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Investing in Bioengineering: Securing America's Leadership Role in a 21st Century Global Economy

The Importance of Bioengineering in the U.S. Research and Development Portfolio

Bioengineering is an interdisciplinary field that combines engineering principles and knowledge of the physical and life sciences to solve problems in biology, medicine, behavior and health. It is used to advance our understanding of biological systems, as well as to develop novel medications and medical devices to prevent, diagnose, and treat disease. Bioengineers have employed mechanical engineering principles in the development of many life-saving, and life-improving technologies such as robotic surgery, the artificial heart, prosthetic joints, diagnostics and numerous rehabilitation technologies. ASME (American Society of Mechanical Engineers) recognizes that robust funding of bioengineering research and development (R&D) is essential to improving public health and maintaining America's position as a global leader in this field.

Founded in 1880, ASME is a non-profit technical and educational organization with over 100,000 members worldwide. The Society includes members from across economic sectors, including industry, academia, government, health care, and bioengineering. ASME is proud to be made up of members whose expertise is helping put the U.S. at the international forefront of bioengineering R&D. Currently, ASME's Bioengineering Division boasts approximately 5,350 members in industry, academia, and non-profits directly contributing to U.S. advances in bioengineering. Based on our expertise in this field, we have the following recommendations to improve the bioengineering R&D environment.

National Institutes of Health (NIH)

The National Institutes of Health (NIH) is the world's largest research organization dedicated to improving health through biological and medical science. Through their leadership, the NIH has played a pivotal role in new research and developments that have increased average life expectancy in the U.S. by 15 to 20 years over the last five decades. The *United for Medical Research* coalition of leading research institutions' 2017 Update, which details NIH's Role in Sustaining the U.S. Economy noted that NIH extramural funding in 2017 generated an estimated $68.8 billion in nationwide economic output. This is double the amount of federal funding they receive, and includes an important feeder effect on small companies clustered around academic research institutions.

The NIH is comprised of 27 different *Institutes* and *Centers* that support a wide spectrum of research activities including basic research, disease and treatment-related studies, clinical research, and epidemiological analysis. The mission of individual Institutes and Centers varies from studying a particular organ to a given disease to sequencing the human genome. In a broad capacity, NIH funding encourages economic growth, both in the research and development jobs it supports, as well as the generation of biomedical innovations that subsequently come to market in the form of new products. The National Institute of Biomedical Imaging and Bioengineering (NIBIB), which focuses on the development, application, and acceleration of technologies to improve outcomes for a broad range of biomedical applications and health care challenges is particularly important to ASME. ASME has been supportive of the mission of the NIBIB since its inception in 2001.

As the outcomes and benefits of biomedical research continue to grow, ASME is pleased that Congress has recognized these meaningful advancements and sustained NIH funding over the past several years. However, funding and the competitive edge that comes with it are at risk because of reduced purchasing power, austerity-minded budget proposals and looming budget caps.

ASME has the following recommendations related to future NIH budgets:

1) Provide robust funding for NIH at a level that outpaces the inflation rate. The most recent Biomedical Research and Development Price Index (BRDPI) projects a GDP Price Index of roughly 2 percent through 2023.
2) Continue to fund both extramural research that is awarded to universities and nonprofit organizations (e.g., R01/R21/R03 grants) and commercial innovation (e.g., STTR and SBIR grants).
3) Resist efforts to significantly reduce research overhead costs, which would have long-term negative economic impacts for local communities, long-term consequences for patients, and would adversely affect America's global competitiveness.
4) Include more bioengineers on NIH grant review panels as they pertain to future NIH funding.

U.S. Food and Drug Administration (FDA)

Former FDA Commissioner Dr. Scott Gottlieb noted the importance of the agency, stating that "the FDA's broad mission is to promote and protect [how] the nation's public health touches the lives of all Americans. Over $2.4 trillion annually, roughly 20 cents of every dollar, is spent by consumers on a product that FDA regulates." The FDA oversees 100% of drugs, vaccines, medical devices, cosmetics and 80% of our nation's food supply. The FDA's budget consists of both Congressional appropriations and user fees, which totaled $5.14 billion in FY17.

ASME supports the FDA's mission and the directive set forth in the 21st Century Cures Act that the FDA "support innovation while maintaining the evidentiary standards that provide assurance to the American public about the safety and efficacy of medical products." While congress acknowledges that the FDA's public health mission is vital and growing, current FDA funding levels are inconsistent with this mission. With FDA's increasing public health and safety responsibilities, ASME is concerned that FDA's budget is insufficient and should be increased while limiting FDA user fees. Additionally, ASME recommends that the FDA should increase the percentage of participants on their cutting-edge initiatives with bioengineering expertise to ensure comprehensive, technologically informed overview before such advances are brought to market.

ASME encourages the FDA to continue developing its forward-looking regulatory efforts with regard to medical devices and products and promoting the clinical translation of innovative manufacturing technologies such as additive manufacturing and bioprinting, which will determine the future of medical devices in the U.S. and abroad.

International Competition in the Bioengineering Space

The most recent *Science and Engineering Indicators* report from the National Science Foundation (NSF) notes that the U.S. is currently the global leader in R&D funding, but other countries, including China in particular, are on track to catch up and surpass us within the next few years.

Since 2000, China has increased R&D spending at an accelerated rate of roughly 18 percent annually, with a focus on commercial development and “high-risk” research that can lead to disruptive “high-reward” innovations. By contrast, U.S. R&D investment has only averaged 4 percent annual growth, and focused mainly on “low-risk” research. As the NSF’s *Indicators* note, while the US currently spends more, that leadership margin is slim and overall R&D intensity is falling. Conversely, R&D spending intensity in China is quickly growing.

China’s most recent *Five-Year Economic Plan* stipulates that a quantifiable percentage of the country’s GDP be generated by Biotechnology outputs, with the goal that this percentage will increase in the future. In 2008, China created the *1000 Talents Program* which provides incentives for trained academics and scientists to come work in China. This program represents a growing challenge to America’s previously undisputed position as the global R&D leader. Without a renewed and robust funding plan for R&D and Bioengineering, the U.S. will see greater competition in this space as more and more countries continue to devote resources into boosting their R&D capabilities.

United Kingdom and Canada

Countries closer to home are also quickly proving their prowess and strength in the bioengineering arena. The U.K. and Canada are rapidly scaling up their capabilities and output. There were initial concerns that Brexit would ruin the UK bioengineering sector. However, despite ongoing challenges from Brexit, the UK BioIndustry Association’s December 2017 report, *Pipeline Progressing: The UK’s Global Bioscience Cluster in 2017*, concluded that the UK had the “strongest clinical and preclinical pipeline in Europe,” and ranked third globally in R&D funding (behind the U.S. and Switzerland), with relatively stable funding for British biotechnology.

Canada’s biotech industry has also rapidly bounced back from the global tech bust at the beginning of the millennium. In 2017, the Canadian government pledged $950 million to various tech industries through its *Innovative Superclusters Initiative*. The goal of the program is to position Canada at the forefront of innovative R&D. The Canadian investment firm Bloom

Burton and Co. reported that “Canada is gearing up for a new golden era in Biotech.” As it moves away from its risk-averse research funding tendencies of the past, we should expect some Canadian biotech companies to shift toward riskier and potentially disruptive biomedical R&D. As Bloom Burton and Co. explained, “Within 10 years, these emergent companies could surpass the stars of the last Canadian biotech boom and even rival the large Biotechs in the U.S.”

While the US still leads the UK and Canada in R&D funding, these historically close allies are rapidly becoming our adversaries in the biotech arena, and the ASME strongly endorses increased federal funding for bioengineering-focused R&D to ensure America’s continued leadership and reclaim our position of dominance.

Workforce Development

America is facing a dearth of qualified STEM workers that is impeding the success of bioengineering R&D. For the US to remain competitive in the bioengineering arena and beyond, we need a strong, “STEM-capable” workforce. As the National Academies explained in their 2016 report *Developing a National STEM Workforce Strategy*, a STEM-capable workforce is not only trained with a comprehensive technical skillset, but also with “soft” skills such as communication and critical thinking. One of the many challenges to ensuring that a workforce is STEM-capable is that the responsibility for developing a competent, skilled workforce is split between governments, employers, and educators, and there are no formal structures linking these entities. Individuals within these institutions must have effective collaboration and communication skills to bridge this workforce development divide.

To maintain its competitive status through the 21st Century, the U.S. needs to improve and coordinate its workforce development programs. In a 2010 survey, roughly 16.5 million workers, from STEM and other fields, stated that their job required at least a bachelor’s degree level of science or engineering expertise. As technology continues to develop at breakneck speeds, the need to educate technologically competent workers will increase. There is already a projected deficit of skilled workers for the number of STEM jobs coming through the pipeline. It is estimated that by 2020 there will be between 12 and 24 million unfilled jobs in STEM-based careers, with 75 percent of manufacturers stating that they are already being negatively impacted by this skills shortage.

Another major challenge facing educators today is not knowing what skills their students need to be successful beyond graduation. In a recent workshop, NSF director Dr. France Cordova noted “there is a clear need for communication about workshop training expectations between business and higher education.” To develop more focused course offerings, one solution is to create academia-industry partnerships by involving industry employers in academic curriculum development, and providing academic faculty with experiences within industry.

The federal government is getting more involved with programs such as the *NSF INCLUDES Initiative* (Inclusion across the Nation of Communities of Learners of Underrepresented Discoverers in Engineering and Science), which makes STEM education and careers more accessible to students and workers of all backgrounds. In addition, the 115th Congress recently voted to reauthorize the *Carl D. Perkins Career and Technical Education Act*, a key source of federal funding for secondary and post-secondary career and technical education programs. **ASME enthusiastically supports this forward-thinking legislation, and is eager to serve a consulting role on engineering-related STEM curriculum development.**

Summary and Conclusion

Bioengineering-based solutions to health care problems improve health outcomes and reduce health care costs. Biomedical research generates commercializable technologies from federally funded research.

While the U.S. currently enjoys a leadership position in the global Bioengineering space, this status cannot be maintained in the future without continued support and stable funding. Therefore, ASME strongly urges Congress to increase funding for bioengineering R&D across NIH, NSF, FDA, and other federal agencies, and to strengthen STEM workforce development initiatives. This support will ensure continued dominance in bioengineering R&D, reduce health care costs for the U.S. and her citizens, and help secure America's leadership role in the 21st century global economy.