

STUDIES RELEVANT FOR DEPARTMENT OF COMMERCE INNOVATION
COUNCIL

1. The Lewin Group, “State Economic Impact of the Medical Technology Industry,” June 7, 2010. Describes jobs creation by the medical technology industry, including recent employment growth, employment by state, and average wages compared to national and manufacturing average.
2. PriceWaterhouseCoopers, “Medical Technology Innovation Scorecard: the Race for Global Leadership,” January 2011. Compares the U.S. to eight other competitor nations and finds the U.S. industry still leads the world, but the U.S. lead is slipping on all dimensions of competitiveness. Notably, the U.S. ranks eighth out of nine on speed of regulatory review.
3. Josh Makower, M.D., et al., *FDA Impact on Medical Technology Innovation: A Survey of Over 200 Medical Technology Companies*,” November, 2010. Surveys 200 small medical technology companies and finds high levels of dissatisfaction with FDA as compared to EU regulators, a significant device lag between Europe and the U.S., movement of clinical trials and first product introductions to Europe as the result of problems with the FDA, high costs associated with FDA review delays, and companies that have been unable to bring products to market because delays at FDA have caused financing to dry up.
4. Boston Consulting Group, “Competitiveness and Regulation: the FDA and the Future of America’s Biomedical Industry,” report prepared for the California Healthcare Institute, February, 2011. Finds significant device lags between Europe and the U.S., movement of clinical trials and first product introduction to Europe because of problems with the FDA, and large increases in review times (43 percent for 510(k)s and 75 percent for PMAs) at the FDA between the 2002-2007 period and 2010.
5. John H. Linehan, Ph.D. and Jan B. Pietzsch, Ph.D., “A Comprehensive Analysis of the FDA 510(k) Process: Industry Practices and the Implications for Reform,” National Press Club, Washington, D.C., May 21, 2011. Reported on a survey of industry regulatory specialists and leaders regarding 510(k) submissions and found that respondents felt the FDA was slow, inconsistent and arbitrary. Most (80%) are now approaching EU regulators first to discuss and plan submissions for approvals of new devices and said 65% of recently approved 510(k) devices received a CE mark before receiving FDA clearance.
6. Ralph Hall, “Using Recall Data to Assess the 510(k) Process,” presentation to the Institute of Medicine, July 28, 2010, sought to assess the effectiveness of the device review and company development process in keeping unsafe products off the market and found very low rates of class I recalls—0.45% for 510(k) products and 0.3% for PMAs over a five year period. Less than half of recalls were due to premarket issues. Class I recalls are those that involve the most significant threats to patient safety.

7. Boston Consulting Group, “EU Medical Device Approval Safety Assessment: A Comparative Analysis of Medical Device Recalls 2005-2009,” January, 2011, found little difference between the number or timing of class I recalls in Europe and the U.S., suggesting that both systems perform equally well in screening out unsafe devices.
8. Battelle Memorial Institute for the Council on Medical Innovation, *Gone Tomorrow? A Call to Promote Medical Innovation, Create Jobs, and Find Cures In America*, June 10, 2010, conducted a broad range of stakeholder and expert interviews, as well as reviewing relevant literature and concluded that American leadership in medical innovation was at risk. The report identified four key problems—FDA regulatory policies and competence, access to capital for small and start-up firms, lack of support for translational research, and gaps in pipeline for scientists, engineers, and other skilled workers—and suggested a wide range of potential policies to address the problems.
9. “Background: The American Medical Technology Industry and International Competitiveness” reviews the extensive data on the challenges the American technology industry faces in sustaining world leadership and describes in detail six policy pillars to maintain and restore competitiveness.
10. “Sustaining American Leadership: A competitiveness policy for the Medical Technology Industry” summarizes the challenges facing the medical technology industry and the six pillars or effective policy to maintain and improve competitiveness.