Innovation Agenda

The medical technology industry is central to the development of medical devices and diagnostics that will provide the life-saving and life-enhancing treatments of the future. Patient access to advanced medical technology generates efficiencies and cost savings for the health care system, and improves the quality of patient care. Between 1980 and 2010, advanced medical technology helped cut the number of days people spent in hospitals by more than half and add five years to U.S. life expectancy while reducing fatalities from heart disease and stroke by more than half. The industry is also an engine of economic growth for the U.S., generating high wage manufacturing jobs and a favorable balance of payments.

But the innovation ecosystem that supports medical technology is severely stressed. The U.S. has historically been the world leader in medical technology, but our leadership is eroding. Venture capital investment, especially investment in the start-up firms that are the seed corn of the industry, has plummeted. While there have been recent improvements at the FDA, the regulatory process remains too time-consuming, too inefficient, and too inconsistent. The payment environment is far less hospitable to new technology today than ever before, with the result that investment in new treatments is discouraged and patient access to new treatments that are developed is slower and more difficult. The U.S. tax system is uncompetitive and discourages location of research and development and manufacturing in the United States, a situation that has dramatically worsened as the result of the medical device excise tax. The basic and applied public infrastructure that is critical to long-term advances in the life sciences is eroding.

To respond to these challenges and rebuild the innovation ecosystem, AdvaMed proposes a new Innovation Agenda. Enactment of this agenda will unleash the potential of medical technology to extend and improve lives, reduce the cost and burden of disease, and maintain and enhance U.S. scientific and economic leadership. Failure to act will mean lost lives, unnecessary suffering, reduced job formation, and diminished economic growth.
Improving FDA’s regulatory processes so that the cost and time of development and approval of devices and diagnostics is reduced and the CDRH mission statement that American patients will be the first in the world to have access to new devices is achieved, while maintaining the highest standards of safety and efficacy.

Restructuring CMS’s coverage and payment processes to support development of new technologies that improve treatment, diagnosis or prevention, and provide prompt patient access to these technologies.

Reform the U.S. tax system to create a level playing field, starting with repeal of the medical device excise tax—a tax that is draining resources from American manufacturing jobs and research.

Improving access to international markets by insisting on free and fair trade in medical technology and working with foreign governments to achieve innovation-friendly regulatory and payment policies.

Supporting the maintenance and growth of an R&D infrastructure second to none.

Establish access to breakthrough products:

- Establish a streamlined, seamless path for FDA approval and CMS coverage and payment under the Medicare and Medicaid programs for breakthrough products that make significant improvements in treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

Improve the FDA’s regulatory processes:

- Meet and exceed the groundbreaking 2012 user fee agreement goals for such key objectives as reductions in total review times and more frequent and substantive interactions between FDA and product sponsors.
- Revitalize the “least burdensome standard” for regulatory review through enhanced reviewer training and encouraging the use of valid scientific evidence from such sources as registries, experience in foreign markets, and peer-reviewed journal articles, where appropriate, to support safety or effectiveness determinations.
- Encourage FDA to accept international consensus standards.
- Streamline the CLIA waiver process to accelerate the availability of point-of-care, rapid diagnostic information to physicians and patients.
- Allow the use of central Institutional Review Boards to facilitate the conduct of multicenter clinical trials.

Responding to patient challenges and to rebuild the innovation ecosystem, AdvaMed proposes a new Innovation Agenda.
• Reduce the review burden on FDA and companies by allowing companies to self-certify minor changes to devices if their quality system has been certified as capable of evaluating such changes.
• Improve the advisory committee process to reduce delays in product approvals and enhance the fairness and transparency of the process.
• Encourage the development of technologies for rare diseases and pediatric populations.
• Work with FDA to assure that post-market surveillance is effective and efficient; provides timely, reliable, and actionable data; minimizes unnecessary burdens on providers and industry; and is facilitated by smooth implementation of the Unique Device Identifier program.

Restructure CMS’s coverage and payment processes:

Enactment of AdvaMed’s Innovation Agenda will unleash the potential of medical technology to improve lives, reduce the cost and burden of disease, and enhance U.S. scientific and economic leadership.

• Establish automatic Medicare coverage of FDA-approved clinical trials rather than requiring a duplicative and potentially time-consuming separate Medicare approval process.
• Expand coverage of telehealth services, including remote monitoring, and of disposable, prevention and treatment technologies used in the home.
• Streamline Medicare’s process for granting temporary outpatient and physician payment codes to new technologies and prohibit Medicare contractors from arbitrarily denying payment for these technologies.
• Require state Medicaid programs to take patient views into account in making coverage decisions.
• Increase the transparency and fairness of the local coverage determination process.
• Improve the new technology add-on payment program to capture a larger share of important new technologies and set payments more appropriately.
• Establish payment levels more promptly for new technologies used in the inpatient setting, using the best available data.
• Improve the methodology for establishing payment for technologies used in the outpatient setting and for updating payments to ambulatory surgical centers.
• Implement ICD-10 this fiscal year.

Reform the U.S. tax system:

• Repeal the medical device excise tax.
• In the context of comprehensive tax reform, create a level competitive playing field for made-in-America medical technology:
  – Enact new tax incentives to invest in start-up companies creating new treatments and diagnostics;
  – Lower the overall corporate tax rate;
  – Provide incentives comparable to those of other countries for development and manufacturing of technology; and
  – Conform the treatment of international earnings to that of competitor nations.
Proposals Continued...

Improve access to international markets:

- Work with the U.S. government to encourage foreign governments to establish regulatory and payment systems for medical technology that are fair, transparent, nondiscriminatory and based on international best practices.
- Enact Trade Promotion Authority to negotiate the Trans-Pacific Partnership and the Trans-Atlantic Trade and Investment Partnership, and assure that those agreements include provisions that improve market access for medical technology.
- Enforce provisions of existing trade agreements such as the U.S.-Korea Free Trade Agreement to assure fair access for U.S. technology products.

Support the maintenance and growth of an R&D infrastructure second to none:

The medical technology industry is central to the development of medical devices and diagnostics that provide life-saving and life-enhancing treatments of the future.

- Provide steady growth in funding for the National Institutes of Health and the National Science Foundation.
- Improve the Small Business Innovation Research and Small Business Technology Transfer programs by raising the amount of funding (in the context of rising NIH and NSF funding), allowing larger individual grants to better recognize the costs actually incurred by start-up companies.
- More effectively tap the vast intellectual resources of our nation’s universities and academic health centers by providing federal technical assistance to establish and diffuse technology transfer best practices.
- Streamline Institutional Review Board activities to reduce barriers to initiating collection of clinical data on new treatments, particularly for multicenter trials, without sacrificing protection of human subjects.