



Sustaining American Leadership: A Competitiveness Policy for the Medical Technology Industry

The American medical technology industry creates the medical devices and diagnostics that are central to modern health care. Not only is the industry a source of life-enhancing and life-sustaining treatments and cures, it is an important manufacturing industry and a driver of current and future U.S. economic growth. The industry employs more than 400,000 Americans directly, with total direct and indirect employment exceeding two million. Between 2005 and 2007, the industry created 70,000 new jobs in America, a workforce growth of 20 percent in just two years. Medical technology jobs are good jobs, with wages exceeding those for the work force as a whole by 40 percent and exceeding average wages in other manufacturing industries by 22 percent. Medical technology is one of the few American manufacturing industries that consistently exports more than it imports, and exports doubled between 1998 and 2008, to \$33 billion annually.

The future potential for American economic growth driven by the medical technology is great. World-wide markets for medical technology will expand dramatically as populations age in countries around the globe and as hundreds of millions of people in countries like India and China enter the middle class and demand modern, quality health care.

Growth in medical technology will also be fueled by scientific progress in this new century of the life sciences, as fundamental discoveries in the life sciences and continued advances in computing, materials, engineering, and physics create the knowledge base for an explosive growth in the creation of new treatments and cures. To quote Dr. Laurence Summers, president emeritus of Harvard University and former head of the National Economic Council, *“The 20th century was an American century in no small part because of American leadership in the application of the physical sciences...If the 20th century was defined by developments in the physical sciences, the 21st century will be defined by developments in the life sciences.”*

Today, America is the acknowledged world leader in medical technology, as it is in the other life sciences industries. But that leadership is being challenged. Without new public policies to provide a level playing field between the U.S. and foreign competitors, America’s leadership will be lost and with it an important engine of economic growth and manufacturing job creation. At a more profound level, if American leadership in the life sciences industries is lost, America’s long-term future as the world’s most powerful economy will be jeopardized.

Fortunately, America's leadership can be preserved. For America to remain number one, AdvaMed recommends six key policy initiatives. The specific proposals underlying these policies are described in more detail in the attachment.

1. **Innovation in the life sciences must be a government priority.** *Since the ability of the life science industries to thrive is affected by a broad range of government policies across many agencies, it is critical that that supporting medical innovation be a priority for the whole government. An office of medical innovation policy should be created in the White House to serve as an advocate for medical innovation across the government and as a focal point for groups committed to promoting medical progress. All major government rules affecting medical care or research should be required to include an "innovation impact statement" analogous to an environmental impact statement.*
2. **The FDA review process must be reformed.** *The FDA must set a goal of achieving a review and approval process that is as predictable, consistent, and timely as our European competitors, while continuing to assure that products are safe and effective.*
3. **Payment policy must support medical innovation.** *Medicare, Medicaid, and private insurers alike must assure that the new payment modalities established by health reform to provide incentives for quality and cost control also support medical progress, innovation and access to appropriate technology. The current Medicare coding and payment processes must be improved to allow more rapid recognition of new technologies.*
4. **A vigorous trade policy must support export growth and provide a level playing field for U.S.-based manufacturing.** *If trade barriers remain or increase, U.S. efforts to improve domestic competitiveness and expand exports would be undermined. Companies will relocate outside the U.S. to manufacture behind the barriers and foreign companies will thrive at the expense of U.S. competitors. Other countries are pursuing bilateral and regional trade agreements that will put U.S. manufacturers at a competitive disadvantage. Countries in the developing world are increasingly using regulatory policy to promote domestic industries or to force U.S. companies to locate research, development, and manufacturing within their borders. Small and medium size companies need additional assistance to become successful exporters.*
5. **Strategic tax policies to level the playing field must be implemented.** *American tax policy must support R&D intensive industries at a level sufficient to level the playing field with foreign governments eager to attract American jobs and develop home-grown competitors to American firms. The R&D tax credit must be reformed and made more generous;*

tax incentives need to be created for keeping R&D based manufacturing in America; assistance must be provided for the research costs of small, start-up firms with no profits. The medical device excise tax should be repealed.

- 6. The American research and development infrastructure must be sustained and improved.** *American policy must support the maintenance and growth of an R&D infrastructure second to none, with special emphasis on creating the structures necessary to support r and d directed at commercialization.*

Adoption and execution of these policies will not be easy, but the pay-off will be great. Medical technology companies can be a driver of long-term economic growth and prosperity, but government must do its part by sustaining the innovation ecosystem that is essential for long-term success.