped to keep up with the industry it is charged with regulating. For example, 58 percent of survey respondents agreed politics has too much influence on the approval process. Forty-six percent of those surveyed said they did not feel that user fees accelerate the review process, while 40 percent said that FDA had denied approvals on time primarily because of inadequate resources.

President Barack Obama has called for American innovation to strengthen the economy and ensure the nation will remain globally competitive. To do this effectively the U.S. needs an FDA that can support Commissioner Hamburg in her desire to approve novel products. We support this goal.

Veteran members of Congress, including industry critic Rep. Henry Waxman, D-Calif., have said the FDA has been "reduced to management by crisis" and is in danger of being perceived as a "failed agency" by the American public. The federal government invests more than \$30 billion annually in basic biomedical research within the National Institutes of Health. Our industry invests twice that amount annually to bring new products to market. None of that investment can be effective, if FDA is mired in politics, bureaucracy and other challenges that prevent the agency from meeting its goals.

Some of this nation's biomedical innovation is already moving overseas. Investors have begun encouraging companies to seek their first regulatory approvals through FDA's counterpart, the European Medicines Agency, because its approval process is seen as clearer and more predictable. The remedy for FDA is clear: The agency, the president and Congress must make a commitment to encouraging innovation throughout FDA's ranks, with a focus on processes and accountability that will bring modern medicines, devices and diagnostics through review and to patients with greater success.

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