Orthopaedic Device Forum
Meeting Summation Report
October 17-18, 1999
Rockville, MD (Draft)

Present:

Scientific Orthopaedic Community	Government	Industry	Consumer
AAOS, AOA, ORS, ASTM	FDA, NIAMS	OSMA	ARTHRITIS FOUNDATION

Members of CDRH, CBER, and the Arthritis Foundation were welcomed and introduced to the Orthopaedic Device Forum.

Approval of July 18-19, 1999 Summation Report
Members reviewed, amended, and approved the summation report from the July 1999 meeting of the Orthopaedic Device Forum. In the future, FDA will work on reviewing the summation report prior to the meeting.

Structure of Forum Meetings
Members discussed the structure of future Forum meetings. Experts are extremely beneficial to the Forum however, in the past it has been difficult for speakers to commit to Sunday evenings. Members proposed that Sunday evenings are informational and Monday could be delegated to producing work product. The Forum may want to revisit some topics that have been discussed in the past and may invite different speakers.

NIH
The National Institutes of Health Technology Assessment Conference on Improving Medical Implant Performance through Retrieval Information will be held January 10-12, 2000 in the Natcher Conference Center in Bethesda, Maryland. The objective of the conference is to assess the challenges and opportunities for developing a framework for independent research of implants with the objective of providing benefits to patients through implant retrieval and analysis.

HCFA
Members voted in the affirmative to extend an invitation to a representative of HCFA to join the Orthopaedic Device Forum. The synergies of FDA and HCFA need to be explored due to the fact that even if a device is FDA approved, HFCA may not allow reimbursement. Many insurers use HCFA policies to set their

levels of reimbursements. HCFA can, in effect, decide how technology is introduced. Manufacturers would encourage a consistency in medical device coverage.

Neurosurgeons & Plastic Surgeons

The Neurosurgeons and the Plastic surgeons have expressed a desire to formulate a group based on the Orthopaedic Device Forum model. FDA has been in contact with these groups and is supportive of their efforts. The Forum voted in the affirmative to allow members from each of these groups to attend one Forum meeting so that they will have a better understanding of the format and interactions between personnel.

FDA Update

Centers within FDA such as CDRH and CBER are collaborating on more guidance documents. Inter-center cooperation is ongoing which is beneficial, in that, devices will have biologic components in the very near future.

The final order for reclassification of polymethylmethacrylate (PMMA) bone cement from class III to class II was filed October 14, 1999 by the CDRH division of FDA. Members of the Device Forum have participated in compiling the reclassification petition.

The reclassification comment period for the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis ended in August 1999.

Susan Alpert, MD, PhD, formerly the Director of the Office of Device Evaluation in CDRH has accepted a new position as Deputy Director in the Center for Food Safety and Applied Nutrition (CFSAN) of FDA.

The WLF v. Shalala ruling states that manufacturers can disseminate information if it has been printed in peer-reviewed publications. The Academy may want to incorporate the ruling with regard to scientific exhibits at Annual Meeting. In the past, industry was required to provide a disclaimer on unapproved uses and that they had a financial interest in the product. The ruling is currently being appealed.

Bone Dowels

CDRH postponed the Orthopaedic and Rehabilitative Devices Panel discussion of bone dowels. This issue will be addressed at some future panel meeting. FDA received several comments prior to the cancelled panel meeting that was scheduled for November 5, 1999. FDA believes that there are many important issues to consider such as currently proposed tissue regulations including

definitions, remuneration for tissue processing, and the development of biological tissue into dowels which look similar to some manufacturers' devices.

Single-Use Devices

The regulation of reprocessing single-use devices has become a significant issue. FDA hopes to have a proposal out before the end of the calendar year that will stratify devices into categories. HCFA has stated that they will not reimburse for reprocessed single-use devices. Manufacturers suggest that reprocessors should be held to the same standards as the original product.

Wear Workshop

A grant application was filed with NIH for support of the Wear Workshop 2000. Dates of the workshop are Friday, October 20, 2000 -Sunday, October 22, 2000. A document will be developed from the proceedings of this workshop and posted on the Internet. This web-based format will allow answers to be drafted directly and posted on the World Wide Web. The format will allow future updates of answers as new research findings become available. The AAOS Biomedical Engineering Committee chair will arrange a review of the site at least once every three years. A book will also be available from the AAOS Publications Department.

Medical Device Reporting (MDR)

CDRH has determined that many events involving orthopaedic devices may have been exempted after a review of documents dating back to December of 1984.

Orthopaedic Surgical Manufacturers Association (OSMA) prepared a draft guidance on proposed exemptions from Medical Device Reporting for Orthopaedic Devices.

Standards

Division F-04's ASTM Fall meeting is November 16-19, 1999 in Kansas City, Missouri. The symposium will address "Synthetic Bioabsorbable Polymers for Implants." The Committees on Biomedical Engineering and Biological Implants will hold their fall meetings in conjunction with the ASTM meeting.

The Committee on Biomedical Engineering will send three representatives to the International Standards Organization (ISO) meeting in Germany in October 1999. The members will continue to have input into international harmonization of standards and will seek international membership for a work group on standards.

Board Report

The new AAOS Director of the Washington office has been chosen. The Board of Directors wishes to continue the financial support of the Forum.

ORS Clinical Trial Course

ORS is developing a three-day workshop for Annual Meeting 2000. The course will run Sunday, Monday, and Tuesday and will focus on issues relating to the design of a clinical trial.

Clinical Trials Course

The proposed date for the AAOS clinical trials course is October 14-15, 2000. The purpose of the AAOS course is to teach practicing orthopaedic surgeons how to participate in clinical trials- i.e. what it means to be a principal investigator, a clinical investigator, and a site coordinator. This course is differentiated from the ORS course that will focus on how a principal investigator designs clinical trials. ORS and the Academy will need to coordinate the efforts of these two courses. The Biomedical Engineering committee will examine the possibilities of producing a CD-ROM from the proceedings of the AAOS course.

Bone and Joint Decade

To date, sixteen nations have endorsed the Bone and Joint Decade as well, as the states of Texas, Missouri, Georgia, and Illinois. The focus of the Bone and Joint Decade is on the burden of musculoskeletal disease upon society. Several areas that have been targeted include arthritis, osteoporosis, spinal disorders, limb trauma, and children's musculoskeletal conditions. A toll free number (888-671-4900) has been established to urge the President of the United States to issue a proclamation designating 2000-2010 the Bone and Joint Decade.

Outcomes

The Board of Directors has assembled a Clinical Quality Improvement Initiatives Task Force to assess guidelines and outcomes measurement. Dr. Katz, Director of NIAMS, of the National Institutes of Health (NIH) has suggested sponsoring a workshop on outcomes effectiveness research.

CBER Proposed Rule

The Center of Biologics and Evaluation and Research (CBER) has developed the proposed rule, "Suitability Determination for Donors of Human Cellular and Tissue-Based Products" that was published in the Federal Register on September 30, 1999.

The FDA is proposing new regulations for manufacturers of tissue-based or human cellular products to screen and test donors of cells and tissue for clinical evidence and risk factors of communicable diseases.

The proposed regulations will increase the number of diseases that tissue and cells are tested for and increase the number of products that are tested. FDA is proposing to broaden its regulatory oversight over all human and cellular tissue-based products including reproductive cells and tissues.

FDA is requesting comments on the proposed rule due December 29, 1999. In particular FDA requests comments on current donor screening and testing practices in manufacturing facilities and ways to enhance the quality and clarity of information to be collected.

Cartilage Guidance

The work group continues to develop the guidance document for the repair of hyaline articular cartilage. The CDER, CBER, and CDRH guidance, "Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)" is an important source for the work group.

Different companies use various animal models and the rabbit tends to be an important screening model for articular cartilage. It is problematic that outcomes are difficult to define in animal models. The work group will further define the draft document with personnel from CDRH and CBER.

Bone Graft Guidance

The bone graft guidance work group has prepared an outline and it is very reliant on ASTM standards. Chapters 11, 12, and 13 of the An and Friedman book, "Animal Models in Orthopaedic Research" are used as background material for the guidance. Currently, there approximately five types of bone graft substitutes on the market which are used in orthopaedic applications. Members remarked that approximately twenty types of bone graft substitutes are used in craniofacial surgery and that the issues of making the structure functional appear to be similar. Members of the bone graft work group will solicit expertise from the Biological Implants committee.

NIAMS Update

NIAMS is without a budget for fiscal year 2000 as of October 1999 and are operating under a continuing resolution. In the near future, NIAMS will issue a program announcement that will solicit grant applications for studies on deep infection in total joint replacements.

Forum 2000

Proposed Sunday Night Discussion Topics

1.) Surveillance Update
2.) Global Harmonization
3.) CDRH Director
4.) Re-Use of Medical Devices
5.) Outcomes Measurement in Musculoskeletal Diseases/ Instruments
6.) Analyze Forum format/issues/effectiveness
7.) Medical Technology Leadership Forum (MTLF)

Proposed Monday Day Discussion Topics

1.) MDR – Surveillance
2.) Cartilage Guidance
3.) Bone Graft Guidance
4.) Re-Use of Medical Devices
5.) Role of Outcomes Measurement Instruments/ Useful Endpoints
Clinical Trials Courses/ Clinical Study Design (standardizing clinical performance)
6.) ISO and ASTM Activities
7.) NIH sponsored Technology Assessment Conference
8.) RSA Update
9.) PDP
10) Hard/Hard bearings
11) Labeling –Orthopaedic Device Reference