



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0293]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee;
Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of Meeting.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA) to discuss current knowledge about the safety and effectiveness of Metal-on-Metal (MoM) hip arthroplasty systems. FDA is convening this committee to seek expert scientific and clinical opinion on the risks and benefits of these types of devices based on available scientific data.. The meeting will be open to the public.

DATES: The meeting will be held on June 27 and 28, 2012, from 8 a.m. to 7 p.m. FDA is opening a docket to allow for public comments to be submitted to the Agency on the issues before the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee. Submit either electronic or written comments by May 9, 2012.

ADDRESSES: Meeting location is to be determined (TBD). Prior to the meeting, FDA will announce the meeting location in a future Federal Register notice. We will also provide the meeting location on FDA's Advisory Committee Information line, 1-800-741-8138 (301-443-0572 in the Washington, DC area) and on the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>.

FOR FURTHER INFORMATION CONTACT: Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993-0002, 301-796-3805, Avena.Russell@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Agenda: On June 27 and 28, 2012, the committee will discuss current knowledge about the safety and effectiveness of Metal-on-Metal (MoM) hip arthroplasty systems. FDA is convening this committee to seek expert scientific and clinical opinion on the risks and benefits of these types of devices based on available scientific data.

Hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

There are two categories of metal-on-metal hip arthroplasty systems:

1. Metal-on-Metal total hip replacement (THR) systems consist of a metal ball (femoral head), a metal femoral stem in the thighbone, and a metal cup in the hip bone (acetabular component). MoM THR systems are typically indicated for use in total hip arthroplasty in skeletally mature patients with the following conditions:
 - a. Non-inflammatory degenerative joint disease (NIDJD) such as osteoarthritis, avascular necrosis, post-traumatic arthritis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
 - b. Inflammatory degenerative joint disease such as rheumatoid arthritis;
 - c. Correction of functional deformity; and,
 - d. Revision procedures where other treatments or devices have failed.
2. Metal-on-Metal hip resurfacing systems consist of a trimmed femoral head capped with a metal covering and a metal cup in the hip bone (acetabular component). Hip resurfacing arthroplasty is intended for reduction or relief of pain and/or improved hip function in skeletally mature patients having the following conditions:
 - a. Non-inflammatory degenerative arthritis such as osteoarthritis, traumatic arthritis, avascular necrosis, or dysplasia/developmental dislocation of the hip (DDH); or
 - b. Inflammatory arthritis such as rheumatoid arthritis.

Resurfacing systems are intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip arthroplasty due to an increased possibility of requiring ipsilateral hip joint revision.

In February 2011, FDA published a Web site on MoM total and resurfacing hip systems with information for orthopedic surgeons and for patients with or considering hip replacement (<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/default.htm>).

Numerous recent publications, studies and registry reports have raised safety concerns for MoM THRs. In February 2012, the United Kingdom's (UK) Medicines and Healthcare products Regulatory Agency (MHRA) published a Medical Device Alert with updated advice on the management and monitoring of patients implanted with MoM hip systems recommending more aggressive followup of patients with larger THR systems (≥ 36 millimeter (mm)). Further information about actions taken by MHRA, with links to information about MoM hip implants for patients and healthcare professionals, is available on their Web site at <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice%E2%80%93M%E2%80%93T/Metal-on-metalhipimplants/index.htm>. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.)

In December 2011, the American Academy of Orthopedic Surgeons (AAOS) published an overview on MoM hip systems (total and resurfacing) (Ref. 1). The AAOS overview provides a summary of clinical outcomes in patients with MoM hip systems in comparison to other bearing surface combinations, addresses patient, implant and surgical factors that may predict successful/unsuccessful outcomes of MoM hip systems and discusses the prevalence of adverse clinical problems from MoM hip systems in comparison to other bearing surface combinations.

One item referenced in the report is the Australian registry, which reported higher revision rates for patients with implants that have large-diameter heads (>28 mm) (Ref. 2).

While current data are highly suggestive that a large percentage of patients with MoM hip systems have successful outcomes, a recent scientific publication raised serious concerns about the failure rates of MoM hip systems for the UK population (Ref. 3). This peer-reviewed journal article presented the following findings regarding primary MoM THR: (1) Increased failure rate at 5 years for MoM THR related to larger head sizes; (2) significantly higher risk for revision in female patients (Note: In the United States, labeling discourages use of MoM hips in females of child bearing age with warnings in MoM THR labeling and contraindications in MoM hip resurfacing labeling); and (3) revisions for dislocation in men with MoM replacements were slightly lower, showing some benefit to larger head sizes.

The committee will be asked to discuss the following as it pertains to these devices in the U.S. population: Device mechanisms of failure, metal ion testing, imaging methods, local and systemic complications, preoperative and postoperative patient risk factors, as well as clinical followup considerations for patients with MoM hip systems (total and resurfacing).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: FDA will work with affected industry, professional organizations, and societies that have an interest in the MoM hip arthroplasty systems and who wish to make a presentation separate from the general open public hearing; time slots on June 28, 2012, between approximately 9 a.m. and 10 a.m. Representatives from industry, professional organizations and societies interested in making formal presentations to the committee should notify the contact person on or before May 1, 2012.

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 9, 2012. On June 27, 2012 oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 1, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 2, 2012.

Comments: FDA is opening a docket to allow for public comments to be submitted to the Agency on the issues before the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee beginning on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], and closing on May 9, 2012. Interested persons are encouraged to use the docket to submit electronic or written comments regarding this meeting. Submit

electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Divisions of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark, James.Clark@fda.hhs.gov or 301-796-5293 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

I. References

The following references have been placed on display in the Division of Dockets Management (see Comments) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible

for any subsequent changes to the Web site after this document publishes in the Federal Register.)

1. American Academy of Orthopedic Surgeons, “Modern Metal-on-Metal Hip Implants: A Technology Overview” (July 15, 2011), accessed online at http://www.aaos.org/research/overviews/Metal_On_Metal.pdf.
2. Adelaide: Australian Orthopaedic Association, Australian Orthopaedic Association National Joint Replacement Registry: Annual Report 2010, 2010.
3. Smith, A.J., P. Dieppe, K. Vernon, et al., “Failure Rates of Stemmed Metal-on-Metal Hip Replacements: Analysis of Data From the National Joint Registry of England and Wales,” Lancet, (March 13, 2012), accessed online at [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(12\)60353-5/fulltext#article_upsell](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60353-5/fulltext#article_upsell) (doi:10.1016/S0140-6736(12)60353-5).

Dated: March 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-7767 Filed 03/29/2012 at 8:45 am; Publication Date: 03/30/2012]