A CALL TO ACTION:
SUSTAINING AMERICA'S LEADERSHIP IN THE LIFE SCIENCES

The U.S. life sciences industry and the field of biomedical engineering are true American success stories of the past century – characterized by inventions and innovations that simultaneously improve quality of life and contribute immensely to our economic growth. Currently, U.S. life sciences companies employ 1.3 million people with total annual wages of $96 billion. The industry has a $33 billion trade surplus, leads the world with 41% of biotech patents, and accounts for more than 55% of world's biopharmaceutical research and development spending. Further, university degrees awarded in biomedical engineering are the fastest rising discipline with the largest job growth in the nation.

Studies have shown that medical innovations provide economic and health value to patients and the health care system – lowering health care costs by providing higher quality solutions and increased efficiency of care. From 1980 to 2000, for example, medical innovations cut the death rates from heart disease by 50 percent, stroke by 33 percent and breast cancer by 20 percent. From 1991-2004, life expectancy in the U.S. increased by 2.5 years. And from 1970 to 2000 alone, the economic value from decreasing U.S. mortality amounted to $3 trillion per year.

Indeed, our science base – including basic research, a continuous supply of bright, young scientists and engineers, and vital university-based centers of basic and applied research – are critical to maintaining our global leadership in life sciences.

While medical innovation is clearly the key to U.S. economic and human prosperity in this century, a crisis of historic proportion looms in our country. Our innovation ecosystem is threatened by a number of barriers that rival some of the toughest domestic challenges in recent history: onerous and cumbersome regulatory policies on several fronts, increasing efforts to restrict and control already outdated reimbursement policies that are eroding America's global innovation edge, reduced federal funding for basic research, and limitations on accessing and retaining an educated and trained workforce in the life sciences.

Decisive, collaborative public/private action and investment in the nation's medical innovation ecosystem must be initiated to sustain and enhance our predominance in the life sciences.

The American Institute of Medical and Biological Engineers (AIMBE), founded in Washington, D.C. in 1991, is the consistent, authoritative voice and advocate for medical and biological engineering's value to society. We are an organization of leaders in medical and biological

engineering, consisting of academic, industrial, professional society councils and elected fellows. As such, our dialogue with lawmakers and stakeholders in technology innovation is often the foundation for effective policy-making that saves and improves the lives of people around the world. Our policy agenda spans issues central to bioengineering education and research, particularly the process of research translation to products and technologies that positively impact the health and quality-of-life for millions of patients.

Clearly, the 21st century will be dictated and determined by the progress made in our understanding of the life sciences and its role in extending life, reducing disability and improving productivity. At AIMBE's 2013 Annual Meeting in Washington, D.C., a panel of experts identified a set of specific tactics – aimed at both the public and private sectors – to advance a call to action to preserve and improve the medical innovation ecosystem in this country.

CALL TO ACTION

I. Regulatory Initiatives

Improve the inefficient and ineffective FDA regulatory pathway for drugs, devices and biologics from discovery through development and market entry by:

- Conducting an agency-wide formal study of process mapping at the FDA. The FDA needs to engage in the total life cycle of products from discovery through development and delivery, not simply review a product application. We must identify and define specific steps to streamline and smooth critical process areas and develop mechanisms to monitor and measure process outcomes.
- Creating an agency-wide external advisory board consisting of experts across a wide variety of disciplines. This board will focus on the vision, mission and future goals of the FDA – given the rapid pace of innovation – and provide expert cross-sectional accountability for process improvement measures.
- Encouraging FDA to focus on advancing the field of regulatory science by engaging with the newly created *Medical Device Innovation Consortium.* This collaboration will assure the adoption of new methods and tools to appropriately evaluate the risk associated with medical device use.
- Accelerating the FDA's Commissioner's 2-year fellowship program, which provides a mechanism to attract the best and brightest young scientists, engineers and lawyers to the agency. This creates a pipeline of intellectual

capital for subsequent reviewers and establishes a resource of individuals who can effectively facilitate the dynamic interaction between industry and the regulator.

- Expanding the *Executive in Residence* program to further engage industry with FDA in improving the overall innovation pathway.

II. Reimbursement Reform

The current fee-for-service reimbursement system for health care providers is based on volume and unit price, and driven by a revenue management model - neither one of which have anything to do with value. We must move to a system that rewards clinical results and not volume.

Adopt a 5-step framework for accelerating the shift from volume-based reimbursement for health care providers to a value- and performance-based reimbursement system that is open to new technologies and treatments, by:

1. Establishing expectations for clinical and economic performance among health care providers.
2. Creating a system to measure whether or not expectations are met.
3. Ensuring the measurement system is transparent and disclosing the results.
4. Aligning the incentives for health plans, physicians, hospitals and other providers and rewarding each for value-based performance and best practices.
5. Establishing a national scorecard to track how quickly payers and public programs transform from a volume-based to a value-based reimbursement system.

III. Federal Funding of Life Sciences Research

Increase the Federal government's investment in basic and translational research to move innovation from bench to bedside, by:

- Urging Congress to appropriate consistent, incremental budget increases to the National Institute of Health that outpace inflation.
- Enhancing support of university technology transfer established in the Bayh-Dole Act.

- Reforming the SBIR/STTR program to address several regulatory roadblocks to the commercialization of medical innovations, including support for venture-backed start-up companies.

IV. Workplace Development in Science, Technology, Engineering & Math (STEM)

The nation must significantly increase its investment in medical and biological engineering research at the university level as a means to ensure a skilled workforce – and sustain our preeminence in this field.

Urge Congress to address the looming crisis in accessing and retaining scientific and engineering talent in the United States, by:

- Increasing federal support for the life sciences in K-12 STEM efforts.
- Reforming restrictive immigration laws to help America retain American-educated, foreign born life sciences graduates in the U.S., and eliminating the opportunity for this talent pool to become our competitors.
- Earmarking appropriations for the National Institute of Biomedical Imaging and Bioengineering, the National Science Foundation, the National Institute for Standards and Technology and the Department of Education to support STEM initiatives.
- Modifying the higher education curriculum to emphasize entrepreneurship and innovation.

V. Private Funding/Tax Reform

Reverse the steep decline in private and venture capital investment in basic and translational research and start-up companies in the life sciences by:

- Decreasing the anti-competitive overall U.S. tax rate for life sciences corporations.
- Encouraging repatriation of foreign income to increase investment in U.S. manufacturing and R&D.
- Increasing the federal R&D tax credit from 14% to 20% to make it globally competitive, and provide other tax incentives to encourage public/private partnerships.
- Establishing federal financing support for life sciences R&D infrastructure at university-related research centers.

- Eliminating the 2.3% excise tax on medical devices which was included in the Affordable Care Act.

Call to Action is the culmination of comments from a panel of business, academic, health care and industry experts and participants who convened at AIMBE's 2013 Annual Meeting – held in Washington D.C. at the National Academy of Sciences – to address key challenges threatening the American innovation ecosystem. This session was chaired by AIMBE President Elect William Hawkins, Chief Executive Officer, Immuncor, Inc; former Chairman and Chief Executive Officer of Medtronic, Inc.