

**COMPETITIVENESS AND REGULATION:
The FDA and the Future of America's Biomedical Industry**

FACT SHEET

A strong, science-based FDA and efficient, predictable and consistent regulatory processes are essential to biomedical investment, innovation and patient care.

- Companies and investors rely on an efficient, well-articulated and predictable regulatory process in order to make informed decisions.
- FDA policies and organizational structure have historically served as models for regulators around the globe.
- The technical strength of the Agency and the clarity of its regulatory processes helped the United States become the global leader in biopharmaceutical, medical device and diagnostic innovations.

Recent review slowdowns across the Agency are alarming for the entire U.S. biomedical industry.

- Comparing the most recent year for which a representative set of submission data is available (2008) with the average for 2003-2007, review times for drugs and biologics have increased by 28 percent.
- For medical devices, comparing 2010 with the period 2003-2007 510(k) clearances have slowed by 43 percent and PMA approval times have lengthened by 75 percent.

A number of factors have contributed to the slowdowns.

- Faced with accusations from the press, consumer groups, Congress and others for inadequately protecting the public, the FDA has shifted emphasis in product reviews from the benefits of new medicines and technologies to an increasing weight on their possible risks.
- Congress has enlarged the Agency's scope into new fields (e.g., tobacco) and added to its responsibilities and authority, yet federal appropriations have largely failed to keep up with new mandates, forcing greater reliance on industry-funded user fees.
- Additional responsibilities under the Food and Drug Administration Amendments Act of 2007 (FDAAA) have further served to exacerbate these pressures.

The global financial meltdown sharply changed the biomedical investment environment, adding to risks already posed by uncertainty and unpredictability in FDA drug and device regulation.

- The Great Recession devastated investment portfolios, including the pension funds and institutional endowments that historically have been the main source of life sciences venture capital (VC).
- Meanwhile, VC firms themselves also sought to reduce risk, trending away from early-stage investments – ones that combine the greatest innovation with the greatest risk.

- Smaller companies especially have been forced to adapt by redesigning the biomedical business model – receive regulatory approval, demonstrate adoption by physicians and patients, and present to potential acquirers as a lower-risk investment. From the perspective of company and investor alike, winning approval sooner in any market becomes far more valuable than gaining FDA approval later.
- Levels of regulatory uncertainty – delays, missed timelines, doubts about eventual approval – that had been uncomfortable in good economic times became intolerable after the economic downturn. Especially, as investors and executives came to realize, there are practical, more efficient routes to market outside the U.S.

Overseas bodies, especially in Europe, have recognized that regulatory efficiency can bolster biomedical investment, innovation and job creation without undermining patient safety.

- The European Medicines Agency (EMA) has been forthcoming about its ambitions to encourage and facilitate biomedical investment and innovation in the EU. For example, in its strategic document, “Road Map to 2010: Preparing the Ground for the Future,” the EMA stated that “its role in enabling the pharmaceutical industry to achieve the objective of industrial competitiveness is crucial.”
- They have begun to succeed. Complex medical devices approved via the PMA process in the United States today are approved in Europe on average nearly four years ahead of the United States, up from just over a year, earlier this decade. And where new medicines were approved first in the U.S. by an average on nearly seven months between 2004 and 2006, recent years show products approved on average two-and-a-half months earlier in the EU, a shift of nine months.

Together, Congress, the FDA, industry, patient groups and other stakeholders can come together with the will and ideas to restore Agency performance – to rejuvenate, support and sustain a strong, science-based FDA and efficient, consistent and predictable review processes to ensure safe and innovative treatments, technologies and therapies for patients in need.

- To start, let’s get “back to basics.” Instead of creating expansive new authorities and responsibilities requiring even higher user fee levels, work should focus on re-centering the Agency to its primary mission and core competencies, addressing the serious inefficiencies and performance breakdowns of recent years.
- Address an improved, more appropriate balance between benefit and risk. Today, the FDA, the press, Congress, consumer groups and others overwhelmingly focus on “direct” risks: side effects, adverse events and technical product failures. Just as important to consider are indirect risks – distortions in the regulatory process, for example. How do we calculate and consider the public health loss to patients if investors and companies avoid entire diseases and conditions because the FDA’s demands for clinical data are so extensive and its standards for approving new products so uncertain?
- In preparation for 2012 reauthorization of the drug and device user fee acts, the time is also right to evaluate, and where appropriate, correct any measures within those laws that may have detracted from the FDA’s performance without any commensurate improvement to patient safety, such as the new Risk Evaluation and Mitigation Strategies (REMS) and stricter advisory committee conflict of interest rules instituted under the Food and Drug Agency Amendments Act of 2007 (FDAAA).