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PRINCIPAL INVESTIGATOR: Richard Chait, Ph.D.

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Richard Chait, Ph.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
National Academy of Sciences
Washington, DC 20418

E-MAIL:
rchait@nas.edu

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Biomedical Engineering and Materials Applications (BEMA) Roundtable Progress Report

Summary

The National Materials Advisory Board held the first BEMA Roundtable meeting on 20-21 July 2000 at The National Academies, Main Building Board Room, Washington DC. Attendees represented government, industry, and academia. Four speakers spoke on three topics: 1) The Appropriate Determination of Biocompatibility, 2) Improving the Scientific Basis for Regulatory Decision Making, and 3) Supply and Access of Biomaterials.

Based on the briefs presented at this roundtable, three specific, priority topics emerged: 1) Science Based Testing, 2) Partnerships to Improve the Regulatory Process, and 3) Barriers to Innovation in Medical Devices. To kick off discussion of these topics, three pairs of members volunteered to write concept papers, eventually leading to the focus of a June 2001 workshop.

The BEMA members also decided to add a fourth, catch-all topic, "Other Emerging Topics".

The BEMA members also requested creation of a members-only, interactive website for use in planning future workshops and roundtables, and to foster discussion on the four topics above. The members agreed to hold the next roundtable on 5-6 December 2000 in Washington DC. This roundtable will be a planning meeting to finalize the topics for the June 2001 workshop and discuss possible topics for a Fall 2001 workshop.

Since the first BEMA Roundtable, Medtronic Inc has decided to join the BEMA Roundtable. In addition, Zimmer Inc, a manufacturer of orthopedic devices, and a wholy-owned subsidiary of Bristol-Myers Squibb, has expressed interest in joining the BEMA Roundtable.

Finally, NMAB has drafted an agenda for the December 2000 BEMA Roundtable meeting. Scheduled speakers include Dr. David Feigal, Director for the Center for Devices and Radiological Health, US Food and Drug Administration; Prof Henry Piehler, Department of Materials Science and Engineering, Carnegie-Mellon University; Prof Henry Rack, Department of Ceramic and Materials Engineering, Clemson University; and Mark Heller, Senior Partner, Hale and Dorr LLP.

Introduction

The National Materials Advisory Board held the first BEMA Roundtable meeting on 20-21 July 2000 at The National Academies, Main Building Board Room, Washington DC. The roundtable was held under the combined auspices of the National Research Council, National Academy of Engineering, and Institute of Medicine. An Academy roundtable is a convening mechanism for dialogue and exchange of information among individuals, including government officials, who represent all sides of particular, broad-based issues of public policy. This provides a structured opportunity for the exchange of information

and the identification of concerns in a nonadversarial setting among government, industry, and academe. The roundtable will not provide advice or recommendations on any specific issue or policy pending before any government agency.

With respect to BEMA, the roundtable provides a forum for identifying major opportunities for applying engineering principles to create and improve clinical performance of medically useful materials and devices, including implants, as well as for discussion of strategies for overcoming obstacles—technical, legal, or cultural—that impede transition of new materials and devices to clinical application.

Roundtable Attendees and Agenda
Roundtable attendees included:

Government Agencies
- Food and Drug Administration
- National Institutes of Health
- National Institute of Standards and Technology
- National Science Foundation
- U.S. Army (WRAIR)
- U.S. Navy (ONR)
- Veterans Administration

Industry
- Advanced Tissue Sciences
- Boston Scientific
- Dow Chemical
- Edwards Lifesciences
- Advanced Medical Technology Association (AdvaMed), formerly HIMA
- Johnson & Johnson
- MiniMed, Inc.

Academia
- Alfred University
- California State University Program for Education and Research in Biotechnology (CSUPERB)
- Center for Innovative Minimally Invasive Therapy (CIMIT)
- National Academy of Engineering (NAE)
- New Jersey Associated Institutions for Material Sciences (AIMS)
- University of Florida

The agenda covered the following:

Panel I—The Appropriate Determination of Biocompatibility
Speaker: Joachim Kohn (Director, The New Jersey Center for Biomaterials)

Panel II—Improving the Scientific Basis for Regulatory Decision Making
Speaker: Kshitij Mohan (Senior Vice President & Chief Technology Officer, Boston Scientific Corporation)

Panel III—Supply and Access of Biomaterials
Speakers: Paul Citron (Vice President of Science & Technology, Medtronic, Inc), Rachel Kaganoff Stern (Associate Political Scientist, RAND)

Action Items
Based on the briefs presented at this roundtable, three specific, priority topics emerged:

Topic	Concept Paper Authors
Science Based Testing	Goldstein (Alfred)/Sahatjian (Boston Scientific)
Partnerships to Improve the Regulatory Process	Rekow (AIMS)/Rosen (CIMIT)
Barriers to Innovation in Medical Devices	Scopelianos (J&J)/Johnson (Dow)

To kick off the topic discussion, the authors listed above will write concept papers, eventually leading to the focus of a June 2001 workshop.

The BEMA members also requested creation of an interactive website for member use in planning future workshops and roundtables. The members also agreed to hold the next roundtable on 5-6 December 2000 in Washington DC. This roundtable will be a planning meeting to finalize the topics for the June 2001 workshop and discuss possible topics for a Fall 2001 workshop.

The BEMA members also added a fourth, catch-all topic, "Other Emerging Topics". All four topics will be discussed on the interactive web site.

Additional Developments
Medtronic Inc has joined the BEMA Roundtable. Medtronic is a leading medical device manufacturer, producing products such as pacemakers, defibrillators, drug delivery systems, and neurostimulation systems. Paul Citron, Medtronic's VP of Science and Technology, was an invited speaker at the first BEMA Roundtable meeting in July 2000.

NMAB board member Prof Earl Dowell of Duke University provided contact information for Prof Jim Mason, a faculty member in Aerospace and Mechanical Engineering at Notre Dame. Prof Mason is also a consultant to Zimmer Inc, a manufacturer of orthopedic devices, and a wholy-owned subsidiary of Bristol-Myers Squibb. Zimmer has expressed interest in joining the BEMA Roundtable.

NMAB has a draft agenda for the December 2000 BEMA Roundtable meeting. Scheduled speakers include Dr. David Feigal, Director for the Center for Devices and

Radiological Health, US Food and Drug Administration; Prof Henry Piehler, Department of Materials Science and Engineering, Carnegie-Mellon University; Prof Henry Rack, Department of Ceramic and Materials Engineering, Clemson University; and Mark Heller, Senior Partner, Hale and Dorr LLP.