

SCIENCE POLICY

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BEMA Grapples with Biomaterials Issues on the Cutting Edge

Ensuring access to critical biomaterials and improving science-based testing methods to streamline approval of new hybrid devices are just two of many major issues that fall under the purview of the Roundtable on Biomedical Engineering Materials and Applications (BEMA). BEMA is an activity of the National Materials Advisory Board (NMAB) under the U.S. National Academies that was recently renewed after a successful three-year pilot period.

According to NMAB director Toni Maréchaux, the first BEMA workshop, held in February 2001, focused on critical biomaterials access.

"People were concerned about possible material shortages," said Maréchaux. "Many factors contribute to problems with materials availability. In some cases, it may be related to liability issues," she said, pointing to the lawsuits surrounding silicone breast implants and Teflon implants used to treat temporal mandibular joint (TMJ) syndrome as examples. "The materials used in medical devices are a very small part of the cost, but the suppliers can share greatly in the liability," she said.

Congress has already tried to address

this issue with the passage of the Biomedical Access Assurance Act of 1998 (BAAA). However, "the BAAA doesn't end up working the way they intended," said Maréchaux. Most notably, the law prohibits materials suppliers from participating directly in the design, sale, or distribution of medical devices using their materials; this deprives them of protection under the law.

New legislation could address the concerns both of public health and safety, and of materials suppliers and device manufacturers.

Maréchaux said that it is unclear what a new law might cover, however, and that "determining what the real issues were before new legislation was drafted would be a good strategy." So BEMA brought together device manufacturers, materials suppliers, and regulators, as well as representatives from the research community, funding agencies, and several nonprofit organizations, in an industry roundtable.

The next workshop will focus on science-based testing. According to Maréchaux, the Food and Drug Administration (FDA) only approves biomedical devices that have been extensively clinically tested. It does not accept accelerated laboratory testing results, for example, because of the dif-

ficulty in simulating the complex conditions inside the human body. In addition, to date there has been very little explanting of implants to examine how they fail—something of critical importance for materials scientists. Better testing could help alleviate the enormous workload of the FDA's Center for Devices and Radiological Health (CDRH).

Some progress has been made. The CDRH has reduced the average review time for novel and high-risk medical devices from 26 months in 1995 to 12 months in 2000. Meanwhile, in June the FDA announced that manufacturers of certain critical medical devices would be required to conduct postmarket surveillance of their products for up to three years. However, these improvements are only part of the challenge, according to Alan Goldstein, a professor at Alfred University and a BEMA member who is spearheading the workshop on science-based testing. Goldstein hopes that discussion will yield a better definition of what constitutes a biomaterial. The current definition does not adequately address many new medical devices that are the first of their kind and therefore pose unique challenges to regulatory agencies like the FDA.

National Defense Science and Engineering Graduate Fellowships



ACADEMIC YEAR 2003-2004

As a means of increasing the number of U.S. citizens trained in disciplines of science and engineering of military importance, the Department of Defense plans to award approximately 200 new three-year graduate fellowships in April 2003. National Defense Science and Engineering Graduate Fellowships may be awarded for study and research leading to doctoral degrees in, or closely related to, the following disciplines:

AERONAUTICAL AND ASTRONAUTICAL ENGINEERING
BIOSCIENCES
CHEMICAL ENGINEERING
CHEMISTRY
CIVIL ENGINEERING
COGNITIVE, NEURAL, AND BEHAVIORAL SCIENCES
COMPUTER SCIENCE
ELECTRICAL ENGINEERING
GEOSCIENCES (INCLUDES TERRAIN, WATER, AND AIR)
MATERIALS SCIENCE AND ENGINEERING
MATHEMATICS
MECHANICAL ENGINEERING
NAVAL ARCHITECTURE AND OCEAN ENGINEERING
OCEANOGRAPHY
PHYSICS

National Defense Science and Engineering Graduate Fellows selected in 2003 will receive a stipend in addition to full tuition and required fees. The stipend amount starts at \$23,500 annually.

Recipients of National Defense Science and Engineering Graduate Fellowships do not incur any military or other service obligation.

Specific information regarding the fellowship is available from the American Society for Engineering Education, a nonprofit education association, which is administering the program for the Department of Defense.

Additional information and an online application are available at:
<http://www.asee.org/ndseg>

Contact Information:
NDSEG Program Manager
American Society for Engineering Education
1818 N Street, NW
Suite 600
Washington, DC 20036
Phone: 202/331-3516 Fax: 202/265-8504
Email: ndseg@asee.org

Completed applications must be postmarked by January 6, 2003.

In accordance with Federal statutes and regulations, no person on the grounds of race color, age, sex, national origin or disability shall be excluded from participating in, denied the benefits of, or be subject to discrimination, under any program activity receiving financial assistance from the Department of Defense.



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For example, among the CDRH's approvals last year were an implanted pacemaker incorporating a tiny transmitter to communicate data on the patient's heart condition to the physician; a vest-like device that senses heart malfunction and delivers an electric shock to restore normal heart rhythm, designed for patients who cannot have an implanted defibrillator; and a "swallowable" capsule with a tiny camera that snaps pictures as it moves through the small intestine to help detect internal bleeding and other abnormalities.

"These types of hybrid devices cross traditional boundaries," said Goldstein. "How do you regulate a device that is part cellular, part machine, and may also release drugs? Currently nobody is prepared to evaluate these devices because they've never existed before. That's why we need a revision of the working definition for a biomaterial. Before you can decide what kind of testing is adequate, you have to decide what you're going to call the thing you're planning to test."

BEMA does not provide specific recommendations on issues of policy pending before any government agency. Yet, the insights gleaned from its discussions have a direct bearing on future public policy. One solution, said Maréchaux, is

to find sponsorship for an official study on these major topics by the National Academies. She is spending the next few months discussing the prospect of a study on biomaterials access with various federal funding agencies, and while the workshop on science-based testing is still in the planning stages, Goldstein hopes eventually to do the same.

JENNIFER OUELLETTE

Call Issued for Increased Private-Sector Participation in S&T in India

At a national seminar on "India as a Dominant Source of Global Technologies," organized by the Associated Chambers of Commerce and Industry and held in August, the Indian Minister for Human Resource Development and Science and Technology, Dr. Murli Manohar Joshi, told the country's industrial leaders that the government is ready for private-sector participation in projects covering frontier areas of science. The New Millennium Indian Technology Leadership Initiative, launched two years ago, offers a vast scope for joint partnerships, as it seeks to establish a new paradigm in technology perspectives to enable India to secure a global leadership role in technology. One of the projects being undertaken is a

nanoparticle-based drug delivery system, Joshi said. Other technologies he highlighted are the replacement of petroleum-based hydrocarbons and a fuel-cell-based power source.

Science Minister of Australia Announces Expert Advisory Committee

The formation of an Expert Advisory Committee to advise the Australian federal government on the selection of national research priorities was announced on August 15 by Science Minister Peter McGauran. Jim Peacock, chief of the Commonwealth Scientific and Industrial Research Organization Plant Industry and president of the Australian Academy of Science, will chair the 12-member committee that includes chief scientist Robin Batterham. Committee members include Professor Sue O'Reilly and Associate Professor Michelle Simmons, who have backgrounds in materials-related research.

O'Reilly holds a personal chair in geology and is director of the Australian Research Council (ARC) National Key Centre for Geochemical Evolution and Metallogeny of Continents (GEMOC) as well as a professor of earth sciences at

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Nanjing University. She is a fellow of the Australian Academy of Science and the Norwegian Academy of Science and Letters. O'Reilly is a member of the ARC's Physics, Chemistry, and Geosciences Expert Advisory Committee 2001–2003 and a member of the Australian Academy Committee for Earth Sciences.

Simmons is currently the director of the Atomic Fabrication Facility and an ARC Queen Elizabeth II Research Fellow at the University of New South Wales, Sydney. She joined the Centre for Quantum Computer Technology as the program manager in Atomic Fabrication and Crystal Growth in 2000 after completing a research position at the University of Cambridge, where she was in charge of the design, fabrication, and characterization of ultrahigh-quality quantum electronic devices. She has over 14 years' experience in all aspects of semiconductor crystal growth, device fabrication, and electrical characterization of quantum electronic devices and has published more than 150 refereed research papers in journals such as *Nature*, *Science*, and *Physical Review Letters*.

Jamaica's Scientific Research Council Hosts S&T Conference in November

The Scientific Research Council of Jamaica will host a Science and Technology (S&T) Conference on November 28–30 at the Knutsford Court Hotel (formerly Sutton Place Hotel) in Kingston. The focus of this year's conference is "Economic Development: Towards Health, Wealth, and Knowledge." The objective of the annual conference is to continually update the scientific community with developments taking place in various S&T fields in Jamaica. Registration is free, and during the month of November, S&T organizations and institutions will be open to the public. For updates on the conference, access Web site www.src-jamaica.org/Confer.htm. For further information, contact Mr. Hawthorne Watson, Acting Divisional Director, Information & Coordination Services/Conference Director; Scientific Research Council; P.O. Box 350, Hope Gardens, Kingston, Jamaica; tel. 876-927-1771 (-4), fax 876-977-1841, or e-mail merlineb@src-jamaica.org.

U.K. Foresight Program Considers S&T Challenges of the Future

A group of scientists from a range of disciplines met with the U.K. Chief Scientific Advisor, Professor David King, to list 12 potential subject areas for study in the Foresight program managed by Britain's Office of Science and Technology. The program identifies potential opportunities arising from new science and technologies and the actions to help realize those opportunities. In September,

Science Minister Lord David Sainsbury published the consultation document on the 12 subjects that should be studied in the next stage of the program. Among the subject areas identified were the life cycle of products, referring to the reduction of waste in manufacturing and the production of fully recyclable products; and energy for the future, referring to a look into future fuel sources, including renewables. Among the scientists involved in drafting the list was Richard Friend, Cavendish Professor of Physics at the University of Cambridge, whose research interests cover conjugated polymers, time-resolved optical spectroscopy, and molecular conductors and magnets. In addition to the 12 topics, Foresight wants to hear about other areas it should consider. The consultation runs until December 4, 2002. The consultation document can be found on the Foresight Web site at URL www.foresight.gov.uk. Responses to the consultation can be e-mailed to Foresight using the forms on the Web site.

South African S&T Department Embarks on R&D Survey

The Department of Science and Technology (S&T) of South Africa is embarking on a national research and development (R&D) survey. South Africa currently spends about 0.7% of its gross domestic product on R&D. This survey will feed into the overall set of indicators that the government uses to direct and measure the making of policy and its implementation, economic growth, and service delivery, according to the department.

The Human Science Research Council is mandated to develop a reliable methodology, analytical tools, and indicators, together with reports on survey data. The R&D survey is currently being piloted and is to be completed by March 2003. Dissemination of the survey results will be through a dedicated Web site and published reports.

Noting the importance of this survey for the future development of the South African science system and its contribution to socioeconomic development, the Minister of Science and Technology, Dr. Ben Ngubane, urges all those who are approached to participate fully by comprehensively completing and returning the survey questionnaire. In the future, the survey will be conducted biennially and will be declared an official survey by Statistics South Africa.

South Korea Reports Record Levels of R&D Investment

According to a recent survey conducted by the South Korean Ministry of Science

and Technology, research and development (R&D) investment in the public and private sectors has increased by 16.3% and the number of researchers (179,000) has risen 11.9% since 2000. The survey also found that this amount of investment is the largest since 1963 in terms of size and ratio to the country's gross domestic product (GDP). Further findings of the survey, announced in August, said that the proportion of investment to corporate sales also rose from 2.0% to 2.3% in 2001. About 10,000 participants from universities, research organizations, and corporations cooperated in the survey. The ministry anticipates that R&D investment will post an increase of 14.7% in 2002. The sum will be greater than 3% of the GDP, the ministry said.

Information Conferences to be Held Regarding EU Sixth Framework Programme

The European Commission (EC) will hold a major conference on November 11–13, 2002, in the Palais du Heysel in Brussels to mark the launch of the European Union (EU) Sixth Framework Programme (FP6) for research, which will cover the period from 2002 to 2006. The forum will present the objectives and priorities of FP6 and explain the rules for participation. From outside the EU, India's Minister for Human Resource Development and Science and Technology, Dr. Murli Manohar Joshi, has been invited to deliver a special address on technology and fundamental science. Further information can be obtained from the EC/ Directorate-General for Research Information and Communication; tel. 32-3-295-99-71, fax 32-2-295-82-20, e-mail rtd-conference2002@cec.eu.int, and Web site <http://europa.eu.int/comm/research/conferences/2002/>.

Many information seminars on FP6 will be held in various parts of Europe, including a conference to be held in Warsaw on November 25–26, 2002, to address researchers, scientists, and business representatives from Poland, Candidate Countries, and other Central and Eastern European States. More information can be obtained at URL www.kbn.gov.pl. An information day relating to the Netherlands will take place in Rotterdam on December 10, 2002. Further information can be obtained from the EG Liaison, tel. 31-70-361-02-50, e-mail info@kp6.nl, or URL www.kp6.nl. In Hanover, Germany, the information seminar will be held on February 3–4, 2003. Further information can be obtained from URL www.rp6.de. □

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