PREPARING FOR CHANGE:
Strategies for Reducing Costs and Protecting Profits in the New World of Medical Device Manufacturing

March 8, 2013

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Original equipment manufacturers (OEMs) of orthopedic medical devices are facing cost pressures like never before. To reduce cost and make their products more attractive to reimbursement-restricted purchasers, OEMs are curtailing the size of their sales force and the commissions they pay out; establishing a leaner overhead structure; and reducing the cost of goods sold.

While these strategies help OEMs cut costs in the short term, the consequence is that it may put their long-term profit margins and ability to compete at risk. Fortunately, the solution for most OEMs lies simply in rethinking how their orthopedic products are designed and manufactured.

This white paper will examine emerging trends in the United States and abroad affecting the profitability of orthopedic medical devices and introduce effective strategies that will help OEMs sell high-quality products that hit cost targets and improve patient outcomes.
A CHANGING MARKET

“The Only Thing That Is Constant Is Change” ~ Heraclitus

How people access medical care in the United States and globally is rapidly changing. While there are numerous reasons driving this change, the three that predominantly affect the orthopedic medical device industry are: reimbursement reductions, FDA regulations, and growth of emerging markets.

Reimbursements

If the 2012 projection made by the Centers for Medicare & Medicaid Services (CMS) is correct, then healthcare spending in the United States will outpace economic growth and the incomes of those who pay for it.

As the largest payer of healthcare in the United States, CMS has been under tremendous pressure to curtail reimbursements paid to hospital and healthcare providers. As a result, the commercial health insurance industry is likely to also cut or cap their reimbursement costs—especially companies that contract with Medicare to provide benefits to people with Medicare part A and B.

As the largest recipient of Medicare, Medicaid, and commercial insurance reimbursements (see Figure 1), hospitals also have to change how they conduct business. Capped or cut reimbursements for knee implants, for example, means that hospital administrators must renegotiate—and likely reduce—the price they are willing to pay for their medical device suppliers' products.

(Figure 1 showing hospital care and physician/clinical services combined account for half (51%) of the nation’s health expenditures in 2010.)

Healthcare costs grew 3.9% in 2011 and are projected to grow an average of 5.7% per year over through 2021. If this occurs, by 2021, healthcare will account for 19.6 percent of GDP and nearly 50% of federal, state, and local government healthcare spending.
Regulations

A 2011 Northwestern University study found that the average time from device submission to FDA approval in Europe is a little less than five months, whereas it’s about 13 months in the United States. This lengthy approval process can be extremely expensive for a medical device manufacturer and significantly delay their time to market in the U.S.

The FDA has also made changes to their requirements for registration and listing of medical devices. As a part of the new FDA Safety and Innovation Act, all organizations that handle medical devices must register with the FDA every year and pay an annual registration fee (the fee for fiscal year 2013 is $2,575). While the goal of these new regulations and requirements is to make the medical devices safer, the concern is that these new changes may create costly, bureaucratic headaches for the medical device supply chain.

Another significant regulatory market driver is the 2.3 percent excise tax that was included in the 2010 Affordable Care Act. The reality of a tax on the total revenues generated by a medical device company (regardless of whether the company generates a profit), is seen as one of the biggest threats to profitability and innovation over the next 5 years.

Emerging Markets

As the standard of living in highly populated emerging markets (i.e. Brazil, Russia, India, and China) increases, so does the size of their middle class. And as the economic opportunities of the middle class grow, so does their ability to afford better healthcare. Instead of putting up with pain and discomfort, more and more people in emerging markets will elect to have surgery or get their hip or knee replaced. It’s simply a matter of when.

Emerging markets are expected to grow at a much faster rate than the U.S. in years to come. For example, China’s medical device market could expand to $42.8 billion in sales by 2019 while India is expected to reach $10.7 billion.

Although the middle class in these markets will have more means by which to afford quality healthcare, most will not be able to afford the same medical device products available in the U.S. In order for a medical device company to make gains in these emerging markets ahead of the competition, they’ll need to make high-quality medical devices that are extremely cost competitive.

In addition, many surgeons in emerging markets are likely to have different training, facilities and surgical support compared to surgeons in the U.S. To accommodate the capabilities of surgeons in these markets, orthopedic OEMs need to simplify the design of their products in order to offer the most value.
PRESSING PROBLEMS

These multifaceted market pressures are driving orthopedic OEMs to figure out how to sell high-quality medical devices for a fixed—or lower—cost while still maintaining their profit margins. In their effort to accomplish this, OEMs usually confront three primary challenges: sales and distribution costs, overhead costs, and cost of goods sold.

1) Sales and Distribution

Joint replacements have become one of the highest volume procedures for both Medicare and private payers. It is estimated that over $15 billion are spent per year on hip-replacement surgery in the U.S. alone. The large financial outlay associated with joint replacements has made these procedures the focus of cost-containment efforts by the government and private payers.

However, a factor that is commonly omitted from the discussion of how to reduce the cost of goods sold is the cost of the instrumentation associated with the orthopedic implant.

Currently, most hospitals that utilize an OEM’s orthopedic implant (e.g. hip stem) pay for the implant, but not the related instrumentation required to install the implant. OEMs consign their implant-specific instruments to healthcare providers.

In addition to significant research and development costs, OEMs also take on the tremendous expense of making, packaging, warehousing, maintaining, and repairing these instruments. OEMs also assume the responsibility for training and compensating the representatives who provide the instruments to the hospital’s surgical team.

As the cost of medical procedures is increasingly scrutinized, so is the cost associated with the sales professionals who sell the medical devices to hospitals and medical facilities.

During many implant surgeries – routine and otherwise – a sales representative from the orthopedic implant supplier is often an integral part of the surgical team. In addition to possessing extensive knowledge and sharing their expertise about how the implant and the instruments work together, sales reps help improve patient outcomes by training the surgeons or surgical techs on how to use the instruments correctly with the implant.

However, because the cost of the medical device sales representative’s service is applied to the cost of the implant, many payers and providers are pressuring suppliers to significantly reduce—or even eliminate—that cost.

One approach, some payers and providers argue, is that hospitals and surgery centers need to start paying for both the implant and the associated instruments and take on the responsibility of maintaining and warehousing the instruments. While that might drive
down some of the cost of the implant, it will certainly increase the costs to the hospital, and thus to the payer.

For example, in a letter to the editor, a group of orthopedic surgeons considered the costs associated just with the sterilization process to include:

- Building costs (heating, cooling, ventilation, rental, insurance, etc.),
- Custody and replacement cost of the devices (consumable chemicals, consumable supplies, personal protective costs, electricity and water consumption costs of washing and steam autoclaving materials), and
- Staffing costs (paying someone to complete all the sterilization processes).

Many of these costs will vary from state to state and hospital to hospital, but the reality is that the cost of sterilization alone is significant. As more orthopedic procedures are performed, as they are expected to, these costs—and others associated with maintaining instrumentation—are likely to grow.

Increasing expenditures, declining reimbursements, and narrow profit margins are just a few of the pressures facing hospitals and influencing them to reassess and renegotiate pricing for orthopedic products and services. In order to continue as a preferred hospital supplier, medical device OEMs must find cost-effective ways to design and manufacture their orthopedic implants so they require fewer or more simplified tools to install.

2) Overhead

Now that the 2.3 percent medical device excise tax has taken effect, medical device companies are bracing for the impact. According to a recent survey of 3,000 medical device makers, 40 percent of the respondents said they would raise prices to deal with some or all of the impact of the new tax. However, as payment reimbursements for joint replacement procedures and implants are increasingly capped, simply raising prices to offset rising cost pressures is likely to be less of an option.

As sales prices for orthopedic products continue to shrink, medical device manufacturers must resort to other strategies to keep their margins healthy. For many OEMs, more realistic options, as proven by recent news headlines, involve laying off employees and cutting research and development initiatives. While these austerity measures may maintain balance sheets, they are also likely to mean less support to surgeons and providers, and less innovation.

Reducing overhead is also a main driver behind why OEMs are increasingly outsourcing the manufacturing and design of their orthopedic products to Contract Service Providers (CSP) who can provide a full range of services, including design, engineering, regulatory and packaging as well as manufacturing. It is estimated that outsourcing projects and processes to a CSP with comprehensive capabilities has allowed OEMs to reduce costs by 10-30 percent and focus more on their core competencies.
At present, the contract manufacturing market is highly fragmented with thousands of small to mid-sized companies offering specific services (e.g. prototyping, or design, or coating), but only a select few have the broad range of competencies to offer complete solutions from concept through commercialization.

3) Cost of Goods Sold

A growing challenge facing OEMs is making their high-value medical implants and instruments at a price that hospital administrators will purchase them for, while still maintaining their profit margins.

Implant costs associated with total hip replacement and total knee replacement procedures account for a large share of total costs and reimbursements to hospitals. As reimbursement rates for joint replacement procedures and implants decrease, hospitals face mounting pressure to meet new cost guidelines. Consequently, they put pressure on medical device manufacturers to reduce their implant prices.

However, the cost to design, develop and manufacture innovative, high-quality orthopedic medical devices can be considerable for an OEM. In addition to the high overhead costs to make, maintain and inventory the instruments used to install the implant, OEMs who design and manufacture their own devices have the expense of raw materials, manufacturing machines, coating technology, regulatory and quality assurance, and a host of other essential capital outlays to bring their products to market.

Unfortunately, the current and future reality is that if payers (Medicare, private insurance, etc.) consider the cost of an orthopedic implant to be too high, then physicians and hospitals who use the implant will find it difficult to get reimbursed.

Another aspect of manufacturing that is increasing costs for both the OEM and the CSP are increasing regulatory requirements. More documentation of processes, increased use of risk analysis and more robust validations are being mandated. All of these requirements come with a cost. No longer can an OEM or a CSP get by without understanding impacts of the regulatory climate. A CSP that not only understands these requirements, but makes them a part of their everyday mode of operation is better positioned to help the OEM contain costs.

To help reduce their Cost of Goods Sold, more and more OEMs are choosing to partner with full-service orthopedic Contract Service Providers.
**Reflecting on the Past**

"Life can only be understood backwards; but it must be lived forwards."

~ Søren Kierkegaard

In the past, the relationship between the OEM and the surgeon was the main driver of determining what implant system a hospital would purchase. The OEM would work with the surgeon community to develop products that addressed a host of clinical indications within one product system. Cost was a secondary concern as the surgeon was mostly concerned with patient outcomes than the cost of the procedure.

Although the design of a device was outsourced less frequently than it is today, it was common for an OEM to outsource the manufacturing of their device. However, because mature Contract Service Providers with broad capabilities were not available, getting their product manufactured often required OEMs to work with multiple suppliers, each with different processes and capabilities.

**The Path to Profitable Progress**

Going forward, in order for orthopedic OEMs to maintain their competitive edge and provide the most value to their customers, they need to think differently about the design and manufacture of their medical devices.

The strategy of getting an implant to market as fast as possible, regardless of the cost, and then cost-reducing it later is no longer a viable business strategy for medical device OEMs. In today's environment, hospital administrators have taken a primary role in the purchase of products, and they see the importance of a product's cost on par with patient outcomes.

Due to this new relationship, engineers, who previously concentrated primarily on surgical results, now have to consider manufacturing costs and regulatory pathways if they expect their products to be successful in the marketplace. This is why it's essential for OEMs to identify financial goals at the outset of the project—well before a design exists and prior to establishing the manufacturing process. This includes determining:

- What the product can be sold for;
- What the margins need to be;
- What the target manufacturing cost is.

By identifying these cost goals up front, an OEM can define financial success from the very start of a project and help keep the product development team on the right path. As such, the time to get the cost right is during the design process, not once it is in manufacturing.
If an OEM outsources the design and/or manufacture of their device to a CSP, then those financial parameters must be communicated to the CSP in order for them to properly set up their own development and manufacturing processes to sufficiently meet those economic targets. In addition, by sending the CSP their cost goals for the design or manufacture of a device—ideally well before the design is locked down—, the OEM might learn that while their design concept is unique and innovative, it contains features that are costly to manufacture and will exceed their financial targets. These tradeoffs must be understood and managed early in the process.

**Mutual Benefits**

By working together as collaborative partners from the onset of a project, a CSP with comprehensive capabilities can offer the following benefits to their OEM customer:

- Medical devices that are designed with cost, performance, usability, RA/QA, and innovation in mind from the very beginning;
- Medical devices that are efficiently and cost-effectively manufactured;
- Fewer design iterations late in the project;
- Accelerated time to market and therefore revenue;
- Simplified products (e.g. implant and instruments) that are more intuitive for surgeons to use, thus empowering them to perform surgery without needing a sales rep in the OR;
- A leaner, more economical overhead structure;
- Reduced inventory;
- Access to full design, engineering, manufacturing, and regulatory support and expertise.
- Reduced costs of goods sold and total cost of a project;
- CSP and OEM each focusing on their core competencies.

**Contract Service Provider Considerations**

As the role of medical device Contract Service Providers has increased over the past decade, so has a CSP's responsibility to ensure that they have the proper processes in place to deliver optimal value to their OEM customer. When evaluating an outsourcing partner, it's important for OEMs to consider whether or not the following strategies are being implemented by the CSP:

**Value Engineering (VE):** When it comes to cost-effectively designing and manufacturing a medical device for an OEM, it's vital that the CSP understands the value of the product through their customer's eyes, as well as its value to the marketplace. Value is defined as the ratio of function to cost. For example, by working in partnership with their customer and following a VE methodology at the onset of a project, the CSP may learn that a specific feature on the OEM's hip stem will result in a shorter procedure. Or that a particular component may lead to better patient outcomes.
Understanding the value attributed to the device better equips a CSP to help their OEM partner understand the cost associated with each feature and function. If a certain feature looks impressive, but offers minimal value to the marketplace, then the CSP can recommend eliminating or changing it in order to make the device more economical.

While cost reduction is critical to an OEM, it’s also important to reduce cost strategically and intelligently. There are situations where a CSP can provide more value to their OEM partner at the same cost. For instance, a CSP may be able to justify that by reducing the quantity of their customer’s fleet of orthopedic implants from 15 to 10, the OEM will have less inventory to carry, manage, and maintain. As a result, they will enhance their working capital and cash flow. By applying VE to every project, a CSP is better positioned to identify where to focus their efforts in order to offer the greatest value to their OEM partner.

**Design For Manufacturability (DFM):** As orthopedic OEMs have faced increasing pressure to make their medical devices more economical and get them to market quickly, DFM has evolved from being an optional tool to an essential strategy. Truly effective DFM engages manufacturing expertise at the beginning of a project and fosters a symbiotic relationship between the design team and the manufacturing team so that costly, time-consuming manufacturing issues can be prevented—or at least planned for. DFM also helps bring transparency to the supply chain so target costing at the part and system level can be achieved.

For example, if the CSP is brought into design concept discussions before the device is even a CAD model, the CSP team might recognize features that will add tight tolerances or increase cost of materials. Or the CSP’s manufacturing team might be able to show how eliminating a feature would allow the device to be forged instead of machined, thus allowing the part to go through production more efficiently. The reality is that Engineers can no longer be concerned only with the function of a design. They must also be responsible for cost of the design, which requires Engineers who are savvy about manufacturing process.

**Design Transfer (DT) Process:** A good design transfer process leads to lower overall cost, faster speed to market, and higher quality products in the following ways:

- It focuses the manufacturing and quality processes on only those areas that bring value to the product’s function or risk reduction;
- It drives robust and stable processes that can be reproduced and qualified efficiently;
- It reduces unnecessary scrap and rework initially and long term;
- It brings products to market faster with fewer start-up related issues that can lead to product recalls and revisions.

However, if not done correctly, transferring the design of a medical device to the manufacturing team can be frustrating, expensive, and waste a great deal of time.
Traditionally, DT was thought of as a “late phase” process. However, because there wasn’t enough focus on DT early in the design process and manufacturing wasn’t included in the discussion until much later, it was common for expensive mistakes to be made that resulted in significant scrap, rework and quality problems.

A CSP that starts the DT process at the beginning of a project—even right at the design concept phase—will address all the potential design, quality, and manufacturability issues simultaneously. By the time the product reaches the last phases of the project, how the design to be transferred will have already been extensively thought-out and integrated into each of the processes. As a result, the cost and time associated with manufacturing the device is greatly reduced and expensive product and quality issues are avoided.

**Lean Manufacturing**: Lean often refers to processes and practices that eliminate waste along entire value streams. However, Lean is not a tactic or a cost reduction strategy. It’s a culture—a way of thinking and acting for an entire organization. When everyone within an organization (employees and management) embraces continuous improvement, waste reduction, and just-in-time, a CSP can create more overall customer value with fewer resources.

For example, in a truly Lean CSP organization, teams manage the entire value stream for specific goods and services and identify all the steps and time required to get a job done in a way that will reduce inventory and lead time. Standardized work is then created so that the job can be completed using only the appropriate number of processes and minimum inventory. Each team member has a clear understanding of their responsibilities for building a quality product and doing so on time. If an issue arises that interrupts a process, then team members work cohesively to address the issue and restore continuous flow of the value stream.

An OEM that is able to tie their value stream to their CSP partner’s is better positioned to remove waste, decrease cost, and add more value to the marketplace.

**ORCHID ORTHOPEDIC’S FULL SERVICE SOLUTION**

Orchid Orthopedic Solutions is a leading Contract Service Provider for OEMs worldwide. In addition to implant and instrument manufacturing, Orchid provides comprehensive solutions including product development, quality and regulatory consulting, and complete supply chain management through packaging and sterilization.

With more than 1,500 skilled employees, Orchid has unparalleled expertise in design and manufacturing of joint reconstruction, trauma, spine, sports medicine, extremities, craniomaxillofacial, orthobiologics, dental, cardiovascular and general surgical devices.

At Orchid, we understand how important it is to our OEM partners to get their products to market with speed and precision, while protecting their margins. This is why we’ve
invested the time and resources to cultivate a Lean culture that simplifies processes, minimizes waste, and increases value.

In addition to our Lean culture, the Orchid team also has extensive experience applying Design Transfer Processes, Value Engineering and Design For Manufacturing.

As a complete value stream partner with an ISO 13485 certified quality system, Orchid’s turnkey capabilities offer the best total supply chain value in the industry and enable their OEM partners to deliver high-quality, cost-competitive medical devices to the marketplace.

To learn more about how Orchid can help you streamline your supply chain, reduce risk, and flourish in the new medical device economy, call us at (517) 694-2300 or visit us online at www.orchid-ortho.com.
ENDNOTES

i U.S. Congressional Budget Office (CBO), Long Term Budget Outlook, 2009.

Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, National Health Care Expenditures Data, January 2012.


