

# **NATIONAL MATERIALS AND MANUFACTURING BOARD**

## **Roundtable on Biomedical Engineering Materials and Applications**

### **Agenda**

The National Academies  
Keck Center  
500 5<sup>th</sup> Street NW, Washington, DC 20001  
Room 208  
March 8-9, 2020

### **“Issues and Opportunities Regarding the Availability of Biomaterials and Services for the Medical Device Industry”**

#### **Sunday, March 8**

**Working Dinner: Carmine’s Restaurant, 425 7<sup>th</sup> St., NW. Washington, D.C.  
(Seating @ 6:00 p.m.)**

#### **After Dinner Talk:**

**“Overview of Commercial Polymers (Considered/Used/Removed) for Medical Devices over 50 Years”**  
Speaker: Art Coury, BEMA Co-Chair

#### **Monday, March 9**

8:00-8:30 am	Breakfast in meeting room
8:30-9:10 am	"Status and Potential Value of a Materials for Medical Devices Database" Speaker: Mike Helmus, Consultant
9:10-9:50 am	“Have a Heart - The Case of “Biomer”: Supply Pathway From Materials Supplier Device Manufacturer (DuPont – J&J (Ethicon) – Syncardia): Potential Materials Assurance Strategy” Speaker: Marvin Slepian (U. of Arizona, Founder of Syncardia)
9:50-10:05 am	Break
10:05-10:45 am	“Biomaterials Standards in Regard to Supply Chain Issues” Speaker: Carl Simon, NIST
10:45-11:25 am	“Material and Service Outsourcing Issues in the Medical Device Supply Chain” Speaker: Larry Thatcher, TESco Associates
11:25- 12:05 am	“Drug Shortages: Root Causes and Potential Solutions” Speaker: Emily Thakur, FDA

12:05-12:45 pm	Lunch
12:45- 1:25 pm	<p>“Biomaterial Access Assurance Act of 1988: Issues and Developments Prior and Subsequent to Passage”</p> <p>Speaker: Scott McNamee, FDA</p>
1:25-2:05 pm	<p>“Corporate Perceptions of the Risk of Developing, Providing, and Controlling Distribution of Biomaterials: The Perspectives of a 33-year Dow Corning/Dow Chemical/Dupont Veteran”</p> <p>Speaker: Jim Curtis, DuPont</p>
2:05-2:20 pm	Break
2:20-3:00 pm	<p>“Biomaterials Supply Issues of a Medical Device Leader: Medtronic: Biomaterials Customer and Biomaterials Developer”</p> <p>Speaker: Patrick F. Walker, Medtronic</p>
3:00-3:40 pm	<p>“Metallic Biomaterials Safety and Potential to Affect Availability: Risk vs. Reward Considerations”</p> <p>Speaker: Bob Hastings, Johnson and Johnson</p>
3:40-3:55 pm	Break
3:55-4:15 pm	<p>Summary by Rapporteur</p> <p>Elizabeth Bielski, FDA</p>
4:15-4:45 pm	Planning and Close