

Bio-Medical Marketing

The Charité: Lessons in the Launch of a New Medical Device



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EXECUTIVE SUMMARY

In October 2004, Johnson & Johnson subsidiary DePuy Spine received U.S. approval for the first artificial disc to treat severe cases of chronic lower back pain. Called the Charité, it ostensibly offered a superior alternative to standard of care spinal fusion which had penetrated only a small proportion of the total market. Promising greater range of motion and quicker recovery from surgery, Charité generated significant media, physician and patient attention pre-launch leading to forecasts of sales of \$100M in 2005 and \$1B by 2010. Many thought the Charité had the “potential to revolutionize spine surgery.” DePuy planned an aggressive launch program to meet this expected high demand including training 2,500 spinal surgeons at special three-day training sessions to learn the complicated procedure. However, while initial anecdotal patient stories generated significant excitement in the market, lack of long-term clinical data and safety concerns meant that most insurers refused to cover the \$11,500 device. DePuy responded by citing new peer-reviewed publications, durability tests, as well as successful long-term use in Europe. However, as surgeon support waned owing to rare complications, this failed to have any impact with sales reaching only a third of the initial target in 2005. In early 2006, DePuy was faced with still new obstacles in Medicare’s denial of national coverage (leaving the decision to local carriers) and the near-term entry of three competitors.

BACKGROUND

Market Space

Approximately 65 million people (mainly between the ages of 30 and 50) in the United States suffer from back pain¹ with low back pain being the most common cause of job-related disability and loss of work productivity. Currently, spinal treatments are the second largest musculoskeletal therapeutic area (Exhibit 1).² The most severe pain is generally caused by degenerative disc disease (DDD) in which intervertebral discs begin to breakdown with aging resulting in chronic and debilitating lower back pain – DDD is estimated to afflict about 12 million Americans.³ If first-line conservative treatments fail (Exhibit 2), the current “gold standard” in surgical treatment is spinal fusion (Exhibit 3). In this invasive procedure, two or more adjacent discs are fused together with bone grafts and increasingly biological proteins, as well as other devices (including fusion cages or metal rods) to create a solid bone bridge and stability between adjacent vertebrae. An estimated 350,000 spinal fusion procedures

¹ American Association of Neurological Surgeons

² www.ninds.nih.gov

³ www.medicalcenter.osu.edu

were performed in the U.S. in 2004⁴. However, only a small percentage of patients with DDD opt for fusion mainly due to the loss in mobility resulting from the surgery. Today, the overall spine segment as a whole is dominated by Medtronic and DePuy Spine (Exhibit 4) due to strong sales in spinal fusion devices.

Recently, however, the treatment of spine disorders (DDD in particular) has begun to shift away from fusion technologies towards non-fusion. The emergence of new technologies along with an aging population is expected to propel the spinal implant market from \$2.4B in 2004 to \$5B in 2009.⁵ The most promising technology is total disc replacement (TDR) which, unlike fusion, allows for the preservation of motion in the spine. This market includes both cervical and lumbar spine disc replacements with analysts estimating the cervical market to be larger – only 10 to 20% of lumbar fusion cases are candidates for TDRs versus over 50% of cervical fusion cases⁶. Because of TDR success overseas, an aging US population, and fusion candidates switching to discs, analysts predict a strong market for artificial discs for the spine – the U.S. spine disc market is expected to grow to about \$1 billion in 2010⁷.

Competition: Market leadership in spine treatment is up for grabs as the disc replacement market begins to take shape. It is estimated that worldwide, more than 60 companies are working on non-fusion technologies⁸ and since 2001, the three market-leading spine fusion companies have invested nearly \$1.4 billion in acquisitions of non-fusion companies and technologies. The first artificial disc to be introduced was the Charité from DePuy in late 2004 with the next entrants in the lumbar disc market – Synthes (ProDisc), Medtronic (Maverick) and Stryker (FlexiCore) likely to reach the market in late 2006, 2007 and 2008 respectively. While some analysts argue that Synthes' ProDisc has superior results to the Charité, others believe they are relatively comparable. With clinical trials for other lumbar discs ongoing, their relative positioning is unclear.⁹ However, Medtronic is expected to be the market leader in the cervical market with the launch of Bryan in 2007 (Exhibit 5).

Referral Chain

A patient experiencing back pain will typically try over the counter pain killers first and will then visit their primary care physician. The physician will perform a medical history and physical examination

⁴ Wall Street Journal, May 12, 2004

⁵ Spinal implant sales expected to double in five years. Device & Diagnostics letter. October 25, 2004.

⁶ Prudential Equity Report, December 2005.

⁷ Prudential Equity Report, December 2005.

⁸ www.medicaldevicelink.com

⁹ Kelly, Susan. Competition about to heat up for J&J spine disc. Reuters. May 16, 2006.

before conducting an imaging test, usually an MRI. Depending on the results the patient will be referred to a back specialist. The specialist will usually start with conservative treatment options such as bed rest, controlled exercise and sometimes injections. However, if the patient experiences neurological deficit or severe and disabling pain after four to six weeks of conservative treatment then surgery will be considered (Exhibit 6).¹⁰

The Company

The Charité Artificial Disc was originally developed at the CHARITÉ University Hospital in Berlin, Germany in the mid-1980's by leading spine specialists Prof. Karin Büttner-Janz and Prof. Kurt Schellnack. In 2003 DePuy Spine acquired the Link Spine Group, Inc., for \$325 MM gaining exclusive worldwide rights to its principal product, the SB Charité Artificial Disc. DePuy Spine, Inc. is an operating company of Warsaw, Indiana based DePuy, Inc., a Johnson & Johnson company. DePuy is one of the world's leading designers, manufacturers, and suppliers of orthopedic devices and supplies. Of J&J's \$47.3 B in revenue in 2004, DePuy accounted for \$3.4 B.¹¹ DePuy Spine is headquartered in Raynham, Massachusetts with its international office in Leeds, England.¹²

The Product

The Charité Artificial Disc is a three-piece articulating medical device consisting of a sliding core sandwiched between two metal endplates. The sliding core is made from a medical grade plastic and the endplates are made from medical grade cobalt chromium alloy. These materials usually do not harm the human body and are used in many other medical implants such as total knee replacement implants. The endplates support the core and have small teeth which secure them to the vertebrae above and below the disc space. The sliding core fits in between (Exhibit 7).

Laboratory testing showed that the Charité design allowed more flexibility in the spine. In the clinical study, patients were observed to have motion between 0 and 21 degrees while bending forward and backward.¹³ Another benefit from the disc replacement surgery was that no bone graft was required. With some forms of spinal fusion, the bone graft used to pack the disc space was bone that the surgeon had removed from the patient's hip resulting in a second incision as well as pain in both the back and hips during recovery.

¹⁰ Humphreys, C., Eck, J., *Clinical Evaluation and Treatment Options for Herniated Lumbar Disc*, American Family Physicians, Vol. 59, No. 3, Feb. 1, 1999.

¹¹ Johnson & Johnson 2004 Annual Report. <http://www.jnj.com/2004AnnualReport/financials/discussion/index.htm>

¹² <http://www.depuyspine.com/about/about.asp>

¹³ http://www.charitedisc.com/charitedev/domestic/patients/about_whatIsCHARITE.asp

When undergoing surgery with the Charité Artificial Disc, a patient would lie on their back and the surgeon would operate on the spine through an incision near the belly button. During the disc replacement surgery, the surgeon would remove the diseased disc and replace it with the Charité disc (Exhibit 8).

Potential risks, either singly or in combination, which can occur during disc replacement surgery with the Charité include bladder problems due to an allergic reaction, infection and bleeding, and pain and discomfort (Exhibit 9 provides a complete list).

Clinical Trial

A randomized clinical trial including 304 patients was initiated in 2001 (Exhibit 10). Patients were evaluated immediately following surgery, again at six weeks, and at three, six, 12 and 24 months afterwards. More than 90 percent of patients were seen at key follow-up time points. Two-thirds of the 304 patients enrolled in the pivotal study received the Charité and one-third had traditional spinal fusion surgery which involved bone grafts. Both devices were implanted using the same anterior surgical technique to minimize variables related to surgical approaches.

In clinical trials, both patients implanted with the Charité and spinal fusion patients experienced improvement in pain and functional test scores compared with their pre-operative status. However, patients implanted with the Charité improved more quickly, and their pain and functional test scores were statistically superior to those of the fusion patients at all points through 12 months and numerically superior at 24 months. The overall complication rate was equivalent between the two groups. Also, on average, patients implanted with the Charité were discharged from the hospital a half-day sooner than fusion patients (3.7 vs. 4.2 days).

At 24 months, 88 percent of patients implanted with the Charité expressed satisfaction with the procedure, compared with 81 percent of fusion patients. When asked if they would have the same procedure again, 82 percent of the patients implanted with the Charité said they “probably would” or “definitely would” decide to undergo the procedure, compared to 65 percent of fusion subjects.¹⁴

THE LAUNCH PLAN

DePuy’s launch plan was commended as a prudent, measured approach with the company at full readiness. Analysts praised the 1) company’s pricing strategy 2) extensive surgeon training 3) sales

¹⁴ http://www.ini.com/news/ini_news/20040318_090644.htm;jsessionid=AO5CPYJAYKU3MCQPCAOWU3YKB2IIWTT1

force preparedness and 4) available inventory.¹⁵ Each aspect of the company's launch program is discussed below from the perspective of the different players. Exhibit 11 provides a summary of DePuy's perceived pre-launch positioning status.

Providers

Physicians

By the time of the U.S. launch the Charité disc had already been used in Europe on 6,500 patients for over a decade, and a clinical trial had been conducted in the U.S. Thus, DePuy had access to physicians who were already trained in the implantation procedure and who could speak of positive results first hand. Selected key opinion leaders who were orthopedic surgeons and neurosurgeons were recruited to talk to groups of physicians and give presentations. At the 20th Annual Meeting of the AANS/CNS in March 2004, Fred Geisler, M.D., Ph.D, a clinical trial investigator, presented the Charité clinical trial results. These results, as discussed above, were convincing for many physicians, although the trial was later criticized for comparing the Charité disc to a form of fusion no longer considered state-of-the-art. Despite criticism, a primary appeal of the Charité was the benefits to patients who experienced wider degree of motion. Thus, with physicians, DePuy emphasized the visible benefits of the Charité discs that would allow physicians to clearly demonstrate patient benefit. The seemingly non-ambiguous nature of the benefits provided a strong advantage to fusion. One physician claimed that even his receptionist can tell difference between Charité and fusion patients¹.

Prior to launch DePuy built up huge demand with the result that 60% of spinal surgeons were advising patients to delay spinal fusion for the artificial disc.¹⁶ The physician groups performing the surgeries were orthopedic surgeons as well as neurosurgeons who numbered 17,000 and 3,100, respectively.¹⁷ However, approximately only 6,000 of the orthopedic surgeons performed spinal surgeries.¹⁸ Since, the surgical procedure was very difficult, DePuy initially targeted only surgeons who had expertise in anterior surgery, the approach used in disc replacements.¹⁹ DePuy provided extensive, mandatory training before surgeons were allowed to use the device, announcing plans to train 2,500 surgeons in

¹⁵ Bear Sterns analyst report, October 29, 2004; Deutsche Bank analyst report, October 28, 2004.

¹⁶ Spinal implant sales expected to double in five years. Devices and Diagnostics Newsletter. October 25, 2004.

¹⁷ Kruger, Kurt. The medical device sector. The Business of Healthcare Innovation. Cambridge University Press. 2005; Press Release: Relative shortage of neurosurgeons in the U.S. alarms the medical specialty. May 3, 2004. <http://www.aans.org/Library/Article.aspx?ArticleId=21791>

¹⁸ Calculated based on statistics from the American Academy of Orthopedic Surgeons Census, 2004.

¹⁹ Emerging technologies put spine market in motion. Medtech Insight. Vol. 11/12. Nov/Dec 2004.

the first year at three day sessions.²⁰ The training was a combination of hands-on surgery, consultation and visitation with top spine surgeons, lectures and web-based educational materials. DePuy also provided reimbursement training and a guide on coding, pre-authorizations, appeals etc. for surgeons. More than 50 regional training centers were set up throughout the country to provide the training.²¹

Traditional marketing channels were also important in DePuy's marketing program. The existing DePuy sales force and senior marketing executives called on the surgeons to educate them about the Charité. Journal advertisements in Spine and Neurosurgery were also placed.²² DePuy also used spinal surgeon associations such as the Spine Arthroplasty Society to promote the advancement of "natural spinal mobility". Importantly, the society's website claims the focus is on the "science" of spinal treatment and not the "product".²³

Hospitals

An important advantage of the Charité was that it reduced hospital stays by 15% compared to fusion. DePuy believed this presented a clear cost-saving for hospitals which would lead to a positive response from hospitals. Further, before launch, hospitals stated that they would cover any shortfall in CMS reimbursement because "what their spine surgeons require to deliver top patient care, they get".²⁴ It seems that DePuy then relied on physicians to convince hospitals to buy the Charité, instead of proactively working with hospitals to determine where the money would come from.

Patients

Prior to FDA approval and market launch DePuy focused patient attention on the benefits of the Charité disc, such as increased motion, reduced pain, decreased adjacent level deterioration, and the elimination of bracing or bone grafts. Reduced pain and increased mobility particularly resonated with patients. Direct to patient education was an important component of DePuy's marketing strategy. However, it did not involve the mass media as DePuy had so successfully done for knee replacement. Instead, the benefits of the disc were conveyed through targeted channels such as physicians, the news media (including PBS, NPR and local media), the web, and patient advocacy groups. So strong was patient enthusiasm for the Charité that some who had undergone the surgery during clinical trials

²⁰ Hensley, Scott. Artificial spine disc may open new era in treating back pain, but worries linger. The Wall Street Journal. November 2, 2004.

²¹ FDA Approves First Artificial Disc For Treatment Of Low Back Pain New Motion Preserving Device Offers Alternative to Spinal Fusion Surgery. October 26, 2004

²² Interview with Neurosurgeon, May 2006.

²³ Spine Arthroplasty Society, from: <http://www.spinearthroplasty.org>, May 11th, 2004

²⁴ Young, Robin. The struggle to reimburse disc arthroplasty. Healthpoint Central. August 23, 2004.

created websites to provide information and guide prospective patients through the pre-and post-operative process.²⁵ One physician advisor stated that two patients a week asked about the device with the result that 49% of patients, who were candidates for spinal fusion, postponing fusion surgery in the hopes of getting a disc.²⁶

Politicians (FDA)

DePuy submitted its Premarket Approval Application (PMA) to the FDA on February 17, 2004. In early June 2004, the Orthopaedic and Rehabilitation Devices Panel of the FDA unanimously recommended approval of the company's Charité Artificial Disc for degenerative disc disease. Less than 9 months after the submission of the PMA, on October 26, 2004, the FDA approved the Charité. The approval was indicated for treatment of spinal arthroplasty in skeletally mature patients with DDD at one level from L4-S1.²⁷ The patients also should have failed at least six months of conservative treatment prior to any surgery. The FDA also required a post- approval study to collect long-term safety and effectiveness data as well as surgeon training. The FDA finally reviewed the content of the training program, finalized product labeling, finalized the requirements of the post approval study, and inspected the manufacturing facilities. All of this was done prior to approval. Once approval was assured, DePuy could focus on the rest of the launch.²⁸

Pricing

Before launch, DePuy indicated that the price of the Charité would be around \$11,500. At that time the Charité was being sold in Australia and Europe for \$4,500 to \$5,000.²⁹ DePuy positioned the Charité as an alternative to modern spinal fusion which involved both a BAK cage and bone morphogenetic protein (BMP). The BAK cage and the BMP cost approximately \$4,500 each. Thus, DePuy believed it was only pricing the device at a 10-15% premium to the alternative.³⁰ The total costs of the spinal fusion surgery vs. the disc implantation (physician fees, hospital facilities use) were estimated to be in a similar range of \$30,000 - \$50,000.

²⁵ First artificial disc patient education site debuts. Market Wire. December 16, 2004.

²⁶ Emerging technologies put spine market in motion. Medtech Insight. Vol. 11/12. Nov/Dec 2004.

²⁷ <http://www.fda.gov/cdrh/pma/pmaoct04.html>

²⁸ <http://www.fda.gov/cdrh/PDF4/p040006b.pdf>

²⁹ Harvard Pilgrim Healthcare Technology Assessment: TA 6.30 Artificial Disc (Total Disc Replacement) as an Alternative to Apinal Ausion for Degenerative Disc Disease, December 2004.

³⁰ Deutsche Bank analyst report, October 29, 2004.

Payors

Since the overall costs of the artificial disc replacement procedure were believed to be similar to that of spinal fusion, DePuy didn't expect significant resistance from payors. Instead, DePuy expected payors to be moderately supportive as the Charité was expected to reduce overall system costs through better outcomes. Yet DePuy didn't have any proactive strategy or health economics data to prove this but relied on patients, physicians, and advocacy associations to push for reimbursement.

Before launch, the Charité did experience a reimbursement setback. Since it was positioned as a replacement device for a drug-device combination, existing codes did not sufficiently reimburse its cost. CMS, however, refused to grant a new DRG code for disc arthroplasty products, including the Charité. Instead, the disc was covered for reimbursement under DRG codes 499 and 500 for the "excision of the intervertebral disc material." This would only allow for reimbursement at less than half the expected price of the Charité or \$4,800. Since Medicare patients are not the ideal target for this product (the primary target are those between 45 and 65 years), DePuy didn't expect this to have major implications. However, it still rallied patients and physician groups to convince CMS to overturn the decision.

This left hospitals with a huge monetary shortfall to fill. In response to the reimbursement challenges, at launch DePuy announced volume discounts for hospitals with trained surgeons and who purchased 20 discs. This brought the average price of the disc down to \$8,000.³¹

Company

Within the company, excitement had been building even before the FDA application was filed. With what they viewed as strong clinical trial data, DePuy was confident of transforming the spinal category. "We believe the Charité Artificial Disc's motion preservation technology has the potential to transform the treatment of spine disorders in the United States," said Earl R. Fender, worldwide president, DePuy Spine, Inc. "We also believe this first-ever submission for a total disc replacement device represents what could be the beginning of a promising era of new treatment of physiologically desirable options for degenerative disc disease."³² The strong pre-launch response from the medical and patient community only added to the expectations from the disc. Parent company Johnson & Johnson prominently featured the Charité in its annual report in both 2003 and 2004 calling it a

³¹ Emerging technologies put spine market in motion. Medtech Insight. Vol. 11/12. Nov/Dec 2004.

³² http://www.jnj.com/news/jnj_news/20040217_112104.htm

“revolutionary advance to current spinal surgery.”³³ J&J expected to gain 3%-5% market share or \$72-120 MM in sales in the first year.³⁴

RESULTS

Initially, the Charité benefited greatly from strong word-of-mouth generated by individual patient success stories. Surgeons received many calls from would-be patients who had heard about the Charité’s touted superior efficacy and shorter recovery times. Reports of shortages and wait times of several weeks owing to lack of trained surgeons did nothing to diminish patient excitement. What did, however cause enthusiasm to wane was the strongly negative reaction from insurers.

Even though Medicare patients were not the ideal target, CMS’s decision on DRGs was important to private payors as they historically use Medicare as a basis for their own decisions.³⁵ Payors publicly criticized the lack of long-term data as well as the use of traditional spinal fusion, not the current standard of care modern spinal fusion, as the control. Most used this as justification in denying coverage. Internally, however, private payors were worried by the overwhelming response from the patient and physician community which they feared would lead to a dramatic expansion of the number of procedures and have huge economic implications despite the similar overall cost. Containing the financial hit may have thus been an important driver of the non-coverage decision. Eventually, only 60 regional insurers, of which just 2 were national, agreed to cover the device.³⁶

DePuy responded to the payer criticism by pointing to European results of a leading French surgeon which showed “good or excellent” results in 90 of 100 patients followed for 10 years or more. It also performed simulations which showed that the Charité could withstand wear or tear for 80 years.³⁷ However, critics cited other European data which they claimed showed a rapid deterioration. With no comprehensive, controlled trials, the European data did not change opinions significantly.

With most insurers refusing to cover the device, the few approvals that did occur were on a case-by-case basis requiring the patient to go through a complex appeal process. So endemic did this problem become that DePuy developed a detailed manual for patients as well as provided extensive training to surgeons on appealing against unfavorable insurer decisions (Exhibit 12).

³³ <http://www.jnj.com/2003AnnualReport/letter/index.htm>

³⁴ Rosenberg, Daniel. J&J’s 2005 Charite sales in U.S. could reach \$100 M. Dow Jones Newswires. October 29, 2004.

³⁵ Young, Robin. The struggle to reimburse disc arthroplasty. Healthpoint Central. August 23, 2004.

³⁶ Feder, Barnaby. When FDA says yes, but insurers say no. The New York Times. July 6, 2005.

³⁷ Rundle, Rhonda and Hensley, Scott. Back Fire: J&J’s New Device For Spine Surgery Raises Questions --- Artificial Disk Aims to Help Body’s Natural Movement; Some See Risk if It Slips --- ‘Big Money Riding on This’. The Wall Street Journal. June 7, 2005.

What may have proved to be the tipping point for the Charité's fate was that surgeons were becoming more skeptical and less enthusiastic champions of the product as time wore on. This may be because the procedure was highly complicated and much more difficult than fusion. It was estimated to require 20-30 cases before the surgeon became comfortable with the procedure.³⁸ As the pivotal clinical studies showed, the best results are only achieved from "well trained surgeons with excellent technique who perform the procedure on patients who meet the selection criteria outlined in the study and on the device's label."³⁹ Because of surgeon's early lack of skill at the procedure as well as off-label use, anecdotal reports soon began filtering in about less-than-ideal results as well as emergency surgery in some patients soon after disc implantation. This rescue surgery, which required the disc to be removed, was much more complicated than repair surgery in spinal fusions as it required the abdomen to be cut open, raising the likelihood of severe blood loss. The highly visible nature of this adverse effect, while quite rare, reduced surgeon's support of the Charité. As the benefits became more ambiguous and the risks more non-ambiguous,

- Surgeons performed fewer disc procedures;
- This reduced their comfort with the procedure;
- It increased the risk and lowered the benefit of the disc; and
- Thereby formed a vicious cycle of slowing surgical adoption of the device

The strongly positive pre-launch positioning was looking much weaker now (Exhibit 13). Consequently, implant levels were running at 25% below projections by May 2005.⁴⁰ Hospitals initially had no choice but to purchase the Charité owing to overwhelming surgeon support. However, they themselves were skeptical about the Charité, despite the clinical results showing shorter hospital stays, as DePuy did not provide any health economics data. Thus, as surgeon enthusiasm diminished for the device, hospitals were quick to erect another barrier for DePuy.

The Charité's trouble with insurers was not yet over. Sparked by surgeons who were skeptical of the device, CMS decided to make a "national coverage decision" on use of the Charité. In March 2006, it published a preliminary decision to deny national coverage, deeming the disc not "reasonable and necessary." This was based on most of the same criticisms leveled by private insurers against the

³⁸ Hensley, Scott. Artificial spine disc may open new era in treating back pain, but worries linger. The Wall Street Journal. November 2, 2004.

³⁹ Charité artificial disc clinical trial data published in peer-reviewed journal, Spine. July 18, 2005. <http://www.charitedisc.com/charitedev/domestic/patients/news.asp>

⁴⁰ Feder, Barnaby. When FDA says yes, but insurers say no. The New York Times. July 6, 2005.

device.⁴¹ However, after receiving numerous appeal letters from patients, physicians and industry associations (driven by DePuy) ,in mid-May 2006, CMS reversed its earlier decision and went back to the status-quo of letting local Medicare carriers make the decision for patients under 60 while not reimbursing it for those above 60 years.⁴² While DePuy hoped this would lead to greater private reimbursement, given CMS’ ambiguous position, it is unlikely to lower private coverage barriers.

With strong payor resistance and waning hospital and provider enthusiasm, Charité sales in 2005 were just \$41M against initial expectations of \$100 M. Analysts expected 2006 sales to fall by 50% to just \$21 M.⁴³ Officially terming Charité a disappointment in early 2006, J&J no longer featured the Charité in its 2005 annual report. DePuy replaced the Charité management team and announced plans to release in the “near future” five and ten-year data for the Charité in a bid to revive the fortunes of what once promised to be a blockbuster.⁴⁴

LESSONS LEARNED

It is always difficult being the first entrant into a new segment as one needs to educate the market both on the category as well as the product. While pre-launch, physician and patient dynamics were strongly in DePuy’s favor, it was not enough to quell the negative reaction from hospitals and payors. There are several ways we believe that DePuy could have better harnessed surgeon and patient enthusiasm for the Charité while also building better support for the device among the less enthusiastic players.

Consistency between marketing and clinical trial development: While DePuy positioned the Charité disc as an alternative to modern spinal fusion (using BMP), the clinical trials employed traditional spinal fusion (using bone grafts) as the control. Thus, the pricing was inconsistent with the available clinical data. DePuy should have either priced the Charité relative to BAK levels or conducted trials that used modern spinal fusion or found other ways (see below) to justify the pricing for the device.

Perform health economics study pre-launch: Knowing that the price of a Charité disc would be almost 2.5 times that of a BAK cage, DePuy should have supplied CMS, and other payors, with an economic rationale for covering the Charité and granting new codes. This was the tactic employed by Cordis Corporation, also a J&J company, with the Drug Eluting Stent (DES). Similar to the Charité Disc, the DES was priced many times greater than its predecessor, in this case the bare metal stent. But, unlike

⁴¹ Feder, Barnaby. Spinal disc closer to losing Medicare aid. The New York Times. March 18, 2006.

⁴² Reuters. Medicare will pay for J&J spinal disc. The New York Times. May 17, 2006.

⁴³ Hensley, Scott. Johnson & Johnson disc implant might not get Medicare coverage. The Wall Street Journal. February 17, 2006.

⁴⁴ Interview with J&J management, April 2006; J&J Presentation at 26th Annual Cowen Healthcare Conference. March 7, 2006.

DePuy, Cordis commissioned an economic analysis to be performed alongside its two clinical trials. The favorable results were published in a peer reviewed journal⁴⁵ and were leveraged to obtain CMS reimbursement before FDA approval. Cordis did not passively wait for reimbursement but rather, they proactively collected information and used hard data to gain early coverage.

Better targeting: The Charité allowed much faster recovery times. Charité patients were able to return to work 6 weeks after surgery vs. 4-6 months for spinal fusion. Thus, one of the major benefits of the disc was lower worker productivity loss and lower worker compensation payments. DePuy should therefore have targeted employers and workers compensation insurance carriers and used them to influence payors to cover the disc.

Pilot launch: Given the fundamentals of Scott Ward’s Patient Access Acceleration product life cycle framework, DePuy focused heavily on driving rapid growth rather than first building a standard of care (Exhibit 14). Instead of pushing forward with a mass national launch, DePuy should have focused on a smaller segment of highly skilled “early adopter” surgeons who conduct most of the surgeries. This would have allowed DePuy to collect longer follow-up data of likely better outcomes in a more controlled population. This would have helped in negotiations with payors and also delayed competitor entry by providing a benchmark for the duration data was needed. Further, narrow use of the device would have lessened payor resistance by reducing the expected economic impact.⁴⁶

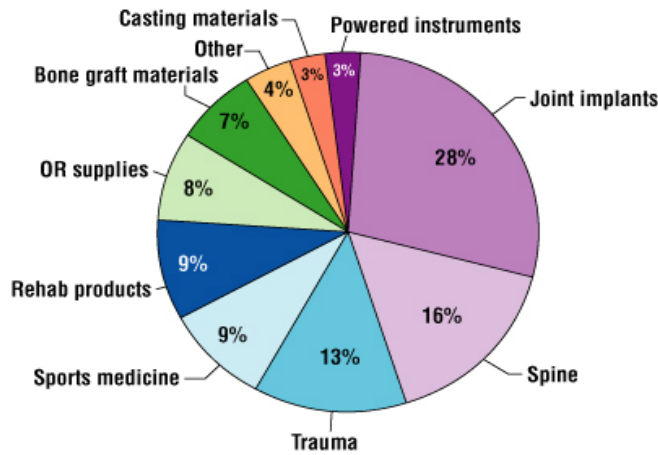
Stick to the label: Knowing that on-label usage was crucial to the success of the complex Charité procedure, DePuy should have been more aggressive in monitoring its usage. While there are limits to the extent a company can restrict surgeon off-label use, it likely has significant power given the reliance on the sales force in the medical device industry and the newness of the technology.

⁴⁵ Hodgson JM, Bottner RK, Klein LW, Walpole HT Jr, Cohen DJ, Cutlip DE, Fenninger RB, Firth BG, Greenberg D, Kalisky I, Meskan T, Powell W, Stone GW, Zito JP, Clark MA., Drug-eluting stent task force: final report and recommendations of the working committees on cost-effectiveness/economics, access to care, and medicolegal issues. *Catheter Cardiovasc Interv.* 2004 May;62(1):1-17.

⁴⁶ TA 6.30 Artificial Disc (Total Disc Replacement) as an alternative to spinal fusion for degenerative disc disease. Technology Assessment Policy. Harvard Pilgrim Healthcare. May 2005.

APPENDIX

Exhibit 1 – 2004 Musculoskeletal Market (Market shares)



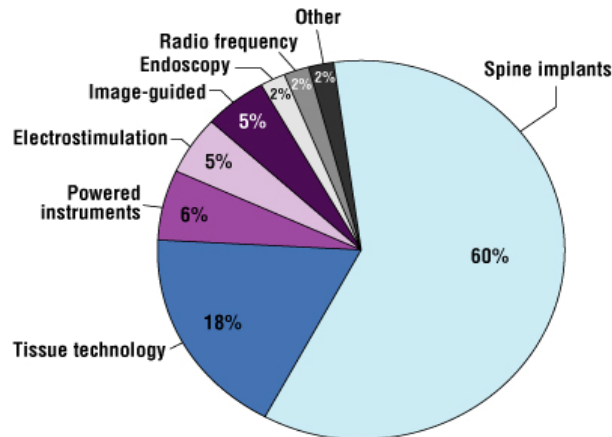
Source: *MX Magazine, January/February 2005*

Exhibit 2 – Treatment Options for DDD

Conservative	Surgical
<ul style="list-style-type: none"> • Physical Therapy • Pain Medication • Exercise • Manipulation • Massage 	<ul style="list-style-type: none"> • Discectomy • Spinal Fusion • Total Disc Replacement

Source: *Team Analysis*

Exhibit 3 – 2004 Spine Treatments (Market shares)



Source: *MX Magazine, January/February 2005*

Exhibit 4 – Overall Spine Market

Company	Market Share
Medtronic	41%
JNJ	19%
Synthes	10%
Stryker	6%
Kyphon	5%
Biomet	4%
Zimmer	3%
Other	12%

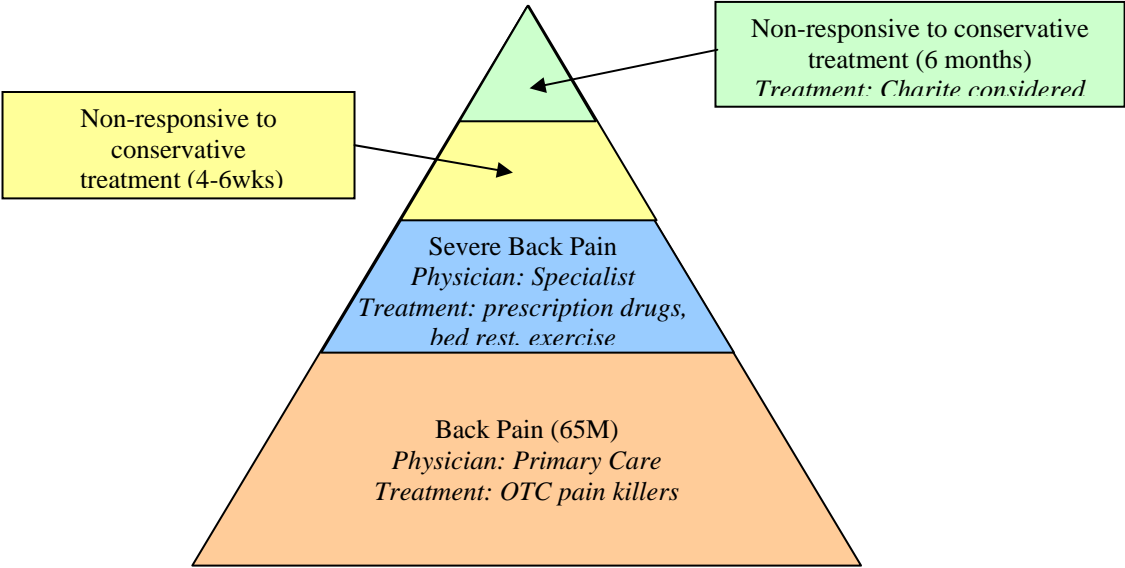
Source: *Prudential Equity Report, December 2005*

Exhibit 5 – Disc Launch Cycle

Company	Product	Type	Launch – US
JNJ	Charité	Lumbar	4Q-04
Synthes	ProDisc	Lumbar	Mid-2006
Medtronic	Maverick	Lumbar	Mid-2007
Stryker	FlexiCore	Lumbar	2H-08
Medtronic	Bryan	Cervical	Mid-2007
Medtronic	Prestige ST/LP	Cervical	Mid-2007
Synthes	ProDisc-C	Cervical	1Q-08
Stryker	CerviCore	Cervical	2H-09
Cervitech	PCM	Cervical	2H-09
Nuvasive	Ceramic-on-Ceramic	Cervical	2H-09
JNJ	TBD	Cervical	2010

Source: *Prudential Equity Report, December 2005*

Exhibit 6 – Back Pain Treatment Pyramid



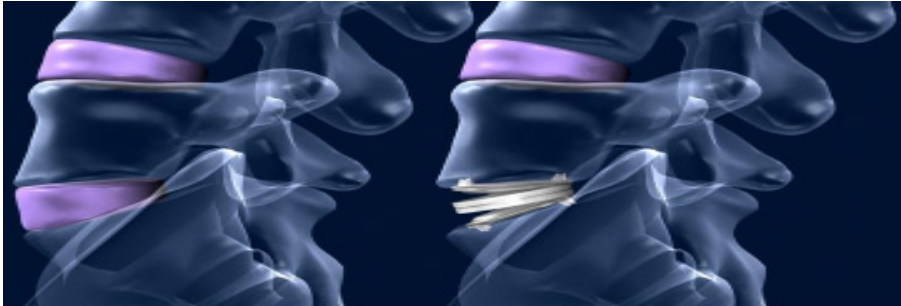
Source: Team Analysis

Exhibit 7 – Charité Components



Source: DePuy Spine

Exhibit 8 – Charité Implanted in Lumbar Spine



Source: DePuy Spine

Exhibit 9 – Main Side Effects of Implant

bladder problems	allergic reaction to the implant materials
infection	bleeding, which may require a blood transfusion
pain or discomfort	implants that bend, break, loosen or move
paralysis	side effects from anesthesia
spinal fluid leakage	slow movement of the intestines
incision problems	the need for additional surgery
spinal cord or nerve damage	tears of the dura (a layer of tissue covering the spinal cord)
death	problems with your blood vessels other than bleeding

Source: DePuy Spine

Exhibit 10 – Trial Summary

	Charité	Spinal fusion (Traditional)
No. of patients	205	99
Range of motion (t=24 months)	113.7%	82.7%
ODI Score	48.5%	42.4%
Device failure rate	5.4%	9.1%
Hospital stay	3.7 days	4.2 days
Satisfaction rate	73.7%	53.1%
Willingness to have repeat procedure	69.9%	50%

Source: Spine journal article review, July 18, 2005

Exhibit 11 – Pre-launch positioning status per DePuy

Value Proposition	Patient	Physician	Hospital	Payor
When the Charité is used instead of...	Traditional Spinal Fusion			
I get...	<ul style="list-style-type: none"> Better outcomes (range of motion, mobility) Shorter recovery time 	<ul style="list-style-type: none"> Superior outcomes Same/reduced risk of complications Happier patients “Innovator” reputation 	<ul style="list-style-type: none"> Happy surgeons and patients Reduced in-patient utilization 	<ul style="list-style-type: none"> Better outcomes lead to system savings Modest increase in procedure costs
I give up...	<ul style="list-style-type: none"> Pain and aches Bone grafts 	<ul style="list-style-type: none"> Some familiarity Peace with administration 	<ul style="list-style-type: none"> Margin (if lower coverage) 	<ul style="list-style-type: none"> Cost predictability
OVERALL ASSESSMENT	HIGHLY POSITIVE	HIGHLY POSITIVE	POSITIVE	NEUTRAL

Source: Team Analysis

Exhibit 12 – Sample Appeal Letter

[Name of Representative from Insurance Company]
 [Insurance Company Name]
 [Insurance Address]
 [City, State ZIP]

Re: Request for Reconsideration of a Denial of Coverage
 [Your Name]
 [Type of Insurance]
 [Group Number/Policy Number]
 [Subscriber ID Number]

Dear [Name of designated representative of insurance company]:

Paragraph 1

- State that you wish to appeal the plan’s denial of coverage for the CHARITÉ Artificial Disc
- Indicate the date of the letter of denial
- State that you understand that the healthcare plan has determined that the CHARITÉ Artificial Disc is an investigational device

Paragraph 2

- Mention the condition that you have been diagnosed with and the date of the diagnosis.
- Explain that all other conservative treatments or previous surgeries employed in an attempt to treat have failed.

- Describe your condition, the various treatments you have tried and the impact of the condition on your life and on your family
- Explain that your doctor believes that you are a good candidate for surgery with the CHARITÉ Artificial Disc, that the CHARITÉ Artificial Disc is the best treatment for you, and believes that you will significantly benefit from it
- Add that your doctor has submitted a letter of medical necessity that includes an overview of your medical history and diagnosis, a discussion of how the CHARITÉ Artificial Disc will be used to correct your condition and his or her rationale for the surgery
- Emphasize that you meet the FDA approved **indications for use** and comply with the **inclusion/exclusion criteria** for the CHARITÉ Artificial Disc
- Mention your goals for surgery with the CHARITÉ Artificial Disc, such as: maintain motion of the spinal segment, restore proper disc height, maintain segmental stability, and re-establish lordotic angle and any personal goals you have.

Paragraph 3

- Point out that the CHARITÉ Artificial Disc has extensive clinical experience behind it, noting:
 - FDA approved the device in October, 2004
 - There is worldwide literature available on the device and disc arthroplasty
 - A large number of patients in the United States – approximately 4,000 as of February, 2006 – have already received the CHARITÉ Artificial Disc
 - The positive outcomes reported from the U.S. study that included a low complication rate and high patient satisfaction
- Mention that your doctor is well trained in this surgery
- Ask that the insurer reconsider the earlier decision and allow coverage for the CHARITÉ Artificial Disc for your case

Paragraph 4

- State that the manufacturer reports that a growing number of insurance companies are now developing medical policies favoring the use of total disc arthroplasty for the treatment of Degenerative Disc Disease (DDD)
- Thank the insurer for taking the time to review your letter
- Conclude by indicating that you look forward to hearing from the insurer by [date].
- Include your contact information

Sincerely,

[Your name]

[Your address, phone number and email address]

cc:

[Your doctor]

[Your employer]

[Your file]

Enclosures

- Copy of denial letter
- Medical records
- Supporting literature/articles
- [Include any other documentation you feel would be helpful to your case, such as
 - Health benefit information from your employer
 - Supporting letter from your employer]

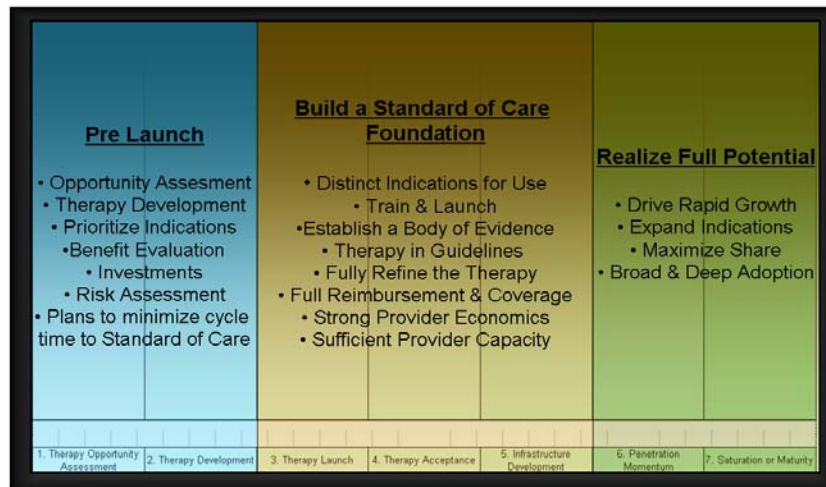
Source: *DePuy Spine*

Exhibit 13 – Post-launch positioning status

Value Proposition	Patient	Physician	Hospital	Payor
When the Charité is used instead of...	Modern Spinal Fusion			
I get...	<ul style="list-style-type: none"> Better outcomes (range of motion, mobility) Shorter recovery time 	<ul style="list-style-type: none"> Better outcomes in “right” patients only Higher prob of life-threatening “rescue” surgeries 	<ul style="list-style-type: none"> Reimb headaches 	<ul style="list-style-type: none"> Unclear outcomes Huge claims increase Pressure to reimburse new entrants
I give up...	<ul style="list-style-type: none"> Pain and aches Bone grafts 	<ul style="list-style-type: none"> Peace of mind Peace with administration 	<ul style="list-style-type: none"> Margin 	<ul style="list-style-type: none"> Profits
OVERALL ASSESSMENT	HIGHLY POSITIVE	NEUTRAL	HIGHLY NEGATIVE	HIGHLY NEGATIVE

Source: Team Analysis

Exhibit 14 – Patient Access Acceleration Matrix



Source: Scott Ward, Medtronic