Sunday Evening Program
Kathleen McDermott of Sonnenschein, Nath & Rosenthal, LLP, addressed the Forum on the issue of conflict of interest. Ms. McDermott provided background on the anti-kickback investigations involving orthopaedic device manufacturers and compared previous interpretations of business activities to the revised perspectives resulting from the federal monitors. Points for consideration included the existing structures for managing conflicts and the importance of the intent of incentives, regardless of the size.

Pediatric Device Development
AAOS staff presented an overview of the National Institutes of Health Pediatric Medical Devices Stakeholders Workshop on July 23, 2008. The goal of the meeting of the Interagency Pediatric Devices Working Group, which includes NIH, AHRQ, and FDA, was to elicit feedback, including responses to a Request for Information (RFI), about expanding pediatric device research and development from interested communities and the public to help inform the plan that the DHHS Secretary will submit in accordance with the legislation. Additional information about the workshop is available at www.nichd.nih.gov/about/meetings/2008/devices.cfm.

FDA Sentinel Initiative
On May 22, 2008, FDA launched the Sentinel Initiative with the ultimate goal of creating and implementing the Sentinel System – a national, integrated, electronic system for monitoring medical product safety. FDA representatives from the Division of Postmarket Surveillance discussed recent activities related to the initiative and outlined its goals, particularly with respect to orthopaedic implants. The initiative’s timeline spans several years and The Sentinel Initiative’s short- and long-term objectives for orthopaedics include:

- Identify & characterize existing U.S. orthopedic implant registries. Explore potential for establishing distributed system
- Explore the utility of orthopedic registries outside the U.S.
- Assess HMO capabilities (stand-alone & linkage)
Assess device identification (industry- & registry-specific methods)
A concept paper was electronically distributed to the Forum representatives.

Center for Devices and Radiological Health (CDRH)
- The Division of General, Restorative, and Neurological Devices (DGRND) is in the process of reorganizing. It is hoped that the reorganization will occur by the end of the year with Neurological Devices moving into the Division of Ophthalmic and ENT Devices.
- The FDA Matrix Network went live on July 14, 2008 and Associate Director and Acting Team Leaders for the Orthopaedic matrix have been named. Additional information is available on the CDRH website.
- A public health notification on the use of rhBMP in the cervical spine was released on July 1, 2008.
- There will be a workshop in late fall or early spring for the cartilage and antimicrobial guidances.
- In the last six months, 6 orthopaedic and 11-12 MDUFMA guidances have been released.

Education and Scientific Exhibit
- The Bone Graft Substitutes exhibit will be presented for the final time at the 2009 AAOS Annual Meeting. A new topic will need to be developed for 2010, as exhibits may only run three years concurrently.
- The Orthopaedic Research Society 2008 Workshop on Wear Resistant Polyethylene is now available on the AAOS Orthopaedic Knowledge Online website as well as the ORS website.
- The next Staff College session is scheduled for August 11 and “Orthobiologics: Soft Tissue Options and Alternatives” will be presented for CDRH and CBER personnel. “Spinal Intervention Alternatives: Diagnosis, Devices, Procedures, and Cellular Enhancements” has been submitted for 2009.

Biomedical Engineering Committee
- The committee’s 2008 Scientific Exhibit on adverse event reporting has been converted to an online educational module which will be eligible for free CME to AAOS members. The exhibit has been accepted for 2009 and will be updated for its next presentation.
- Several committee members will be faculty for a North American Spine Society symposium “Wear of Intervertebral Disc Prostheses” at the society’s October meeting.

Orthopaedic Surgical Manufacturer’s Association
The Association has welcomed six new members to date in 2008.
A new representative will join the Forum contingent beginning with the November 2008 meeting. The representative will replace a current rep that will rotate off in 2009.
Downclassification petitions – No new information is available for the metal on metal petition; mobile bearing knee testing standards are being reviewed within ASTM and will be the focus of a 2009 ASTM symposium.

Center for Biologics Evaluation and Research
- The European Union has opened a public consultation period on draft amendments to the “Implementation of the ‘Advanced Therapies' Regulation” regarding the regulation of products containing cells. The comment period is open until October 15, 2008 with the new regulations going into effect on December 31, 2008.
- Public comment periods for “Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells (PBSCs)” and “Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage” guidance documents have closed.
- The FDA Commissioner’s Fellowship Program is meant to train a cadre of investigators intensively in the issues that relate to FDA regulatory science across devices, drugs, biologics, foods, and cosmetics. The intent of the fellowship is to identify and train highly accomplished individuals who will be FDA ambassadors throughout their scientific careers. Applicants are expected to have an M.D., D.V.M., Pharm.D, or Ph.D. degree or equivalent; for engineering applicants, a Bachelor's degree is required. The fellowship is designed as a 2-year program. Additional information is available at www.fda.gov/commissionersfellowships/program.html.

Biologics Subcommittee
- The National Academy of Engineers Material Advisory Board Bioengineering Materials and Applications Roundtable (BEMA) will focus its next meeting on the use of biomaterials in military medicine.
- The Society for Women’s Health Research ISIS Network is funding research comparing osteoarthritis in males and females at $1 million over the next 4-5 years.
- The Society for Biomaterials will hold its next meeting September 13-15, 2008 in Atlanta, GA focusing on translational biomaterial research.
- Tissue Engineering and Regenerative Medicine Society International (TERMIS) serves as an international forum to promote the informed discussion of challenges and therapeutic benefits of the application of tissue engineering and regenerative medicine technologies. TERMIS holds a World Congress every
2-3 years and will next be held in Daejeon, Korea August 31-September 3, 2009. The next North American chapter meeting will take place December 7-10, 2008 in San Diego, CA.

- Forum members discussed and prioritized topics for education and regulatory activity. The following issues will be the focus of the subcommittees efforts in the next 12-18 months:
  - Nanoparticle proteins
  - Realities of biological surface coatings, including infection control concerns
  - Gene therapy
  - Sensitivity issues with metal-on-metal articulating surface devices
  - Bioavailability of coatings on implants vs. alone (in vivo v. in vitro)
  - Creation of a compendium of biologics, similar to the bone graft substitutes compilation that is the focus of the Forum AAOS Scientific Exhibit

**Biological Implants Committee**

- The committee will add a resident member in 2009, beginning at the AAOS Annual Meeting.
- A JAAOS Supplement, “Osteolysis and Implant Wear”, has been published. The authors’ goal is to update the document every 5 years.
- Recent and ongoing activities include:
  - The creation of an online educational module covering the information from the scientific exhibit “Musculoskeletal Allograft Tissue Safety”
  - The committee’s 2009 Scientific Exhibit will discuss cartilage repair options.
  - The “Bone Defects – When are Orthobiologics Indicated?” was accepted for the 2009 Annual Meeting.
  - Committee members will participate in a radio media tour in October discussing cartilage repair options. The tour matches up surgeons with various radio stations across the country for 10-15 segments focusing on a specific topic. Previous tours have reached cumulative audiences in excess of 2.5 million listeners.
  - Articles for AAOS Now covering metal allergies and xenografts are slated for late 2008/early 2009. In this same timeframe the committee will complete its revision of the “Cell- and Tissue-Engineered Medical Products” information statement.

**Centers for Medicare and Medicaid Services**

- The Thermal Interdiscal Procedures National Coverage Determination is posted for comment through August 14, 2008.
The group held a brief discussion of the types of data that can be collected under Coverage with Evidence Development determinations, as well as access to data for analysis.

**Orthopaedic Research Society**

- “Biomaterials for Tendon and Ligament Repair” was accepted for an ORS Workshop at the 2009 Annual Meeting. It was suggested that the program might present an opportunity to explore opportunities with the National Academies. ORS representatives took the recommendation under advisement.

**Guidance Document Subcommittee**

- The Ultra High Molecular Weight Polyethylene (UHMWPE) document was balloted at subcommittee and received updates from numerous groups.
- Guidances for tissue engineered medical products (TEMPs) see to progress well if they are started in the ASTM TEMPs subcommittees, vetted via the Forum, and then submitted via the FDA’s guidance document submission protocol. Following this path allows FDA input as ASTM members, thereby adhering to established regulations governing the process.
- FDA representatives noted that the 2009 guidance document priority list should be released by the end of July, however the Center list will not be available before mid-August.
- The status of several guidances was updated:
  - Hip guidance due out for comment soon
  - Acellular xenografts is progressing
  - Ceramic-on-ceramic should be a priority

**Standards**

- The November ASTM F-04 Committee week will be held November 18-21, 2008 in St. Louis, MO (note change from Miami Beach, FL) and will feature two workshops of interest to the Forum:
  - Future of Arthroplasty Standards: Planning for the Next Five Years
  - Explant Shipping: The Black Hole between Explantation and Analysis
Both workshops will take place on November 18, 2008 and details are available at [www.astm.org](http://www.astm.org).
- The ASTM TEMPs subcommittees will meet in the United Kingdom October 27-28, 2008 and a summary session will be held during the November committee week.
- The next ISO meeting is slated for September 3-5, 2008 in Berlin, Germany. Planned activities include coordination between technical committees 150 and 104, establishing formal liaisons between the organizations, and efforts to adopt existing ASTM TEMPs standards under a blanket standard within ISO.
AAOS Legislative Update*

H.R. 6478, Access to America’s Orthopaedic Services (AAOS) Act of 2008, was introduced on July 10, 2008 in the U.S. House of Representatives by Congresswoman Hilda L. Solis (D-CA) and Congressman Michael C. Burgess, M.D. (R-TX). This bipartisan legislation represents an historic step for the American Association of Orthopaedic Surgeons (AAOS) as it is the first comprehensive bill to be introduced in the U.S. Congress with a specific focus on musculoskeletal diseases and conditions. Efforts continue to secure Senate support.

*No federal personnel participated in discussions about legislation