ZIMMER BIOMET

Statement Regarding July 29, 2008, New York Times Article

Jul 29, 2008

An article in the July 29, 2008 edition of The New York Times on the need for joint registries to effectively track post-market patient outcomes does not provide sufficient context and data about the life-changing and well documented benefits achieved by millions of hip replacement surgery patients. The article also does not provide a fully balanced review of the real-world challenges associated with applying medical device registry data to follow post-market patient outcomes, nor the comprehensive process Zimmer undertook to investigate performance of the Durom® Acetabular Component (Durom Cup) and take rapid action to address surgical training needs in the United States. The Company therefore provides additional information on these important subjects, including its commitment to post-marketing surveillance and vigilance.

Total Hip Replacement

Of nearly 450,000 new hip replacement patients in the U.S. each year, the vast majority experience a dramatic reduction of hip pain and a significant improvement in their ability to perform the common activities of daily living. It is important for current patients and those considering a hip replacement to know that the long-lasting health benefits of this surgery are well established and the rates of relief from pain, return to function, and patient satisfaction are high. The vast majority of joint replacement patients can expect that their surgery will result in years of relief from the pain and disability due to osteoarthritis and other musculoskeletal diseases. The impact of joint replacement is often so profound that many patients say they wished they had considered getting their surgery done earlier. Numerous long-term clinical studies and implant registries have reported survival of primary total hip replacements to be in excess of 90% at a minimum of ten years.

Patient Registries

A number of international total joint registries exist that are useful in tracking product performance and in some cases may provide early visibility into potential clinical device-related issues. Zimmer believes they can also be helpful tools in improving patient outcomes over time, by providing implant

survivability data (duration of device "survival" until revision) on a variety of device design philosophies. Such data may be used in improving next-generation designs. However, they do not constitute a total solution to the monitoring and evaluation of product performance.

- The best of the international registries enjoy strong surgeon and hospital participation, and comprehensively track and report implant survivorship in large populations, with the goal of improving the delivery of orthopaedic patient care.
- However, many of the registries are relatively new, and, as such, require greater participation from surgeons and hospitals. Until they are statistically powered, newer registries are not an effective early warning system and fundamentally cannot provide the mid- to long-term data that are the most critical indicators of orthopaedic device performance (five-, ten- and fifteen-year data).
- In addition, standards for accessing and communicating data trends identified by registries historically have been inconsistent and require further focused development. For example, some of them publish only an annual report.
- Most registries report data only on implant survival. In many cases, the reasons for revision surgeries are not reported in relation to specific products. The fundamental issue leading to revision is important to identify because this information ultimately determines if any intervention is required. For this reason, registry data alone do not relieve manufacturers from conducting appropriate post-market surveillance and vigilance on all of their products, pursuant to FDA requirements.
- Additionally, the quality of a patient's daily life activities can at times be affected long before revision is chosen as a solution to a device-related issue. For this reason, revision as a singular registry endpoint does not always supply enough visibility soon enough to provide the basis for appropriate action. For these reasons, Zimmer conducts its own post-market studies and maintains its own registries in addition to monitoring reports from the international total joint registries, as part of a comprehensive effort to vigilantly monitor the post–market performance of our devices.

Zimmer strongly supports the development of a U.S. national joint registry as an important component of improved post-marketing surveillance in the U.S. population, and we believe that the American Academy of Orthopaedic Surgeons (AAOS) is the most appropriate medical specialty society to organize and implement such a registry. Along with other members of industry, we are working with AAOS leadership to help bring this concept to reality.

Post-Marketing Surveillance and the Durom Cup

In the case of the Durom Cup, Zimmer took very seriously the elevated revision rates reported by some U.S. surgeons. The Company also had other data points, including extensive clinical experience in Europe, where post-marketing data continue to show excellent clinical outcomes since the Durom Cup

launched there in 2003. With respect to international registries, some of this experience has been described by the Swedish Registry, which has reported a 99.5% survivorship with the Durom Cup after three years of follow-up.

Following evaluation and trending analysis of product complaints (the aggregation of events to identify patterns), Zimmer conducted a comprehensive investigation of the Durom Cup. This investigation included reviews of all post-marketing surveillance data from registries and other sources, clinical experience at high-volume sites in the U.S. and Europe (3100 cases reviewed in total), and product conformance to specifications. Zimmer also filed individual medical device reports (MDRs) with the FDA during the course of the investigation, as reports of revisions of the Durom Cup were received and investigated.

Our comprehensive investigation identified that surgeons who regularly achieve the desired outcome with the Durom Cup consistently execute certain technique steps in a specific manner. Following the investigation, Zimmer has determined that revised surgical technique instructions and a surgical training program are required to more consistently achieve desired clinical results in the U.S. We shared our review and conclusions with FDA and took rapid and appropriate action in the marketplace to suspend U.S. distribution and marketing pending development and implementation of a revised surgical technique and surgical training program.

Zimmer is committed to the continuous improvement of post-marketing surveillance methodologies to ensure the safe and effective use of the Company's products. In our view, best practice in post-marketing surveillance and vigilance includes a healthy combination of access to national registries, targeted and prospective post-market studies, as well as company-sponsored post-market registries. It is important to emphasize that post-marketing surveillance that truly improves patient outcomes is a shared responsibility. Both regulatory authorities and orthopaedic companies are reliant on surgeons, hospitals and industry employees to appropriately report issues as they occur.