

## **Unprecedented International Effort Seeks to Improve Safety of Orthopedic Devices**

Bio-Medicine.Org

NEW YORK, Dec. 21, 2011 /PRNewswire/ -- Responding to a need for better post-market surveillance of orthopedic devices, the U.S. Food and Drug Administration established the International Consortium of Orthopaedic Registries in October 2010.

As outlined in a Dec. 21 special online supplement in the *Journal of Bone and Joint Surgery*, ICOR is in the process of developing a collaborative process for improving the safety of orthopedic devices using outcomes registries from the U.S. and other countries. The combined ICOR registries may include data on millions of orthopedic surgical procedures and all implantable devices on the market.

More than 700,000 joint-replacement devices are implanted in patients in the U.S. every year, and this volume is projected to increase twofold for hip-joint replacements and sevenfold for knee-joint replacements, to a total of more than 3 million annually in the next 20 years.

While there have been dramatic advancements in orthopedics, including new devices and improved surgical techniques, the value of many of these devices has not been established using large studies in real-world settings. The FDA chair of the meeting, Danica Marinac-Dabic, MD, and ICOR meeting co-leads, Art Sedrakyan, MD, (Weill Cornell Medical College and the Hospital for Special Surgery) and Elizabeth Paxton (Kaiser Permanente), believe that the consortium will help ameliorate this problem.

Unlike drugs, devices have a different path of approval that may not require the conducting of clinical trials in the United States. Furthermore, adverse outcomes reporting for devices is voluntary, and the resulting data are often incomplete or inaccurate. While there is currently an effort by the American Academy of Orthopedic Surgeons to develop a large national registry, the mid-term follow up will likely take several years or more, says Dr. Sedrakyan, who coordinated the supplement for ICOR and is directing the Patient-Center  
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