Present:

Scientific Orthopaedic Community
Bernard Stulberg, MD
Barbara Boyan, PhD
Timothy Wright, PhD
Jack Lemons, PhD
A. Seth Greenwald, D Phil
Harlan Amstutz, MD
Kenneth E. DeHaven, MD
Belinda Duszynski, Staff
Rebecca Schwaab, Staff
Richard Coutts, MD

Government
Celia Witten, MD, PhD
Jim Dillard
Mark Melkerson
Susan Alpert, MD, PhD

Industry
Thomas Craig
Robert Smith
James Benedict, PhD
Jack Parr, PhD
Dane Miller, PhD

Approval of January 4-5, 1998 Summation Report
Forum members reviewed and approved the summation report from the January 1998 meeting of the Device Forum.

Discussion with Susan Alpert, MD, PhD – Office of Device Evaluation, Director
Susan Alpert, MD, PhD, attended the Sunday evening meeting of the Device Forum to provide new perspectives about the impact the Device Forum can have following implementation of the FDA Modernization Act of 1997. Dr. Alpert commended the Device Forum on efforts to encourage an environment of open communication among the scientific orthopaedic community, industry, and the government. Dr. Alpert provided a brief overview of the impact that the FDA Modernization Act of 1997 will have on orthopaedic device regulation, addressed concerns about generic labeling, clarified the importance of new policies relating to consensus standards, and discussed briefly issues related to post market surveillance.

FDA Modernization Act of 1997 (FDAMA)
Dr. Alpert imparted her thoughts about the meaning of the FDAMA. The general theme from the new legislation is that the FDA should not work alone, rather it is mandated to work with industry and scientists in an open environment.

Generic Labeling
Members of the Forum identified concerns about device labeling. Dr. Alpert agreed that there is work to be done in the area of labeling to determine the most appropriate and consistent approach.

**Consensus Standards**
Dr. Alpert acknowledged the importance of consensus standard development and the impact of FDAMA on the ability of the FDA to formally acknowledge standards in the device evaluation process. Declaration of conformation to approved consensus standards will enable industry to facilitate the process of getting devices to market. Dr. Alpert indicated that this is particularly important in the 510(k) process.

**Post-Market Surveillance**
Members discussed concerns related to the effectiveness of the FDA’s post-market surveillance, specifically Medwatch. Dr. Alpert agreed that there is much work to be done to define the appropriate post-market surveillance approaches and that the FDA would welcome input regarding what questions need to be asked, what information is useful, method of reporting, what to report, and how to make the data collected more meaningful. Dr. Alpert suggested that Larry Kessler be invited to attend the next meeting of the Device Forum to discuss these concerns and obtain feedback from Device Forum members.

**Liability Issues Update**
Members of the Task Force on Liability Issues presented their draft report addressing liability issues associated with membership in the Device Forum. The potential approaches are listed below:

1. Advanced announcement of meeting dates and agenda on Forum organizations’ websites.

   Concern: What if non-members appear at the meeting?
   Proposed Solution: Advanced announcement will indicate that if further information is needed, please contact Belinda Duszynski, Executive Secretary to the Device Forum.

2. Posting summation reports on Forum organizations’ websites.

   Concern: Individuals will be contacted relative to what they communicate at the Forum meetings.
   Proposed Solution: Specific names will be removed from the summation reports.

3. Making summation reports available for publication.

   Concern: Journals may not be interested in publishing the reports as written.
   Proposed Solution: Make available for publication in its entirety, however, does not prohibit editorials.

Concern: Want this to be a positive statement of what the Forum is doing.
Proposed Solution: Task Force members will work with appropriate legal counsel to develop this statement.

   Concern: What type of document is appropriate?
   Proposed Solution: Review AAOS Disclosure Policy and adapt as appropriate.

6. Formally invite a consumer representative to be a member of the Device Forum.
   Members agreed that this is appropriate and that a potential group to contact would be the Arthritis Foundation.

7. Formally invite an NIH representative to be a member of the Device Forum.
   Members agreed that this is appropriate and that the appropriate branch to contact would be NIAMS.

8. Statement of endorsement of the Forum from the FDA. FDA representatives addressed their concerns about this item. There is no formal mechanism in place by which such endorsement is achieved. FDA representatives indicated that the award presented to the Device Forum for its efforts is the closest to an official endorsement as it will be likely to obtain.

Device Forum members accepted the report with a few minor modifications and agreed to move forward toward implementation using the same task force representatives. The discussion about liability issues closed with a brief discussion of the mission statement. The mission statement will be reviewed by all Forum members and has been redrafted to read:

“The mission of the Orthopaedic Device Forum is to provide an opportunity to foster an environment of open communication among the government, scientific orthopaedic community and related industry to help realize the public health goal to bring innovative, high quality products to the American public in an expeditious and prudent manner.”

FDA Reengineering Update
FDA representatives briefly presented information about the new draft guidance documents. Members of the Device Forum will be appraised of the new documents with a brief summary of content and are encouraged to review and comment as appropriate. Although not in keeping with good guidance document development practice, FDA representatives indicated that because of the short implementation schedule, these guidance documents are implemented once drafted, then they are disseminated for public comment, and will be modified accordingly.

Global Harmonization and Canadian Partnership Update
Mark Melkerson provided a brief update about the Global Harmonization and Canadian Partnership efforts. Currently the global harmonization efforts are focusing on quality
systems regulation, pre-market evaluation issues, and post-market issues. The Canadian Partnership is currently undertaking parallel review activities with some of its goals being shared review and mutual recognition agreements.

**Reclassification Update**
In light of the new FDAMA efforts, the reclassification initiatives have been set aside by the FDA to allow FDA employees to work on drafting guidance documents and implementing policies created by the new legislation. The FDA expects to publish the results of the reclassification initiatives this summer.

**Standards Recognition**
FDA representatives highlighted that the new focus on making use of consensus standards is a highly efficient device regulation tool, and encourage submission of additional standards for FDA consideration.

**Post-Market Surveillance/Medical Device Reporting (MEDWATCH)**
Industry representatives attempted to schedule a meeting with appropriate FDA representatives to openly discuss concerns related to post-market surveillance at the AAOS Annual Meeting in New Orleans. Appropriate FDA personnel were not able to attend the meeting, therefore, no further progress has been made on this issue, however, it is hoped that Larry Kessler will attend the July meeting of the Device Forum to participate in this discussion.

**Metal on Metal**
FDA representatives indicated that the 515(b) for metal on metal has been written due to a lack of publicly available information identifying risks, effectiveness profile, and identifying potential, reasonable special controls. If such information is not available, the FDA must call for PMAs. Members of the scientific orthopaedic community and industry feel that there is publicly available information and a work group will be comprised to draft a reclassification petition compiling available information for review by the FDA.

**Educational Initiatives**
**ORS Workshop on Biologics**
Members of the scientific orthopaedic community updated the Device Forum about the success of the ORS workshop on biologics. Many people volunteered to become involved in reviewing guidance documents and standards activities. Once the summary of the workshop minutes is available, it will be forwarded to all Device Forum members for review.

**Regulatory Aspects in Orthopaedics (1999)**
Members of the Device Forum were updated about the status of the application for a 1999 symposium entitled “Regulatory Aspects in Orthopaedics.” The symposium will be submitted to the AAOS by the Device Forum and the Biomedical Engineering Committee by April 15, 1998.

**JAAOS Article**
A group of Device Forum members will be called upon to draft an article for the “Journal of the American Academy of Orthopaedic Surgeons.” The article will be comprised of two components: 1) Crystallization of the Chantilly Workshop and Changes at the FDA since Chantilly, and 2) Summary of activities of the Device Forum.

**Generic Labeling Update**

Members of the Task Force on Labeling updated the Forum members about progress made in discussion of generic labeling. Forum members discussed the issues surrounding generic labeling briefly and agreed that in order to really provide FDA with necessary feedback, the definition of labeling needs to be clarified. Members agreed that industry needs to discuss generic labeling in greater depth and address the following: educational format to labeling material; simplification, where appropriate; response to the FDA regarding data expectations and claims.

**Guidance Documents**

**Cartilage Resurfacing and Fresh Fracture Repair**

Members of the Forum identified potential work group members to work on the development of the two guidance documents on cartilage resurfacing and fresh fracture repair. FDA representatives will help identify appropriate FDA personnel to serve as consultants to these groups. It is hoped that draft guidance documents will be prepared for review by the July 12-13 Device Forum meeting.

**Customized Devices**

The FDA’s Office of Compliance has developed a guidance document defining customized devices in terms of “true custom device” vs. “specialty products.” Members of the Device Forum are invited to review and comment on this document. FDA representatives will inform members of the appropriate timeframe for comment.

**Agenda Items – July 12-13, 1998**

Standard Updates and Follow-Up Items
Mission Statement Review
Standards Update

Sunday Night FDA Topics:
Post-Market Surveillance/Medical Device Reporting/Medwatch – Larry Kessler