A REPORT

ON

THE FEDERAL GOVERNMENT'S INVESTMENT IN BIOENGINEERING RESEARCH

PREPARED FOR

THE AMERICAN INSTITUTE FOR MEDICAL AND BIOLOGICAL ENGINEERING

BY
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TABLE OF CONTENTS

EXECUTIVE SUMMARY

This report attempts to calculate the Federal Government's investment in bioengineering research. It is believed that a government-wide audit of bioengineering research has been attempted only one time previously. In 1994, the National Institutes of Health (NIH) Bioengineering Working Group conducted a detailed inventory of public and private funding for bioengineering research. The ensuing report identified $484 million in federal funding in FY 1993, with approximately $300 million funded through the NIH.

This report's authors investigated and examined the research portfolios and projects of those Federal Departments and Agencies with extensive research and development budgets to ascertain their current level of support for bioengineering. Interviews were conducted with leading bioengineering experts and detailed research of grant awards, budget materials, program descriptions, and funding solicitations was performed in an effort to develop an informed estimate of the Federal Governments investment in bioengineering research.

Through these efforts, we found that in Fiscal Year (FY) 2005 the federal government provided approximately $2.5 billion in funding for bioengineering research. The majority of this funding ($1.45 billion) was supported by the National Institutes of Health (NIH). Of the remaining funding, the majority was supported by the Department of Defense ($700 million). Significant investments were made by the National Science Foundation ($80 million) and the National Institute of Standards and Technology ($65 million). The Department of Energy also made significant contributions through its National Laboratories and extramural grants to universities and other research institutions, though it was not possible to quantify an exact contribution. Smaller contributions were made by several other agencies, such as the National Aeronautics and Space Administration (NASA), the Department of Homeland Security (DHS), the United States Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC).

While bioengineering research funding has increased since the 1994 report, it remains a relatively small portion of the Federal Government's total research and development budget. The American Academy for the Advancement of Science (AAAS) estimates that the total Federal research and development budget for FY 2005 is $131 billion. Bioengineering research represents just 2 percent of this total.

The future for bioengineering research appears unclear. While the President has requested significant increases in funding for the DOE Office of Science, NSF, and NIST in FY 2007 through the American Competitiveness Initiative (ACI), the NIH is slated to receive a second consecutive real cut in funding and DOD research is scheduled to receive only a nominal increase. These latter two agencies represent the two largest contributors to bioengineering research funding. Should the Congress enact the President's requested funding levels for NIH and DOD, bioengineering research is likely to be negatively affected.

Many Members of Congress in influential positions are supportive of federal research and have previously advocated for increased research funding in the absence of Presidential support. For example, the doubling of the NIH budget from FY 1999 – FY 2003 was initiated and lead by key Members of the House and Senate Appropriations Committees. The bioengineering community will need to work collaboratively with supportive Members of Congress to ensure that adequate funding is provided to bioengineering research across the Federal Government.

INTRODUCTION

PURPOSE

This report attempts to calculate the Federal Government's investment in bioengineering research. Its intent is to provide an informed estimate of the federal funding dedicated to bioengineering research rather than an exact quantification.

The report authors hope that this report will be a springboard to a thorough, vigorous, and ongoing examination and collaborative debate within the bioengineering research community that will lead to a continual identification and quantification of federal investment in this crucial and growing research field.

HISTORICAL PERSPECTIVE

It is believed that a government-wide audit of bioengineering research has been attempted only one time previously. In 1994, the National Institutes of Health (NIH) Bioengineering Working Group conducted a detailed inventory of public and private funding for bioengineering research (as it relates to medical and health research) in fiscal year (FY) 1993, per Section 1912 of Public Law 103-43, the National Institutes of Health Revitalization Act of 1993.

The Working Group, lead by Dr. John Watson, was comprised of representatives from each of the NIH Institutes and Centers and the Division of Research Grants and advised by a Steering Committee of senior NIH officials. Input was received from representatives of other Federal agencies that support bioengineering research, as well as focus groups from academia and industry. Representatives from academia, industry, and bioengineering societies and foundations formed an External Consultants Committee for the Working Group.

The ensuing report identified $484 million in federal funding for bioengineering research in FY 1993, with approximately $300 million funded through the NIH. The Department of Defense (DOD) was found to provide the second highest investment towards bioengineering research. The Working Group report can be found online at www.becon.nih.gov/nihreport.htm and in the Appendix of this report (see Attachment #1).

CHALLENGES

The federal budget is a collection of facts, figures, estimates, and projections that makes the calculation of federal spending government-wide for any area of interest an imperfect exercise. Research spending can be particularly difficult to quantify due to the dispersal of research dollars over numerous Departments and Agencies and the lack of a central federal clearinghouse for gathering and analyzing such data.

Identifying funding for research related to bioengineering presented additional hurdles. This is due to the vagaries and occasional subjectivity as to whether particular research projects constitute "bioengineering" and the difficulty raised by bioengineering being embedded within and cutting across several scientific and research fields.

DEFINITION OF BIOENGINEERING

The most fundamental challenge in quantifying the federal financial commitment to bioengineering is how to define the term “bioengineering.” The NIH Working Group recognized this difficulty when it stated in its 1994 report that “no definition [of bioengineering] could completely eliminate overlap with other research disciplines or preclude variations in interpretation by different individuals or agencies.” This qualifier was repeated by the NIH Bioengineering Definition Committee (BDC) in its 1997 report that developed a definition of bioengineering that continues to be used today by the NIH.

For the purposes of this report, the term “bioengineering” is defined using the BDC definition in order to be consistent with the 1994 report:

> *Bioengineering integrates physical, chemical, or mathematical sciences and engineering principles for the study of biology, medicine, behavior, or health. It advances fundamental concepts, creates knowledge for the molecular to the organ systems levels, and develops innovative biologics, materials, processes, implants, devices, and informatics approaches for the prevention, diagnosis, and treatment of disease, for patient rehabilitation, and for improving health.* (NIH Bioengineering Definition Committee, Working Definition of Bioengineering, July 24, 1997; see www.becon.nih.gov/bioengineering_definition.htm and Appendix, Attachment #2).

DATA GATHERING PROCEDURE

The report’s authors investigated and examined the research portfolios and projects of those Federal Departments and Agencies with extensive research and development budgets to ascertain their level of support for bioengineering. Interviews were conducted with leading bioengineering experts and detailed research of grant awards, budget materials, program descriptions, and funding solicitations was performed in an effort to mold together an informed estimate of the Federal Government’s investment in bioengineering research.

Several leaders of the bioengineering community, both in and out of government, were interviewed. These individuals are recognized in the Acknowledgements section of this report and at various points throughout the report narrative. Their assistance and guidance was invaluable to gaining a better understanding of the location of bioengineering research throughout the Federal Government and identifying the types of bioengineering research conducted within various Departments and Agencies.

Thousands of active grant award titles and/or abstracts were reviewed individually to identify those with bioengineering components in order to calculate the total financial investment of various Departments or Agencies in bioengineering research. Budget Justifications and other budget materials and reports available from the Departments’ or Agencies’ budget offices, detailed program descriptions, and funding solicitations were used to supplement this information and assist in cross-referencing, identifying sources of bioengineering research, and estimating the financial investment.

The report authors attempted to locate the most granular level of budget and financial information available in order to calculate and quantify the investment in bioengineering research. Many of these materials are available in the Appendix of the report.

LIMITATIONS

There is intrinsic subjectivity in individuals determining whether a particular research project does or does not contain a bioengineering component. Certainly, there are numerous instances in which the determination is reasonably objective and obvious or where no determination is necessary because the research has been coded as bioengineering in nature by the government entity being studied and reviewed.

However, there are several cases in which the report authors were required to make a judgment call as to the nature of the research based upon the project's title or abstract or the government's description of the project in budget justification material. Readers of this report are encouraged to review the raw data collected by the report authors and available in the Appendix to the report.

ACKNOWLEDGEMENTS

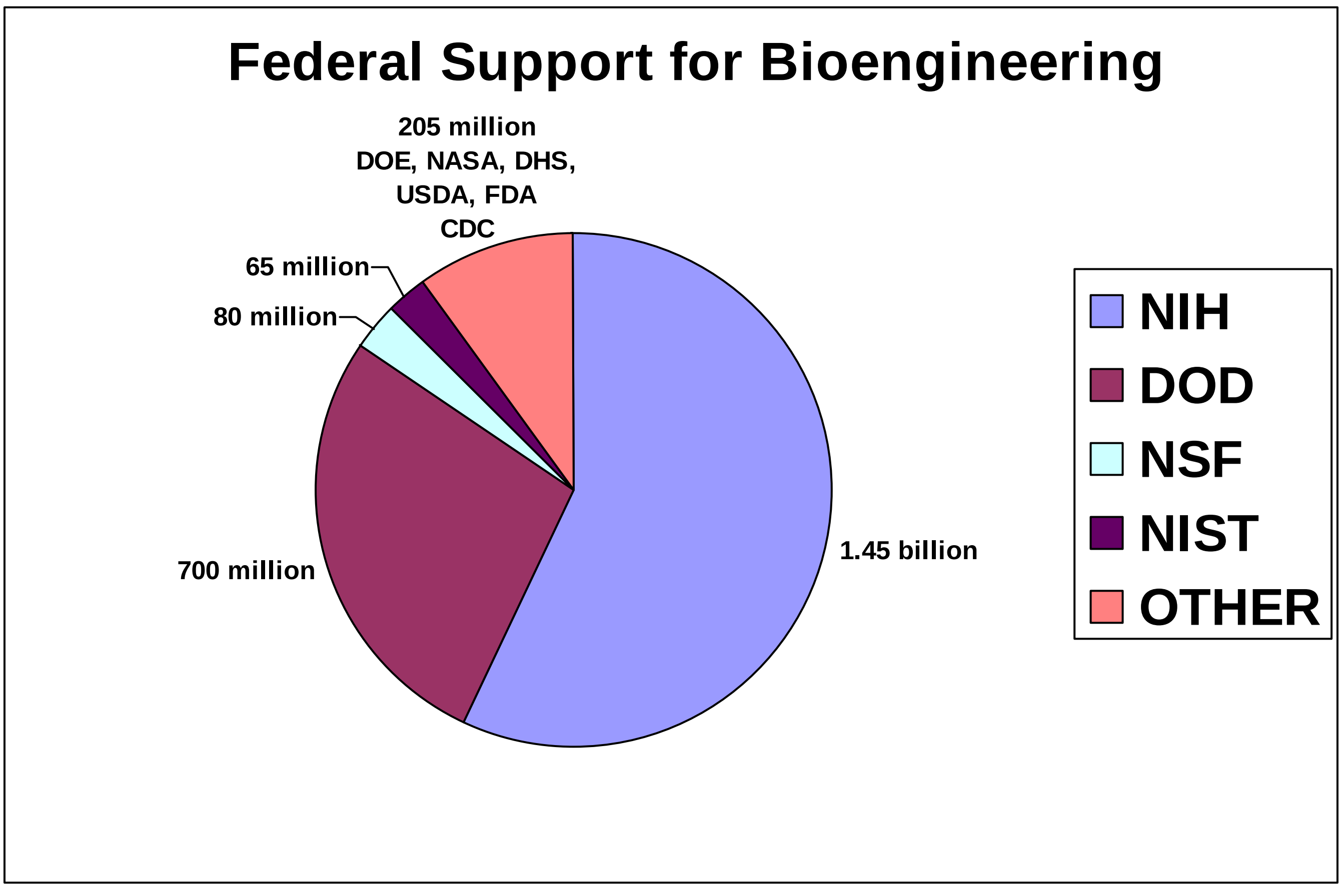
Before proceeding to the results portion of the report, it is imperative that the report authors thank the following individuals for their assistance and guidance in developing this document. These individuals, listed alphabetically, offered their expertise and advice, which was invaluable in navigating the information related to federal support for bioengineering research:

- Ms. Colleen Guay-Broder, Director of the Office of Science Policy at the National Institute of Biomedical Imaging and Bioengineering
- Dr. Bruce Hamilton, Director of Bioengineering and Environmental Systems at the National Science Foundation
- Dr. William Heetderks, Director of the Extramural Science Program at the National Institute of Biomedical Imaging and Bioengineering
- Dr. Luis Kun, National Defense University
- Dr. Sohi Rastegar, Program Director of the Engineering Research Centers Program at the National Science Foundation
- Dr. Richard Swaja, Oak Ridge National Laboratory
- Dr. Michael Viola, Director of the Medical Sciences Program at the Office of Biological and Environmental Research at the Department of Energy
- Dr. John Watson, University of California at San Diego, former Chairman of the National Institutes of Health Bioengineering Working Group

RESULTS

GENERAL OVERVIEW OF RESULTS

In Fiscal Year (FY) 2005, we estimate that the federal government provided approximately $2.5 billion in funding for bioengineering research. The majority of this funding ($1.45 billion) was supported by the National Institutes of Health (NIH). Of the remaining funding, the majority was supported by the Department of Defense ($700 million). Significant investments were made by the National Science Foundation ($80 million) and the National Institute of Standards and Technology ($65 million). The Department of Energy (DOE) also made a significant contribution through its National Laboratories and extramural grants to universities and other research institutions, though we were unable to quantify an exact contribution. (The reasoning behind this is described in greater detail in the section of the report on DOE.) Smaller contributions were made by several other agencies, such as the National Aeronautics and Space Administration (NASA), the Department of Homeland Security (DHS), the United States Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC). A breakdown of the funding for bioengineering research by Department and/or Agency is provided below.



NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health (NIH) is the preeminent federal agency for the funding of biomedical research. It has a budget of over $28 billion that is divided between 27 institutes and centers.

Historically, the NIH has been the leading federal supporter of bioengineering research. The NIH Bioengineering Working Group found that it funded approximately 60 percent of the Federal Government's investment in bioengineering research in FY 1993. This report found that NIH funds approximately the same percentage of the overall federal investment in FY 2005.

The NIH maintains detailed information on its contribution to bioengineering research. Unlike most other federal agencies reviewed for this report, the NIH has in place a definition for bioengineering and protocols to identify bioengineering research funded through its institutes and centers (ICs). Each IC budget office is responsible for transmitting to the Office of the Director its annual investment in bioengineering research. This information is tabulated and available on the NIH website at www.nih.gov/news/fundingresearchareas.htm along with the NIH investment in other disorders, condition, and research areas. A printout of this table is available in the Appendix of this report (see Attachment #3).

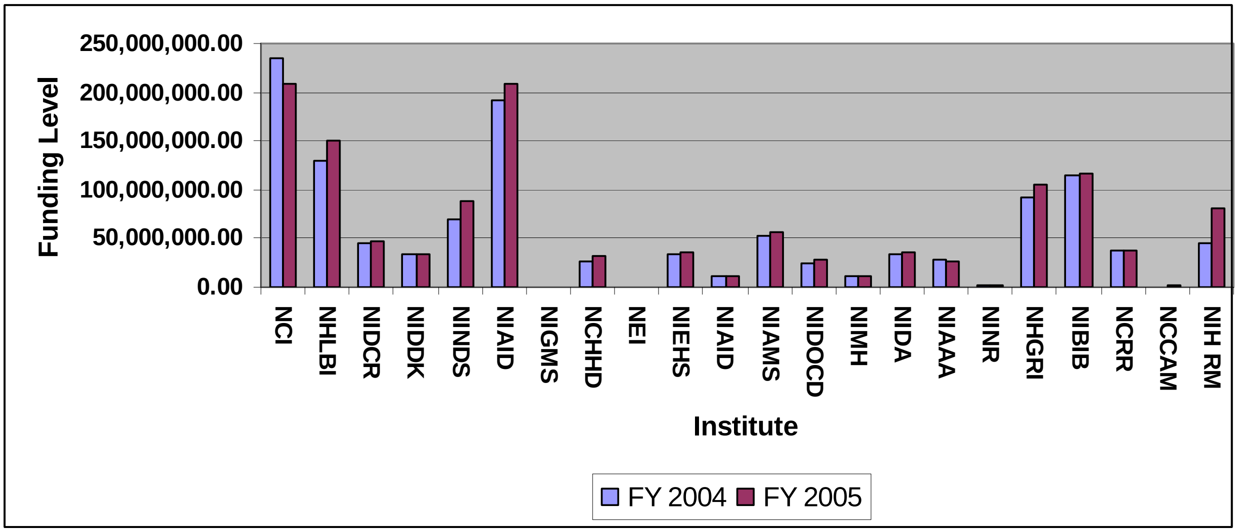
The NIH estimates that it provided $1.317 billion in funding for bioengineering research in FY 2005. This funding is dispersed throughout the entire NIH. The report authors worked with the NIH Office of Budget to obtain a breakdown of the NIH's bioengineering funding by IC. This information can be found in the Appendix (see Attachment #4).

The chart below identifies the breakdown of bioengineering research funding by IC as reported by the NIH for FY 2004 and FY 2005. Only the National Institute of General Medical Sciences and the National Eye Institute did not report funding bioengineering research:

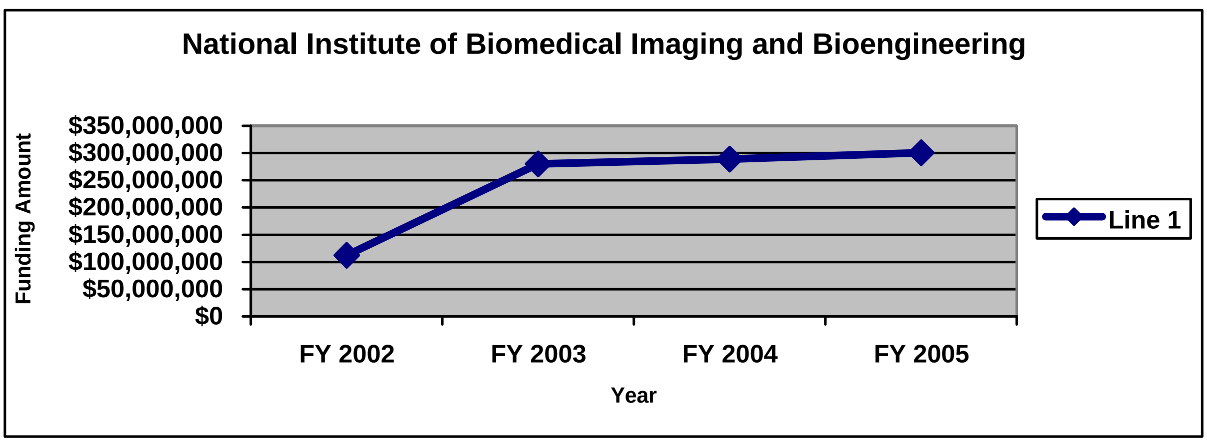
Institute	**FY 2004 Funding**	**FY 2005 Funding**
National Cancer Institute	$234,594,000	$208,189,000
National Health, Lung, and Blood Institute	$129,803,000	$150,090,000
National Institute of Dental and Craniofacial Research	$44,650,000	$47,785,000
National Institute of Diabetes and Digestive and Kidney Diseases	$33,800,000	$34,600,000
National Institute of Neurological Disorders and Stroke	$69,466,000	$88,319,000
National Institute of Allergy and Infectious Diseases	$192,310,000	$209,391,000
National Institute of General Medical Sciences	0	0

National Institute of Child Health and Human Development	$26,899,000	$31,169,000
National Eye Institute	0	0
National Institute of Environmental Health Sciences	$33,481,000	$35,732,000
National Institute on Aging	$11,331,000	$11,936,000
National Institute of Arthritis and Musculoskeletal and Skin Diseases	$53,457,000	$56,270,000
National Institute on Deafness and Other Communication Disorders	$23,628,000	$28,952,000
National Institute of Mental Health	$10,633,000	$10,541,000
National Institute on Drug Abuse	$34,439,000	$35,388,000
National Institute on Alcohol Abuse and Alcoholism	$27,791,000	$26,887,000
National Institute of Nursing Research	$1,261,000	$2,515,000
National Human Genome Research Institute	$91,588,000	$104,748,000
National Institute of Biomedical Imaging and Bioengineering	$115,281,000	$116,513,000
National Center for Research Resources	$36,769,000	$36,800,000
National Center for Complementary and Alternative Medicine	$100,000	$1,517,000
NIH Road Map	$44,914,000	$80,304,000
Total	**$1,216,195,000**	**$1,317,646,000**

The following graph shows another representation of the dispersal of bioengineering research throughout the NIH:



The report authors found that the $1.317 billion figure reported by NIH may under-represent the true agency funding level. This is due to an issue with how bioengineering research is coded at the National Institute of Biomedical Imaging and Bioengineering. The NIBIB is the newest institute at the NIH, having been created in 2000, and it is the nominal focal point of bioengineering research at NIH. It funds research related to bioinformatics, biomaterials, drug delivery, biomedical imaging, medical devices, micro-biomechanics, micro and nanotechnologies, nuclear medicine, sensors, simulation, and tissue engineering, among other program areas. The NIBIB has a budget of approximately $300 million. Its historical funding level is represented in the graph below and in the Appendix as Attachment #5:



According the figures tabulated by the NIH, the NIBIB supported $116.5 million in bioengineering research in FY 2005. This figure is less than the amount contributed by the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), and the National Institute of Allergy and Infectious Diseases (NIAID) and represents less than 40 percent of the NIBIB budget.

Dr. William Heetderks, Director of the Extramural Science Program at the NIBIB, and Dr. John Watson explained that some bioengineering-related research has been “coded” by NIBIB as bioimaging research, and thus it does not appear in the NIH tabulation of total bioengineering funding. If the bioimaging funding is calculated as bioengineering, Dr. Heetderks estimates that the NIBIB supports over $250 million in bioengineering research annually. This would raise the total NIH contribution to bioengineering research to approximately $1.45 billion, which is the total quoted by this report.

It is important to note that even if the bioimaging research at NIBIB is calculated as bioengineering research, NIBIB provides only about 17 percent of the total NIH contribution to bioengineering research. Each of the ICs funds bioengineering-related research projects that are relevant to their core mission. While not comprehensive, the following list provides a flavor of the types of bioengineering-related research that has been funded at each of the ICs in recent years. This information was gleaned by reviewing all of the active funding opportunities available at NIH. This information is available through the NIH Office of Extramural Research at http://grants1.nih.gov/grants/guide/index.html. A printout of the active grants is available in the Appendix of this report (see Attachment #6):

National Cancer Institute	• Imaging to detect cancers • Nanotechnology for curing cancers • Cancer biomarkers • Computational cellular research
National Heart, Lung, and Blood Institute	• Tissue engineering (creation of blood vessels) • Tissue delivery related to transplantation • Cell-based therapies for curing cardiovascular and blood diseases
National Human Genome Research Institute	• Genome sequencing • Nanotechnology
National Institute on Aging	• Imaging related to Alzheimer's disease
National Institute on Alcohol Abuse and Alcoholism	• Genomics (i.e., genetic predisposition to alcoholism) • Imaging related to the neurological damage caused by alcoholism • Tissue injury detection and repair
National Institute of Allergy and Infectious Diseases	• Vaccine development • Microbicide innovation • Biodefense
National Institute of Arthritis and Musculoskeletal and Skin Diseases	• Tissue engineering (e.g., skin and skeletal material)
National Institute of Child Health and Human Development	• Neonatal treatments using imaging technologies and nanotechnology
National Institute on Deafness and Other Communication Disorders	• Cochlear implants

National Institute of Dental and Craniofacial Research	• Saliva-based diagnostics • Drug delivery for oral diseases • Regeneration • Oral microbial research • Nanotechnology
National Institute of Diabetes and Digestive and Kidney Diseases	• Imaging of the pancreas • Islet cell transplantation • High-density genotyping for diabetes • Biomarkers for diabetes
National Institute on Drug Abuse	• Neuroimaging of damage caused by drug abuse • Simulation
National Institute of Environmental Health Sciences	• Molecular structure of contaminents and its affect on the human body
National Institute of Mental Health	• Drug delivery for anti-depressants and other pharmaceuticals • Imaging of the brain related to mental illness • Probes for microimaging
National Institute of Neurological Disorders and Stroke	• Imaging of the brain • Microtechnology and cellular interactions in the brain and brain stem • Stem cell research • Targeted drug delivery to the brain
National Institute of Nursing Research	• Drug delivery • Imaging

In addition to the research conducted within the ICs, there are three trans-institute bioengineering initiatives of note at NIH. The most significant of these is the Bioengineering Consortium (BECON), which is administered by the NIBIB. BECON is the focus of bioengineering activities at NIH. It consists of senior-level representatives from all of the NIH institutes, centers, and divisions as well as representatives of other federal agencies concerned with biomedical research and development. One of BECON's most important responsibilities is to coordinate the Bioengineering Research Partnership (BRP) Program, which has been in existence since October 1999. The BRP Program encourages and supports multi-disciplinary biomedical research with a focus on bioengineering. To date, more than 150 BRP awards have been made by 16 institutes and centers for a total investment of $700 million.

The NIH Office of the Director (OD) is spearheading two trans-institute initiatives that relate to bioengineering research. The NIH Roadmap for Medical Research was launched in 2003 in order to synergize various institutes to accelerate the pace of discovery and improve translational research for transforming medical research. Specifically, the Roadmap seeks to identify and study complex networks of cellular machinery at the level of proteins, metabolites, molecules, and atoms. As such, it highlights research into molecular imaging and molecular imaging probes. The Roadmap also supports National Technology Centers for Networks and Pathways, National Centers for Biomedical Computing, and Nanomedicine Centers, which are explained below:

- National Technology Centers for Networks and Pathways: These centers focus on tool development for measuring protein activity and interactions, such as communication between genes, molecules, and cells.

- National Centers for Biomedical Computing: These centers are part of a long-term initiative to establish an integrated national biomedical-computing environment that can analyze, integrate, visualize, and model large volumes of biological data.

- Nanomedicine Centers: These centers work to discover interventions at the cellular level to cure disease or repair tissue such as bone, muscle, and nerves.

In total, the NIH Roadmap contributed $80 million to bioengineering research in FY 2005 according to the NIH.

The OD is spearheading, too, the NIH Blueprint for Neuroscience Research, which is supported by 15 institutes and centers, including the NIBIB. Included within the $12 million in FY 2005 funding for the blueprint is funding for developing genetically engineered mouse strains for nervous system disease research, training in neuroimaging and computational biology, and support for centers that focus on animal models, cell culture, computer modeling, DNA sequencing, drug screening, gene vectors, imaging, microarrays, molecular biology, and proteomics as it relates to neuroscience research.

DEPARTMENT OF DEFENSE

The Department of Defense (DOD) has the largest research budget of any Department within the federal government. Congress appropriated over $70 billion for research, development, testing, and evaluation (RDT&E) in FY 2005. The principal points of contact for military research reside in the Service Research Organizations (the Army Research Office (ARO), the Office of Naval Research (ONR), and the Air Force Office of Scientific Research (AFOSR)) and the Defense Advanced Research Projects Agency (DARPA).

The NIH Working Group identified DOD as the second highest contributor to the Federal Government's funding of bioengineering research in FY 1993. This report has found that this is still the case in FY 2005.

Bioengineering research is funded through each of the Service Research Organizations and DARPA. Specific funding levels were ascertained by reviewing the description of the various DOD funded research projects available through the Budget Documentation prepared by each of the services' budget offices. These documents, which are available online at www.dod.gov/comptroller/defbudget/fy2005/index.html, provide detailed descriptions of each of the research projects conducted by the DOD and funding levels. The report authors reviewed these documents and identified those projects that contain a bioengineering component. Due to the fact that these documents are approximately 1,500 pages per service, they are not provided in the Appendix of this report.

- ARO is interested in a wide array of bioengineering-related research topics. This includes: human-robot interaction (HRI), electro-optic sensors and detectors, and microscale and nanoscale materials technology. In FY 2005, ARO provided approximately $230 million in funding for bioengineering research.

- ONR funds bioengineering research through its Engineering, Materials & Physical Science Department and its Human Systems Department. This includes metabolic engineering, creation of novel biomolecular materials, neural engineering and biorobotics, and microbial synthesis of energetic materials. In FY 2005, ONR provided approximately $200 million in bioengineering research.

- AFOSR funds bioengineering-related research through each of its key research interests: Aerospace and Materials Sciences, Physics and Electronics, Chemistry and Life Sciences, and Mathematics and Space Sciences. Specific research areas include: development of nano-composits, simulation, optoelectronic sensors, sensors in the space environment, development of novel biologically inspired sensors and biosensory material, biomimetics, and biointerfacial sciences. In FY 2005, AFOSR provided approximately $175 million in funding for bioengineering research.

- DARPA funds a wide array of bioengineering research through its Defense Sciences Office and its Microsystems Technology Office. Specific research areas include: nano sensors, microelecrtromechanical systems (MEMS), biomolecular motors, biomolecular nano devices, imaging, rapid vaccine assessment, simulation of biomolecular microsystems, long-term blood storage, and development of synthetic blood. In FY 2005, DARPA provided approximately $115 million in funding for bioengineering research.

DEPARTMENT OF ENERGY, OFFICE OF SCIENCE

The Department of Energy's Office of Science is the nation's single largest supporter of basic research in the physical sciences. It also manages the nation's ten National Laboratories. The Office of Science funds most of its bioengineering research through its Office of Biological and Environmental Research (OBER) and the National Laboratories.

The report authors were unable to determine the level of funding contributed to bioengineering research by DOE. This is due primarily to a lack of transparency at the National Laboratories and the absence of a defined methodology for coding bioengineering research at DOE. Dr. John Watson identified similar barriers in attempting to calculate the DOE bioengineering funding for the 1994 NIH Report.

While a specific contribution could not be ascertained, the report authors were able to determine that DOE makes a significant contribution to bioengineering research through interviews with DOE officials and review of DOE reports and budget documents.

DOE has previously attempted to catalogue its bioengineering-related research conducted through its National Laboratories. Dr. Michael Viola, Director of the Medical Sciences Division at OBER spearheaded such an effort in 1999. The ensuing report identified 231 active bioengineering-related projects at the Labs. It did not attempt to quantify the funding level of the identified projects. Dr. Viola believes that the report underestimates of the actual number of bioengineering research projects being conducted at the National Laboratories at that time. He also believes that the number of bioengineering projects has grown significantly in the intervening seven years.

In addition to the bioengineering research conducted at the National Laboratories, there are several other programs with bioengineering components within the Office of Science. The information discussed below can be obtained from the Department of Energy's budget justification, which is available online at www.cfo.doe.gov/budget. The FY 2006 budget justification for the Office of Science is included in the Appendix of this report (see Attachment #7).

OBER is the primary conduit for bioengineering research. It has several areas of interest related to bioengineering. The Life Sciences Research subprogram has significant interest in simulation and genomics. Specifically, it supports research to develop high-throughput and cost effective DNA sequencing technologies, improve understanding human genome organization and human gene function and control as it relates to exposure to proteins at the genomic level, and research related to the implications arising from synthetic biology and nanotechnology. Other areas of interest include further developing computational models that can predict the behavior of complex biological systems, principally microbes and microbial communities, which can be used in the development of clean energy, carbon sequestration, and environmental cleanup to underpin biotechnology-based solutions to energy challenges.

The Medical Applications and Measurement Science subprogram has a significant interest in nuclear medicine, imaging, and simulation. Specifically, it supports research related to developing new radiotracers, developing the next generation of non-invasive nuclear medicine instrumentation technologies, creation of advanced imaging technologies capable of high resolution from the sub-cellular to the whole body level, and the development of neural prostheses such as photo-optics and biosensors. The nuclear medicine component of this program has been eliminated in FY 2006.

Outside of OBER, there is some investment in bioengineering-related research. Most of the research is tangential and not directly related to bioengineering. The Basic Energy Sciences (BES) Program, and its Materials Science and Engineering area and Energy Biosciences area, are interested in discovering new materials and developing an understanding of their properties and behavior in order to improve current energy technologies and develop new energy technologies, including at the nanoscale. The Energy Biosciences' objective is to generate an understanding of fundamental biological mechanisms in plants and microorganisms and develop from their biological processes the foundation for technology developments to achieve environmentally responsible production and conversion of renewable resources for fuels, chemicals, and other energy-enriched products.

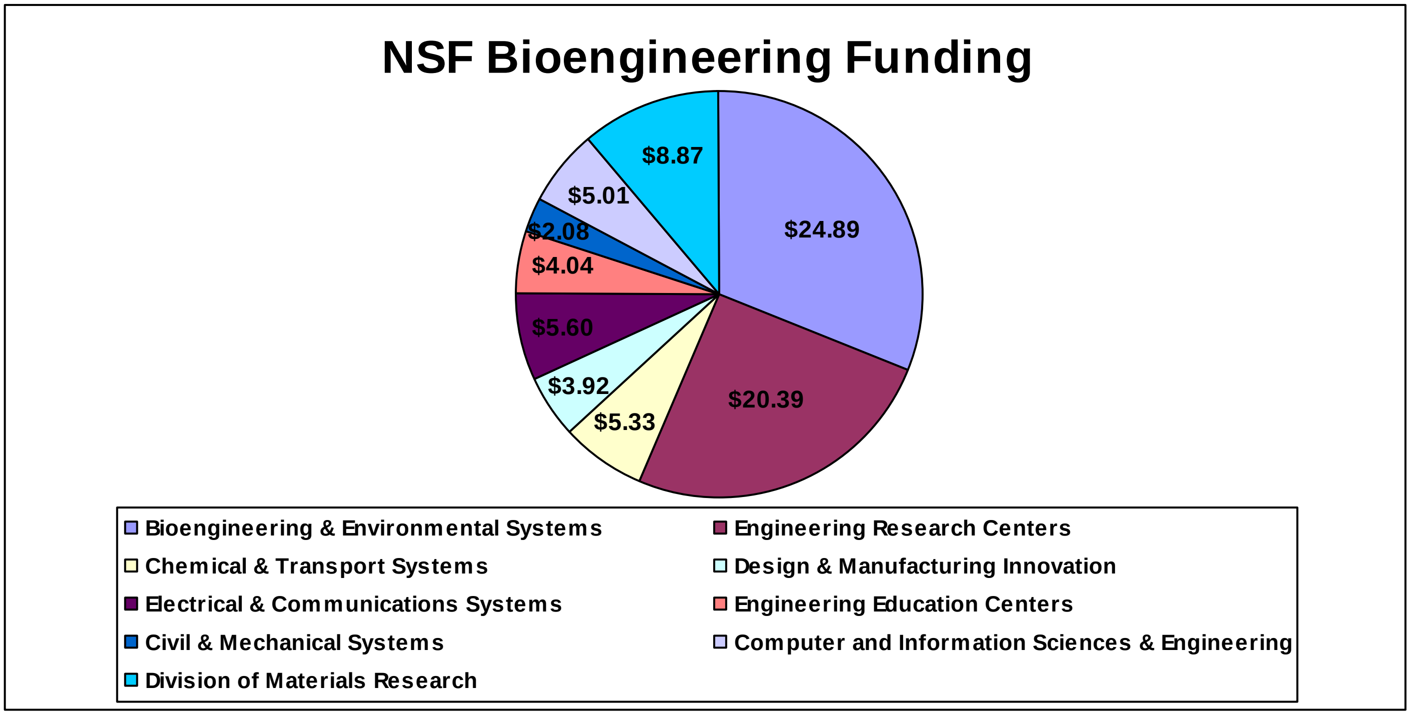
Within the Advanced Scientific Computing Research (ASCR) Program, there is an interest in computer science research in simulation and computational science can lead to modeling a complete microbe genome and a simple microbial community. Additionally, the Mathematical, Information, and Computational Sciences (MICS) Subprogram within ASCR funds research into creating a computer that can analyze, model, simulate, and predict the behavior of complex natural and engineered systems of importance to DOE.

NATIONAL SCIENCE FOUNDATION

The National Science Foundation (NSF), with a budget of $5.5 billion, provides approximately 20 percent of the funding for all basic research conducted by America's colleges and universities. In mathematics, computer science, and the social sciences, NSF is the primary source of funding.

This report identified approximately $80 million in bioengineering research funded by the NSF in FY 2005. This funding level was determined by reviewing each of the grant awards made by NSF in FY 2003 – FY 2005 and identifying those projects that are fully or partially related to bioengineering research. The grant awards reviewed are available at www.nsf.gov/awardsearch. A printout of the documents reviewed by the report's authors is available in the Appendix of the report (see Attachment #8).

The process of reviewing the NSF grant awards would not have been possible without the invaluable assistance of Dr. Sohi Rastegar, Program Director of the Engineering Research Centers Program at the NSF. Dr. Rastegar provided a roadmap for the location of bioengineering research at NSF and confirmation that the report's results were reasonable and consistent with his understanding of the level of support for bioengineering research at NSF.
The following chart displays the division of bioengineering funding at NSF in millions:



The NSF has proposed a restructuring of the Engineering Directorate (ENG) in FY 2007. It intends to combine the Bioengineering and Environmental Systems (BES) and Chemical and Transport Systems (CTS) Divisions into a new Chemical, Bioengineering, Environmental and Transport Systems (CBET) Division; combine the Civil and Mechanical Systems (CMS) and Design and Manufacturing Innovation (DMI) Divisions into a new Civil, Mechanical and Manufacturing Innovation (CMMI) Division; create a new Industrial Innovation and Partnerships (IIP) Division out of the Office of Industrial Innovation (OII) and portions of DMI and Engineering Education and Centers (EEC); maintain the majority of the EEC in its own Division of the same name; and create a new Emerging Frontiers in Research and Innovation (EFRI) Division. This restructuring plan is described in greater detail in the NSF budget justification, which is available at www.nsf.gov/about/budget/fy2007.htm and in the Appendix (see Attachment #9). For the purposes of this report, which examines the NSF's funding of bioengineering research in FY 2005, we looked at NSF in its current structure.

The primary conduit for bioengineering research at NSF is the Bioengineering and Environmental Systems (BES) Division of the Directorate for Engineering (ENG). Within BES are the program clusters Biochemical Engineering / Biotechnology, Biomedical Engineering / Research to Aid Persons with Disabilities, and Environmental Engineering and Technology. The report identified approximately $24.890 million in bioengineering research funded through BES in FY 2005. Of this amount, about $15.875 million derives from the Biomedical Engineering program cluster. This represents the largest contribution to bioengineering research by any core program within the NSF.

BES supports highly promising cutting edge bioengineering and environmental engineering research fields. Its priority areas include: post-genomic engineering, tissue engineering, biophotonics, and nano-biosystems. In recent years, BES has funded research related to gene transfer, modeling/simulation, neural engineering, tissue engineering, biosensors, and visual prosthesis, among others.

The second highest contributor to bioengineering research within NSF is the Engineering Research Centers (ERC). The ERC focuses on developing engineering-related technologies with the potential to spawn or radically transform whole industries. Its contribution to bioengineering research is approximately $20.386 million.

Most of the remainder of bioengineering research at NSF is funded through the Engineering Directorate (ENG). The Divisions that fund bioengineering-related research include:

- Chemical and Transport Systems (CTS): This Division provides approximately $5.322 million for projects related to heat transfer in nanoparticles and biosensors.

- Design and Manufacturing Innovation (DMI): The DMI division provides approximately $3.917 million for bioengineering research. It funds projects related to nanotechnology, computer-aided tissue engineering, and laser micro- and nano-processing of biodegradable polymers.

- Electrical and Communications Systems (ECS): ECS provides approximately $5.598 million for bioengineering projects such as nanoscale probes for imaging, power-minimization in artificial hearts, and various sensors.

- Engineering Education and Centers (EEC): In addition to housing the ERC, this Division provides an additional $4.044 million for projects related to the environmental impact of nanotechnology, real-time nano-material synthesis, and tissue engineering.

- Civil and Mechanical Systems (CMS): This Division provides the smallest contribution to bioengineering research within the Engineering Directorate (ENG), funding only about $2.075 million in bioengineering related projects. Most of this research is related to nanotechnology and sensors.

While most the bioengineering research at NSF is conducted within the Directorate of Engineering (ENG), a significant portion falls within the Directorate of Mathematical and Physical Sciences and the Directorate of Computer and Information Science & Engineering. There is minimal investment from the Directorates for Biological Sciences; Geosciences; and Social, Behavioral and Economic Sciences.

- Directorate of Computer and Information Science & Engineering (CISE): This Directorate funds bioengineering research through the Biology & Information Technology Program within the Computing and Communication Foundations Division. Projects within this Program include microsensors (such as those involved in cardiovascular informatics) and smart sensors, modeling, and simulation. Approximately $5.007 million is devoted to bioengineering research.

- Directorate of Mathematical and Physical Sciences, Materials Research (DMR): DMR funds a good deal of bioengineering research. Approximately $8.866 million is devoted to projects such as thermal and thermo-mechanical analysis of soft materials, micro-analysis of nano-scale materials, high-resolution and 3-D imaging, creation of titanium materials for artificial skeletal repair, electronic noses, biosensors, polymer nanofibers for nerve repair, and computer modeling of osteoporosis.

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

The National Institute of Standards and Technology (NIST) is a $760 million agency within the Department of Commerce's Technology Administration. Approximately $400 million of its budget goes towards funding research through its Scientific and Technical Research Services. NIST's mission is to promote U.S. innovations and industrial competitiveness by advancing measurement science, standards, and technology. It conducts and supports research through its NIST Laboratories and the Advanced Technology Program, respectively.

The NIST Laboratories conduct research in a wide variety of physical and engineering sciences. Bioengineering plays a part in several of its research focus points. Most of the bioengineering research is conducted at the Chemical Sciences and Technology Laboratory, specifically, the Biochemical Science Division.

The Biochemical Science Division is divided into four (4) groups: DNA Measurements, Biospectroscopy, Structural Biology, and Cell & Tissue Measurements. Bioengineering research is conducted within each of these groups.

- DNA Measurements: This Group works closely with the NCI's Early Detection Research Network (EDRN) to develop technologies that will identify cancer biomarkers and DNA diagnostics to identify early cancer and cancer risk. It also performs research related to: measuring oxidative stress DNA damage and DNA repair (which has wide application to a number of diseases, including cancer and Alzheimer's disease), working with the National Institute of Justice to improve forensic DNA testing methods by developing new DNA assays and other work, and developing new technologies to measure mitochondrial DNA for forensic applications and disease diagnosis.

- Biospectroscopy Group: This Group works in biothermodynamics, biodefense (i.e., improving the sensitivity and reliability of biosensors for biological threats in the air and in water), biocatalysis, and biospectroscopy.

- Structural Biology Group: This Group does significant research in developing measurement methods related to X-ray crystallography and nuclear magnetic resonance imaging. It also funds research related to genomics and mass spectrometry.

- Cell & Tissue Measurements Group: This Group focuses on developing measurement standards for the pharmaceutical and biotechnology industries related to cellular and molecular processes. This includes work in bioinformatics, quantitative assessment of biomarker expression, cell-biomaterial interaction, live cell imaging, and gene expression profiling.

A more detailed description of these programs can be found online at the NIST website, www.cstl.nist.gov/biotech.

NIST conducts some research related to bioengineering outside of the Chemical Science and Technology Laboratory's Biochemical Science Division. This includes: materials and construction research within the Building and Fire Research Laboratory, computational sciences research within the Information Technology Laboratory, and intelligent systems within the Manufacturing Engineering Laboratory, among others.

The majority of bioengineering research at NIST appears to be funded through the Advanced Technology Program (ATP), which works cooperatively with private companies to develop innovative technologies that improve the nation's competitiveness in the global marketplace. It focuses on technologies that are unproven and in the early stage of development. This program has been targeted for elimination by the Administration, but Congress funded it at $80 million in FY 2006. In FY 2005, approximately $45 million of its funding was used to support research related to bioengineering. This was determined by conducting a search of the online ATP project clearinghouse at www.atp.nist.gov.

OTHER DEPARTMENTS AND AGENCIES

The Departments and Agencies listed below also fund bioengineering research. It was not possible to ascertain their estimated funding levels due to the fact that these agencies do not define or code bioengineering research. However, based upon a review of their budget documents, program descriptions, and funding solicitations, it is believed that these Departments and Agencies each fund a smaller proportion of bioengineering research than do NIH, DOD, DOE, NSF, or NIST.

National Aeronautics and Space Administration

NASA's bioengineering interest lies mainly in learning about the affect of space and space travel on the human body and ways to counteract its affects, through the Human Systems Research and Technology Theme, called the Biological and Physical Research Enterprise until FY 2005. It also performs some research related to robotics and simulation through its Aeronautics Technology Theme, though this is minimal. Some specific research initiatives related to bioengineering disciplines include: cellular and molecular analysis of saliva, blood, and DNA to determine the affect of microgravity and toxic exposure; and the development of artificial cells.

Department of Homeland Security

The Department of Homeland Security's research apparatus continues to develop slowly. However, it has interest in detection systems for biological weapons, bioagents, and bioinformatics. Funding is provided through the Science & Technology Directorate, and specifically the Homeland Security Advanced Research Projects Agency (HSARPA) and the Office of Research and Development (ORD). Additionally, DHS works very closely with the DOE National Laboratories. The DHS budget also includes biological and chemical countermeasures research within its Science & Technology Directorate, which have bioengineering components.

United States Department of Agriculture

The Department of Agriculture is interested in research that improves crop technologies and human nutrition. It funds bioengineering / biotechnology research that can assist it in these efforts. Intramural research funded by USDA is overseen by the Agricultural Research Service (ARS), which controls over 100 laboratories throughout the United States. Extramural research is funded through the Cooperative State Research, Education, and Extension Service (CSREES).

ARS bioengineering research projects include: biological control of weeds, biosafety of biotechnology derived food products, genomics (as it relates to both plants and animals), development of pest-resistant plants, development of nutritionally sound food products, bioinformatics (as it relates to crops), imaging technologies to identify plant diseases, and others. Specific program areas that relate to bioengineering include: Emerging Diseases of Livestock and Crops, Food Safety, Biobased Products / Bioenergy Research, Genetic Resources, and Genomics.

CSREES bioengineering related research projects include: functional genomics (microbes), plant genome and bioinformatics, nanotechnology, and others. CSREES funds research related to water quality, food safety, and homeland security.

Food and Drug Administration

The FDA funds bioengineering research related to rapid detection of bacterial contamination of food and medical supplies. It also has an interest in bioengineered foods. Specific projects include rapid detection of bacterial contamination of blood platelets and development of a rapid on-site human fecal matter biosensor.

Centers for Disease Control and Prevention

Bioengineering research is funded at the CDC through its National Institute for Occupational Safety and Health (NIOSH). It is particularly concerned with occupational exposure to biological agents. Specific projects include bioelectronic telemetry systems for the safety of firefighters and new air sampling systems and sensors.

NATIONAL TRANS-DEPARTMENTAL INITIATIVES

There are two trans-departmental initiatives that are related to bioengineering research and should be of interest to the bioengineering community.

The National Nanotechnology Initiative

The National Nanotechnology Initiative (NNI) is a $1 billion trans-agency federal initiative to develop nanotechnology. It was initiated in FY 2001 and is funded in the President's FY 2007 budget request at $1.2 billion, which would bring the total funding for the NNI to $6.5 billion.

NNI projects are funded at the discretion of the Federal Departments and Agencies that participate, but the initiative attempts to coordinate spending in order to support academic research and promote partnerships between research and private enterprises. The Program Component Areas (PCA) of the NNI include:

- Fundamental nanoscale phenomena and processes;
- Nanomaterials;
- Nanoscale devices and systems;
- Instrumentation research, metrology, and standards and nanotechnology;
- Nanomanufacturing;
- Major research facilities instrumentation acquisition; and
- Society dimentions.

Several of these areas contain bioengineering components that are supported by the Federal Departments and Agencies discussed in the report. In fact, over 75 percent of the NNI funding has gone to NSF, DOD, and DOE with most of the remaining funding going to NIH, NIST, and NASA. Additional information on the NNI can be found at www.nano.gov.

American Competitiveness Initiative

In his 2006 State of the Union Address, President Bush outlined an American Competitiveness Initiative (ACI) to encourage America to compete globally by increasing the federal investment in critical research and ensure that the American educational system maintains a strong foundation in math and science. The ACI commits $5.9 billion in FY 2007 and more than $136 billion over 10 years.

A key component of the ACI is to double the Federal commitment to basic research programs in the physical sciences and engineering at NSF, DOE, and NIST. This could have a positive impact on the level of federal funding for bioengineering research. More information on the ACI can be found at www.whitehouse.gov/stateoftheunion/2006/aci/aci-booklet.pdf, or a printed copy is available in the Appendix of this report (see Attachment #10).

CONGRESSIONAL ACTION

GENERAL OVERVIEW

Congress has been generally supportive of bioengineering research in an indirect manner. While there is no "champion" for bioengineering research, several powerful Members of Congress are supportive of the research agencies that fund this research. Sen. Arlen Specter (R-PA) and Sen. Tom Harkin (D-IA) are longtime supporters of the NIH and spearheaded the effort to double its budget from FY 1999 – FY 2003. Rep. Frank Wolf (R-VA), Rep. Vern Ehlers (R-MI), Sen. Joseph Lieberman (D-CT), Sen. Michael Enzi (R-WY), Sen. Jeff Bingaman (D-NM), and Sen. Ron Wyden (D-OR) are strong supporters of NSF and played a key role in encouraging the President of the United States to initiate the American Competitiveness Initiative. Sen. Pete Domenici (R-NM), Sen. Lamar Alexander (R-TN), and Sen. Jeff Bingaman (D-NM) are among many longtime supporters of the DOE National Laboratories. There are several Members of Congress who support DOD research.

CURRENT BILLS

There are three bills recently introduced in the Senate that should be of primary interest to the bioengineering community. This package of bills (**S. 2197, S. 2198, and S. 2199**) is collectively referred to as the **Protecting American's Competitive Edge (PACE) Act**. It is sponsored by Sen. Domenici, Sen. Alexander, Sen. Bingaman, and Sen. Barbara Mikulski (D-MD) and cosponsored by nearly 60 senators. The legislation intends to supplement and build upon the President's ACI. One of the key components of the PACE Act is that is authorizes the doubling of the budget for the Office of Science at DOE, NASA, NSF, and basic research at DOD over seven years through annual 10 percent increases. This legislation may face challenges in the House of Representatives from those Members of Congress concerned with the rising budget deficits. However, it is a very strong statement that a filibuster-proof number of Senators have cosponsored legislation that is similar to a Presidential initiative. The PACE Act can be found in the Appendix of this report (see Attachment #11).

There are several bills that have been introduced in the current (109th) Congress that relate to innovation that may be of interest to the bioengineering community. **S. 2109, the National Innovation Act of 2005**, is the most comprehensive of these bills. It is sponsored by Sen. John Ensign (R-NV) and cosponsored by 23 Senators. A companion bill in the House of Representatives (**H.R. 4654**) is sponsored by Rep. Adam Schiff (D-CA). These bills look to promote and incentivize innovation and modernize science education in order to secure America's leadership position as the leading scientific innovator. These bills can be found in the Appendix of this report (see Attachment #12). Specifically, the bills seek to:

- Create a President's Council on Innovation to coordinate the nation's investment in scientific innovation;
- Create Innovation Acceleration Grants to be awarded through various Departments and Agencies;
- Double funding for NSF over five years;

- Support research projects that promote regional economic development;
- Develop advanced manufacturing systems by creating pilot "test beds of excellence" at NIST;
- Expand the Graduate Research Fellowship Program at the NSF;
- Create pilot programs through NSF to assist institutions of higher education in facilitating the creation or improvement of professional science master's degree programs;
- Authorize NSF to award grants to 500 secondary schools and 500 primary schools to implement innovation-based experimental learning;
- Permanently extend the research and development tax credit;
- Create an alternative simplified credit for qualified research expenses;
- Improve defense-related innovation; and
- Direct the National Academies of Science (NAS) to study the barriers to innovation.

Other innovation bills of interest include:

S. 1263, Save America's Biotechnology Innovation Research Act of 2005: Sponsored by Sen. Kit Bond (R-MO), this legislation would amend the Small Business Act to require that businesses eligible for the Small Business Innovation Research Program must be at least 51 percent owned and controlled by U.S. citizens or permanent resident aliens and not more than 49 percent owned by a single venture capital firm. (See Attachment #13 in the Appendix.)

H.R. 4684: Sponsored by Rep. Bud Cramer (R-AL), this legislation would increase the amount of awards under the Small Business Innovation Research Program. (See Attachment #14 in the Appendix.)

H.R. 3331: Sponsored by Rep. Brad Miller (D-NC), this legislation creates a grant program within NSF for institutions of higher education to enable them to bridge the gap between laboratory discovery and commercially viable research. (See Attachment #15 in the Appendix.)

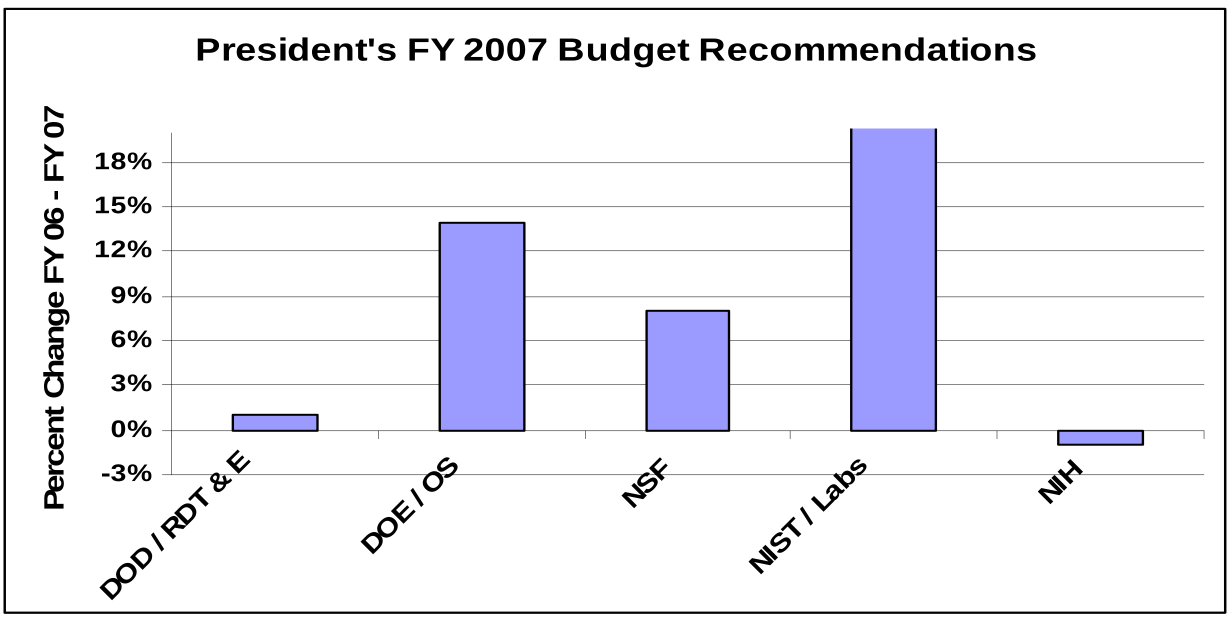
H.R. 4596, Sowing the Seeds Through Science and Engineering Research Act: Sponsored by Rep. Bart Gordon (D-TN), this legislation authorizes funding for NSF, DOE, NASA, NIST, and DOD for support of basic research activities in the physical sciences, mathematics and computer sciences, and engineering with at least 8 percent of the funding available for high-risk, potentially high-payoff research. It also directs the NSF to institute a graduate fellowship program for science, technology, engineering, and mathematics, and directs the Office of Science and Technology Policy to establish a National Coordination Office for Research Infrastructure. (See Attachment #16 in the Appendix.)

H.R. 250, Manufacturing Technology Competitiveness Act of 2005: Sponsored by Rep. Vern Ehlers (R-MI) and passed by the House of Representatives, this legislation creates many changes within NIST to improve manufacturing research and development. This legislation and the Science Committee Report can be found in the Appendix of this report (see Attachment #17). The legislation:

- Creates a pilot program of collaborative manufacturing research grants;
- Establishes a program of manufacturing sciences research fellowships;
- Establishes a program of competitive grants to develop or solve problems related to emerging manufacturing technology;
- Directs the creation of a Teacher Science and Technology Enhancement Institute Program at NIST; and
- Studies the impact of the elimination of the Advanced Technology Program.

OUTLOOK FOR FY 2007 APPROPRIATIONS

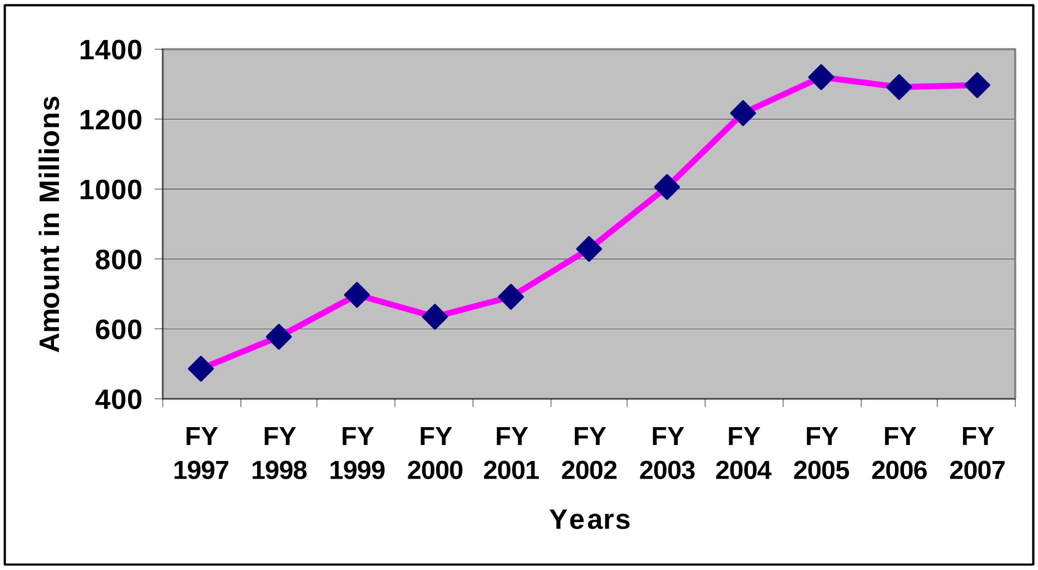
The FY 2007 appropriations process is likely to be difficult and partisan. The consideration of the funding level for research and development will be one of the more high profile debates. While the President has requested significant increases in funding for the DOE Office of Science, NSF, and NIST, he has requested only a nominal increase for DOD RDT&E and a small cut for the NIH (see chart below). Should Congress enact these recommendations, it would be damaging for bioengineering as approximately 60 percent of bioengineering research is funded through NIH and a significant portion of the remaining 40 percent is funded by the DOD. It is likely that supportive Members of Congress will fight to increase the DOD and NIH budgets, but there are no guarantees that they will prevail over the President and those Members of Congress who object to additional government spending due to rising budget deficits.



ANALYSIS

CURRENT TRENDS

We were not able to calculate spending trends across the entire spectrum of bioengineering research. However, we did examine the trend in bioengineering research at the NIH, which represents 60 percent of the total government contribution to bioengineering research. While the overall funding level has grown since the NIH Working Group conducted its audit of funding in FY 1993, bioengineering research funding has leveled off since FY 2004 after significant gains in the late 1990's and early part of the decade. These increases were due primarily to the increased NIH investment that took place over the doubling of the overall NIH budget. As the NIH budget has leveled off, so, too, has the NIH support for bioengineering research. This chart shows the NIH investment in bioengineering since FY 1997:



As the single largest contributor to bioengineering research funding, this trend at NIH should raise concern among the bioengineering community. While gains have been made over the past decade, it is important that the gains are maintained.

Bioengineering remains a relatively small component of the Federal Government's research and development budget. According to the American Academy for the Advancement of Science (AAAS), the total federal contribution to research and development in FY 2005 was $131 billion. Thus, bioengineering represents just 2 percent of this total. The AAAS calculations can be found in the Appendix of this report (see Attachment #18).

OUTLOOK

The outlook for bioengineering research funding remains unclear. The President and a majority of the United States Senate are on record supporting significant increases in funding for key Federal Departments and Agencies that fund significant portions of bioengineering research. However, the focal point of the Federal Government's bioengineering research portfolio, the NIH, is on track for its second consecutive real cut in FY 2007. This will be damaging to bioengineering research in general. Additionally, while the DOD budget continues to increase at a significant rate, RDT&E funding has leveled off. Thus, there are challenges ahead for bioengineering. The planned increases at NSF, NIST, and DOE represent positive steps, but they must be buttressed by similar increases at NIH and DOD if federal support for bioengineering research is to increase in a manner that will have an impact on the discipline.

There are many important Members of Congress who understand this principle. In fact, key Members of Congress have previously supported increases for NIH without the support of the President. The doubling effort from FY 1999 – FY 2003 was spearheaded by Members of the Senate and House Appropriations Committees. It is important to grow support in Congress and convince the Administration of the wisdom of funding NIH generally and bioengineering specifically if the NIH and bioengineering research are to receive increases in funding in FY 2007.

CONCLUSION

INVITATION FOR FEEDBACK

This report is not intended to be the final word on the Federal Government's investment in bioengineering research. The bioengineering community is encouraged to provide feedback. It is hoped that this information will initiate an open discussion within the community about federal funding for bioengineering research and the need to encourage its continued growth.