AdvaMed
Advanced Medical Technology Association

A Competitiveness Policy for the Medical Technology Industry: Six Policy Proposals to Sustain American Leadership

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.

    A. An office of medical innovation policy should be created in the White House. This office would have oversight responsibility for major proposed and current government policies to assure that they support medical innovation. The office would serve as a focal point for groups and individuals advocating for medical innovation and could develop an innovation index to track how well the United States measures up to its major competitors in policies to encourage innovation.
    B. An "innovation impact" statement would be required for major regulations or other actions that affect the health sector. This statement would be analogous to an environmental impact statement. The goal would be to assure that every agency takes into account the effect of its actions on medical innovation and related domestic employment, and economic growth in promulgating government rules.

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.

    A. FDA must reduce total review times, not just time on the FDA clock, to a level that will significantly speed up review of both 510(k) and PMA products, including reforming the de novo process to make it an efficient and workable system for class II products with no predicate.
    B. FDA must effectively implement least burdensome processes throughout its operations to eliminate requirements that are not necessary to protect public health.
    C. FDA must streamline the IDE process to assure timely initiation of clinical trials.

D. FDA must develop a full range of guidance documents that identify FDA's requirements for a specific product submission to ensure a timely and consistent review process.
E. FDA must adopt the risk-based review pathway for diagnostic tests.
F. The FDA must take steps to ensure that its staff is properly trained, has access to independent scientific and technological information, and to develop a program to monitor the predictability and consistency of the review process.
G. FDA must take steps to converge its regulatory practices with the principles established by the Global Harmonization Task Force.

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.

A. New payments systems such as accountable care organizations, bundling, and value-based purchasing should include specific provisions to avoid penalizing health care organizations or individual providers for offering patients the opportunity to benefit from new treatments that are not yet the standard of care.
B. New payment systems should be carefully designed to support continued patient access to care appropriate for their individual needs and to recognize the long-term value of treatments.
C. CMS should reform the process of coding and determining appropriate payment to avoid delays of up to two years or more before a treatment can be properly recognized for payment purposes.
D. CMS should reform payment for new diagnostic tests to encourage the development of high value diagnostics and of personalized medicine.

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.

A. The President's National Export Initiative (NEI) should make bilateral and regional free trade agreements (and associated medical technology sectoral agreements) with developed and developing markets alike a priority, including ratification of the Korean-US free trade agreement, negotiation of the TransPacific Partnership free trade agreement and expanding the agreement to include additional Asia-Pacific countries, including Japan.

B. The Administration should continue its policy of vigorous opposition to non-tariff barriers to trade, especially use of regulatory policy to set up artificial barriers to imported products and to force local location of research and development and manufacturing by multinational firms. The Administration should support existing and new trade forums that allow government officials and industry representatives to work together to identify and address barriers to trade. FDA should be part of the team working with trade authorities and indicate that assistance to foreign firms seeking to meet U.S. regulatory requirements is conditional on fair treatment of U.S. firms by foreign regulatory authorities.

C. The Administration should make regulatory harmonization by developing countries a trade priority, including achieving a commitment next year to regulatory harmonization by 2020 at the Leaders meeting of the Asia Pacific Economic Cooperation forum, based on the principles adopted by the Global Harmonization Task Force.

D. Small and medium size enterprises represent the lifeblood of medical technology innovation. Exporting to foreign markets is particularly difficult for companies with little or no foreign trade experience. Under the NEI, US Government agencies – including USTR, SBA, and Commerce – should vigorously pursue policies to assist small and medium size companies to overcome their lack of experience and specialized knowledge, and other obstacles to competing in export markets.

5. **Strategic tax policies to level the playing field must be implemented.** *American tax policy must support research and development (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 created for keeping R&D based manufacturing in America. The medical device excise tax should be repealed.

A. The Research and Development Tax Credit needs to be made permanent; the level of the credit needs to be raised so that it is as

good or better than the credits provided by our major competitors; the administration of the credit should be substantially simplified; the credit should support investment in building research infrastructure, including construction of facilities and purchase of equipment; and the tax code should provide incentives equivalent to the credit for companies with no profits, so that small and start-up companies, which create a disproportionate share of breakthrough treatments, can receive benefits at the time of greatest need.

B. Manufacturing based on R&D wholly or predominantly conducted in the United States should be eligible for a lower corporate tax rate to reduce the cost advantage that research and development intensive companies locating manufacturing abroad enjoy in the form of lower general corporate taxes, special tax breaks, and direct subsidies.
C. The medical device excise tax should be repealed, since it absorbs resources that could otherwise be used for research and development or employment expansion and disproportionately burdens American firms vis-à-vis foreign competitors.
D. The United States should move towards a corporate tax system that provides greater parity with our major competitors in tax rates and treatment of foreign earnings.

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 translational R&D directed at commercialization.

A. America must maintain and expand its commitment to basic research and to graduate research and training programs through the NIH and NSF.
B. Research programs that support moving research farther along the development spectrum toward actual treatments and that support start-up companies developing breakthrough treatments should be improved and expanded, including increasing funding, eligibility, and maximum grant size for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR programs) and fully funding the Cures Acceleration Network. Additionally, the federal government should provide grant funding to states and localities seeking to establish or expand bioscience research and development clusters.
C. Programs should be established to more effectively tap the vast intellectual resources of our nation’s universities and academic health centers, including creating NIH funded Industry-University Cooperative Research Centers analogous to a long-standing and

successful program at the NSF and providing federal technical assistance to establish best practices and improve the effectiveness of university technology transfer programs.

D. Institutional Review Board activities should be streamlined to reduce barriers to initiating collection of clinical data on new products, particularly for multicenter trials, without sacrificing protection of human subjects.