

Generic Orthopedic Implants Time has Come

Editorial

The U.S. orthopaedic implant industry is a \$20 to \$25 billion business and amazingly, almost 75% of these time-tested (stable) technologies have expiring patents. This typically means it is no longer necessary to continue to pay a premium for these products. In most other industries, as technologies become stable, they become a value proposition and thus, price declines over time. My biggest fear in buying an iPhone is that a better (and cheaper) one is going to be released next month. There are a few areas in medicine in which this free market concept has flourished. Lasik eye surgery used to cost \$4,000 per eye. Now you can get the procedure done for \$269, with better equipment.

Only a handful of incumbent suppliers control 90% of the orthopaedic market, and they defend their pricing by stating that they have to pay for R&D and regulatory approvals for their products. Pharmaceutical companies spend about 20% of revenues on R&D. Orthopaedic companies spend 6%. Pharmaceuticals require lengthy development processes and regulatory approvals that cost hundreds of millions of dollars. Most orthopaedic implants, in contrast, receive FDA clearance through the 510(k) process, a regulatory pathway that takes only six to nine months and costs an order of magnitude less than drug approvals. When new drugs eventually lose patent protection and go generic, prices to the consumer decrease by 90% or more. Despite competition between companies, despite a commoditization of the core hip and knee implant product line, and despite a near-doubling of procedure volumes, prices are 60 percent higher today than they were in 2000.

When someone hears generic, he thinks "cheap." They believe the implant was made in a Chinese factory with inferior materials. Generic or stable technology is actually about efficiencies and process. The irony is that the orthopaedic cartel wants you to believe that the cost is in the intellectual property and manufacturing. Most of the devices we use today are based upon expired IP and deserve to be sold as a commodity. The manufacturing costs are a small component of the final price tag of an implant. The average cost of goods for a primary total knee implant is approximately \$300 to \$500.

In order for hospitals to begin to benefit from stable technology,

they need to begin to take back responsibility. Hospitals have spent decades dumbing down their OR staff. This all began when the orthopaedic device companies started sending sales reps to the OR. The sales rep provided a valuable service. They assisted the back table with the instruments and technique. They also managed inventory by bringing their products and instruments to the case. This allowed the hospitals to allow their staff to not know specifics about cases and orthopaedic systems. This provides value to the hospital in that they can train their staff to cover a multitude of different cases, thereby allowing greater cross coverage. The problem is that this comes at a cost. An implant sold by a sales rep commands a significantly higher price. Their services can account for as much as \$37 for every \$100 spent, and are by far their greatest expense. Also, the typical rep model is to push more products into the OR. They are motivated to "sell you more, for more." Studies have shown that the mere presence of a rep in the OR increases implant usage by as much as 30%.

In the end, the hospital will need to align the physician with implant cost. They will have to reward (or punish) the choice of implant based upon cost and quality. This may be through a bundled episode of care, co-management agreements or a gain sharing model. When the surgeon's compensation is linked to these decisions, they will finally begin to participate in the evaluation of an implant based upon cost and quality. And if they don't, someone else will do it for them and keep the net savings for themselves.

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