DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2003 Budget Request

Witness appearing before the
Senate Subcommittee on Labor-HHS-Education Appropriations

Donna J. Dean, Ph.D., Acting Director
National Institute of Biomedical Imaging and Bioengineering

March 21, 2002

Kerry N. Weems, Acting Deputy Assistant Secretary, Budget
Department of Health and Human Services

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering

Statement of the Acting Director

Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB) for FY 2003, a sum of $121,378,000, which reflects an increase of $9,356,000 over the comparable Fiscal Year 2002 appropriation.

Over the past year, it has been my privilege to preside over the formation and early development of the NIBIB, striving to provide a new and enriched focus at the National Institutes of Health (NIH) for bioengineering and imaging sciences. I can report to you today that, with help and support from the trans-NIH community, the NIBIB has taken significant steps in creating a research program in biomedical imaging and bioengineering that Congress envisioned when passing the NIBIB Establishment Act in December 2000.

MILESTONES TO SUCCESS

Guided by legislative language, and with input from the biomedical imaging and bioengineering communities, a mission statement was developed in March 2001, to articulate the NIBIB overall vision, goals and objectives. Upon my appointment as Acting Director in April, I was able to focus immediately on NIBIB's future as defined by the mission - "to improve health by promoting fundamental discoveries, design and development, and translation and assessment of technological capabilities in biomedical imaging and bioengineering, enabled by relevant areas of physics, chemistry, mathematics, materials science, information science, and computer sciences". Our Institute will foster and support an integrated and coordinated program

of research and research training that can be applied to a broad spectrum of biological processes, disorders and diseases and across organ systems.

The foundation upon which the NIBIB will build its success comes from the applications submitted by investigator-initiated research. NIBIB staff worked with the NIH Center for Scientific Review to implement referral guidelines and procedures so that applications relevant to the NIBIB mission would be appropriately directed to the Institute. In addition, Institute staff monitored the ongoing peer review process for grant applications already in the pipeline that would be eligible for NIBIB funding.

In accordance with the NIBIB mission to foster trans-NIH collaboration, the administration of the NIH Bioengineering Consortium (BECON) was transferred to the NIBIB. The BECON has been in existence since 1997 and has served as the focus of bioengineering extramural research at the NIH. The Consortium consists of senior-level representatives from most of the NIH Institutes and Centers (ICs) as well as representatives of other Federal agencies concerned with biomedical research and development. NIBIB joins the BECON as an additional institute representative and, in its administrative role, is committed to maintaining the successful coordination of trans-NIH bioengineering research, training, and communication programs.

The NIBIB is committed to supporting collaborations with other Federal agencies, and outside organizations, as indicated in our mission, to promote translation of cross-cutting technologies in bioengineering and imaging into biomedical applications. For example, the NIBIB and the Department of Energy (DOE) partnered to sponsor a workshop on “Applications of Thermography in Medical Diagnosis and Therapy”, which served to identify clinical applications of the technology and to facilitate research partnerships between the DOE national laboratories and NIH investigators. In addition, with support from the NIBIB and the Institute of Electrical and Electronics Engineers (IEEE), the “International Symposium on Biomedical Imaging: Macro to Nano” will take place this July. These activities provide a forum to showcase current

technology and applications, identify future biomedical needs and the emerging technologies, and assist in the process of planning the future research agenda.

On October 1, 2001, the NIBIB announced its establishment to the public through the launch of the official Institute website (http://www.nibib.nih.gov). The site serves as a conduit of information for those with an interest in the Institute and the fields of biomedical imaging and bioengineering. Comprehensive information about the history, mission, legislative activities, budget, staff, vacancy announcements, research and training opportunities and the administration of the Institute is available on the website. To date the website has received almost 700,000 hits from over 22,000 individuals and groups. Feedback indicates that the website is reaching a wide audience and providing useful information.

In addition, significant efforts are being made to communicate directly with the groups that look to the NIBIB for research support. We have targeted outreach activities specifically for engineering, physical and quantitative science communities, many of whom may be new to NIH programs and procedures. As Acting Director, I have made presentations across the nation to organizations that represent biomedical imaging and bioengineering communities. In addition, our staff have attended numerous meetings to inform the scientific communities about the NIBIB mission and current and planned research opportunities. For example, in recent months, we have met with academic, industrial, and government representatives in the states of Connecticut, Hawaii, Kentucky, New York, Pennsylvania, North Carolina, Indiana, California, and Virginia to discuss the development of consortia that support regional economies and multi-disciplinary biomedical research programs.

BUILDING A RESEARCH PORTFOLIO

The overarching goals of the NIBIB research program are to develop fundamental

new knowledge, foster potent new technologies, facilitate cross-cutting capabilities and nurture a new generation of researchers. To that end, several scientific areas have been identified for targeted research that is uniquely suited to the NIBIB mission. Among these are microtechnology and nanotechnology, diagnostic imaging, molecular- and cellular-level imaging, biosensors, biophotonics, materials, computational biology and computer technology. In addition, the training portion of the NIBIB mission will involve facilitating training programs for scientists with backgrounds that combine the biological and medical sciences with the allied engineering and physical science disciplines to develop the expertise they will need to carry out biomedical imaging and bioengineering research in the years to come. The next phase of building the NIBIB research and research training portfolio involves developing initiatives that will stimulate activities in these areas.

As one of the first steps in building the NIBIB research portfolio, scientific staff worked to identify ongoing research programs within the other NIH Institutes and Centers (ICs) involving areas of biomedical imaging and bioengineering that would be appropriate for NIBIB participation. For example, the "Bioengineering Research Partnerships" Program Announcement (PA) solicits applications from researchers seeking to establish multi-disciplinary research teams to address a significant area of bioengineering research within the mission of NIH. Another PA, "Technology Development for Biomedical Applications," invites applicants who are developing novel instruments, devices, methodologies and software for use in biomedical research. In order to form partnerships with other ICs as articulated in our mission, the NIBIB has joined a variety of other initiatives across NIH.

To further enhance our research portfolio, the NIBIB is proud to announce our first two scientific initiatives in the areas of biomedical sensors and molecular-level imaging. Biomedical sensors can be defined broadly as devices that detect specific molecules or biological processes and convert this information into a signal. Biology

and medicine have gained enormous insight into the life process by discovery, development and application of sensors. To advance this technology, the NIBIB recently issued a Request for Applications (RFA) entitled "Sensor Development and Validation." The purpose of the RFA is to support basic and applied research targeted at sensor development. In addition, the NIBIB will be the lead sponsor of an international assessment of the status of biosensor technology along with several other Federal agencies.

Discoveries in molecular and cellular biology present extraordinary opportunities for biomedical imaging to play an important role in the early detection, diagnosis and treatment of disease. The support of fundamental discovery and technical development of imaging technologies, before specific disease- or organ-oriented applications are determined, is critical, and is highlighted in the NIBIB mission. Another RFA recently issued by NIBIB, entitled "Research and Development of Systems and Methods for Molecular Imaging," addresses this important scientific need, and will support novel investigations for development of molecular imaging and spectroscopy that can be applied to multiple biological or disease processes.

The NIBIB's current portfolio supports a broad range of cross-cutting biomedical research and enabling technology development in areas such as biomaterials that encourage neural regeneration, microneedles for painless drug delivery, high-resolution imaging of soft tissue, and sensor microarrays for instantaneous chemical identification. (see Appendix)

FUTURE STRATEGIES

In the upcoming year, the NIBIB will begin to focus its research agenda and develop programs in such areas as nanotechnology and reparative medicine. Many scientists believe that nanotechnology is a new field of research that will enable the development

of a new generation of scientific and technological approaches, as well as tools and devices used in research and clinical settings. One area where nanotechnology could be applied to medical therapy is the development of nanoparticle materials for drug discovery, production, and delivery. Nanoparticle materials offer significant improvements in bioavailability and efficiency through oral and injectable pathways. Since cellular- and molecular-level interactions occur on the nanometer scale, such technologies have the potential to offer significant improvements over current treatment options. The NIBIB plans to stimulate research in this area, based on recommendations from the 2000 BECON symposium entitled, "Nanoscience and Nanotechnology: Shaping Biomedical Research".

Reparative medicine represents a critical and highly visible frontier in biomedical and clinical research. A key component of the field is tissue engineering, the goal of which is to repair or replace tissues and organs by delivering DNA, proteins, protein fragments, implanted cells or scaffolds to areas where they are needed. The NIBIB has a role in this endeavor to explore the following areas: self-monitoring materials for cell-, drug-, or gene-based therapies; predictive, low-cost *in vivo* and *in vitro* models; accelerated testing and failure analysis; and approaches to understanding the biology-biomaterial interface. In accord with recommendations from the 2001 BECON symposium entitled, " Reparative Medicine: Growing Tissues and Organs", we are developing initiatives to address these needs.

Other areas presenting rich opportunities for NIBIB research are included in our plans for future programs. In imaging device development, we plan to support research and development of generic biomedical imaging technologies before specific applications are demonstrated. In implant science, critical needs are development of tools for assessing loads and stresses in an operating environment, rapid simulation and prototyping methods and life-time predictive methods for design and analysis at the time of implant design, and during dysfunction and failure. Imaging processing and analysis offer challenges in the development, design, and implementation of image

acquisition and information analysis algorithms, image-guided procedures and techniques for deriving physiology and function from multidimensional images.

Planning for a research training program is a high priority for the NIBIB, considering the recent Department of Labor report which indicated that biomedical engineering jobs would increase by more than 31 percent by the end of the decade. To determine needs in trans-disciplinary training, the NIBIB participated in a joint NIH-National Science Foundation (NSF) workshop on training and education in the fields of bioengineering and bioinformatics that brought together researchers and educators from across the nation. Preliminary plans include funding for multiple components at all career levels, including experiences at the pre-doctoral and post-doctoral levels, a summer training experience for quantitative science students, and institutional grants through the NIH National Research Service Awards (NRSA) program. Our goal is to facilitate the trans-disciplinary training and education necessary to assure the availability of future generations of highly-trained professionals to meet the anticipated national demands.

As a dynamic and synergistic Institute, the NIBIB is pleased to be a part of the Federal science and technology research enterprise in the 21st century high-tech information age. We look forward to establishing our role in this important endeavor.

Mr. Chairman, I would be pleased to answer any questions you or the Committee may have.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

BIOGRAPHICAL SKETCH

NAME: Donna Joyce Dean, Ph.D.

POSITION: Acting Director, National Institute of Biomedical Imaging and Bioengineering

BIRTHPLACE AND DATE: Danville, Kentucky
April 22, 1947

EDUCATION:

A.B.	Chemistry	Berea College (Kentucky), 1969
Ph.D.	Biochemistry	Duke University (North Carolina, 1974

EXPERIENCE:

2001 -	Acting Director, NIBIB, NIH
1998- present:	Senior Advisor to Acting Director/Deputy Director, NIH
1997-1998:	Director, Division of Physiological Systems, Center for Scientific Review, NIH
1995-1997:	Acting Chief, Referral and Review Branch, Division of Research Grants, NIH
1988-1995	Chief, Biological and Physiological Sciences Review Section, Division of Research Grants, NIH
1982-1988:	Referral Officer and Scientific Review Administrator, Division of Research Grants, NIH
1979-1982:	Consumer Safety Officer, Food Additives and Veterinary Drugs, Food and Drug Administration
1977-1979:	Research Chemist, National Institute of Arthritis, Metabolism and Digestive Diseases, NIH
1974-1977:	NIH Postdoctoral Fellow, Princeton University
1968:	Research Trainee, Oak Ridge National Laboratories

PROFESSIONAL SOCIETIES: American Chemical Society, American Society for Cell Biology, American Society for Investigative Pathology, Society for the Advancement of Chicanos and Native Americans in Science, Association for Women in Science

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF MANAGEMENT AND BUDGET

BIOGRAPHICAL SKETCH

NAME: Kerry N. Weems

POSITION: Acting Deputy Assistant Secretary for Budget

BIRTHPLACE: Portales, New Mexico

EDUCATION:
B.A., Philosophy, New Mexico State University, 1978
BBA, Management, New Mexico State University, 1978
MBA, University of New Mexico, 1981

EXPERIENCE:

2001 - present	Acting Deputy Assistant Secretary for Budget, HHS
1996 - present	Director, Division of Budget Policy, Execution and Management, HHS
1991 - 1996	Chief, Budget Planning Branch, HHS
1988 - 1991	Program Analyst, Office of Budget, HHS
1983 - 1988	Program and Budget Analyst, HHS (Social Security Administration)
1981 - 1983	Staff Member, United States Senate

HONORS AND AWARDS:

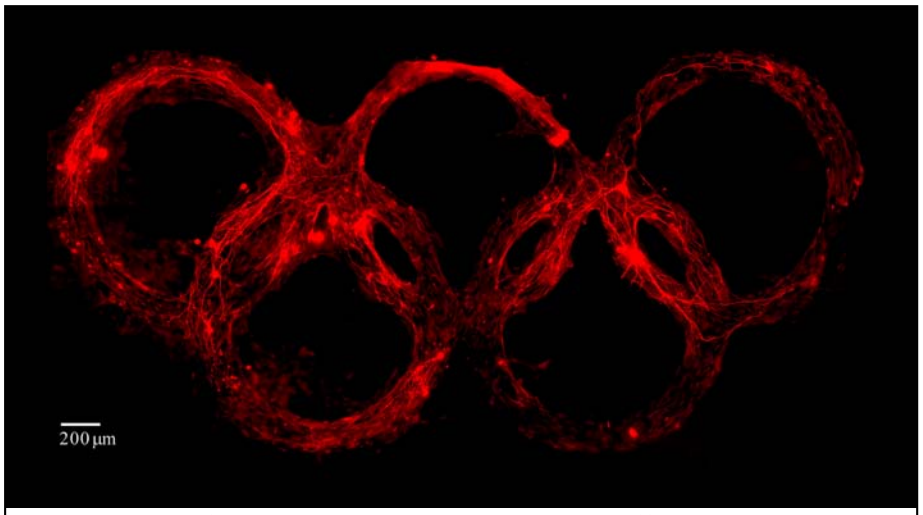
2001	Presidential Rank Award
1995	Secretary's Distinguished Service Award
1993	HHS Senior Management Citation

Appendix

Examples of Research Supported by the National Institute of Biomedical Imaging and Bioengineering

Probing Single-Molecule Neuron-Ligand Pathfinding (8-R01-EB00463-02**)**

Principal Investigator: **Thomas Beebe,** University of Delaware

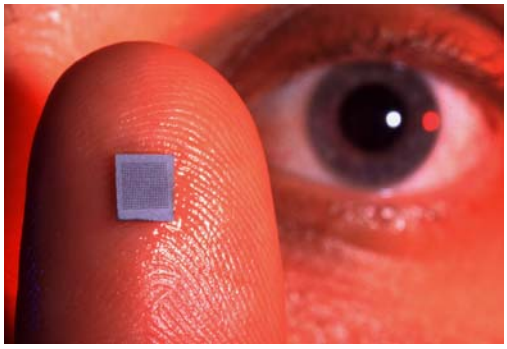


Nerve cells and fibers grow on a bioengineered scaffolding in the shape of the Olympic rings in a demonstration of technology that someday may help people with brain disorders and spinal cord injuries. The "living rings" measure about one-eighth-inch wide.

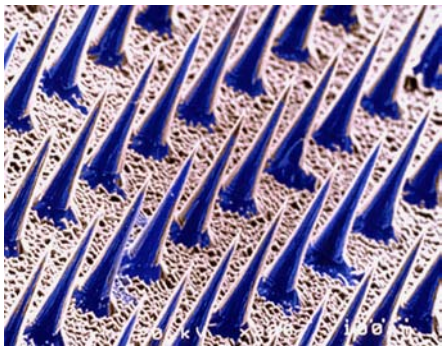
Source: Beebe, T. University of Delaware

Microfabricated Microneedles for Drug Delivery (8-R01-EB00260-03**)**

Principal Investigator: **Mark Prausnitz,** Georgia Institute of Technology



Size of experimental microneedle array is shown by its placement on the researcher's finger. There are 400 needles in the array.



Electron micrograph close-up of the needles, with added color.

Source: Photographs are copyrighted by the Georgia Tech Research Corporation and may be freely used by the news media with credit to the Georgia Institute of Technology. The photographer is Stanley Leary, Georgia Tech Communications Division.

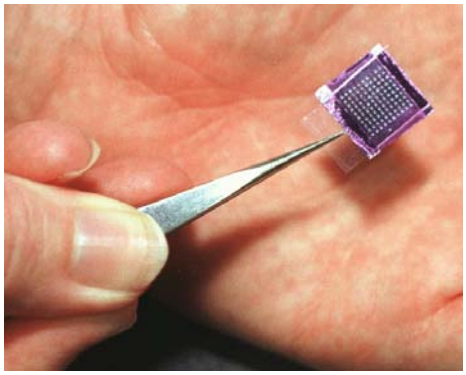
Multidisciplinary Micro CT-3D Imaging Facility (8-R01-EB00305-06**)**

Principal Investigator: **Erik Ritman,** Mayo Clinic

Source: Copyright © 1996-2002 Mayo Foundation for Medical Education and Research.

Development of an Electronic Tongue (2-R01-EB57306-04A1

Principal Investigator: **Eric Ansyln,** University of Texas



Source: University of Texas.