



Covenant
Orthopaedic
Solutions

Future State of the Medical Device
Industry and the Continuum of Care

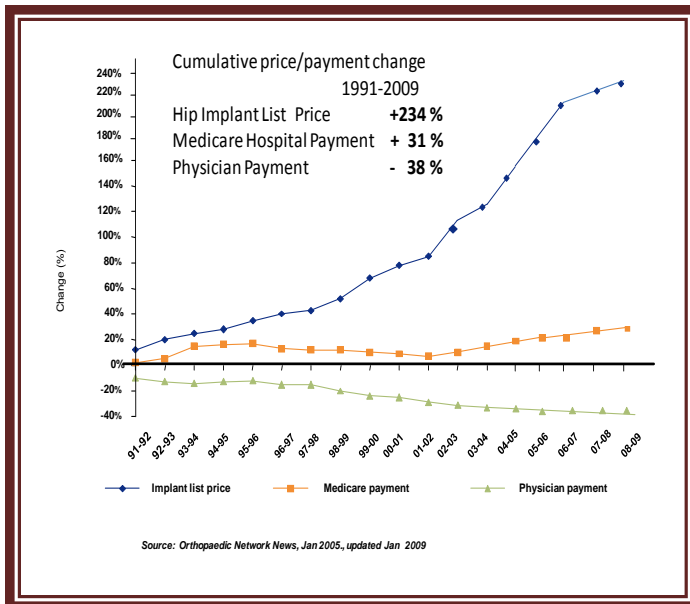
Executive Snap-Shot
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Executive Summary

The U.S. healthcare system is in the midst of a **crisis** and the U.S. public, government and businesses are seeking remedies rather than reasons. According to the 2009 Medicare/Medicaid Trustees Report, the US Medicare and Medicaid system will be out of money to fund the healthcare needs for the emerging baby-boom generation by 2017.

- Musculoskeletal disease of the knee and hip joints is one of the fastest growing orthopaedic problems within the U.S. population.
- In the U.S. today, the orthopaedic implant market is approximately a \$20 billion dollar industry and is dominated by 6 major device companies who control more than 90% of the market.
- The brand name device manufacturers have leveraged their market position **to steadily increase prices** while the U.S. government reimbursement rates have stagnated or declined. The average price increase for 2009 was 5.9%. The chart below, illustrates how the unfavorable gap between the Device manufacturers list price increases and the Medicare reimbursement rates have widened since 1991.



- As the product designs have matured, and the intellectual property protections have lapsed, the price increases realized by these device companies are without commensurate improvement in product and patient effectiveness.

Thus, many orthopaedic physicians today regard the current implant device technologies to be “generic” or “commodities” and are calling for change. Orthopaedic industry leaders such as Dr. John Cherf are saying...**“I think we’re going to enter a new era in which providers really focus on usability and cost of service...the reason is that there’s no good data to differentiate these products.”**

Given the healthcare crisis within the U.S. and the increasing cost of orthopaedic care, the Covenant plan to provide low-cost orthopaedic devices is a very attractive business model. Covenant’s products are high quality devices that are FDA approved and comparable to products offered by the ranking OEM’s.

Covenant has assembled an experienced team of industry professionals who have intimate knowledge of the sales and distribution channels, product designs, quality standards, and manufacturing operations. This inside knowledge of the industry is a strategic advantage that equips Covenant with the necessary credentials that physicians and hospitals require to service their needs. This expertise enables Covenant to provide unique solutions to this crisis within the orthopaedic device market.

Market Overview

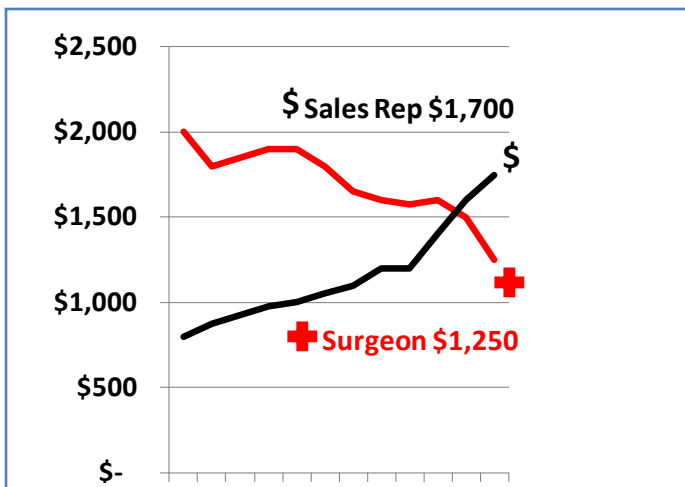
In 2012 the population over the age of 60 in the United States will exceed **61 million** individuals. Individuals over the age of **60** are the primary patients needing reconstructive products (Hips and Knees). For this reason the Orthopaedic Implant market is one of the fastest growing in the medical device industry.

- The U.S. Medical Device market was valued at approximately \$75 billion in 2008.
- Within the U. S. Device market, the U.S. Orthopaedic Implant market was valued at ~\$20 billion in 2008.
- U.S. Orthopaedic Implant market is estimated to exceed **\$23 billion in 2012**.
- Six major branded orthopaedic OEMs dominate over 90% of the market resulting in enormous and unjustified treatment costs.

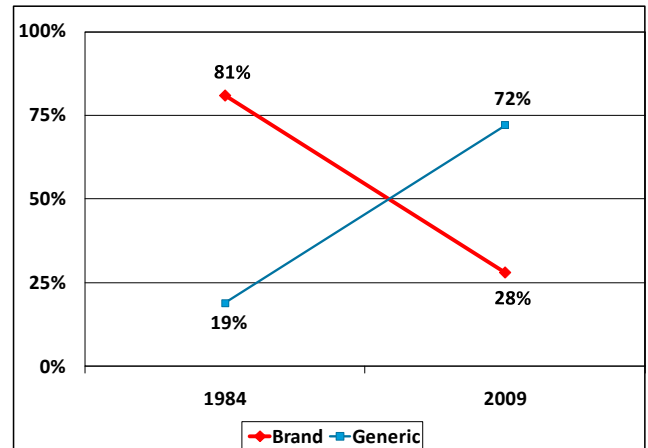
Covenant Orthopaedic Solutions, LLC, will focus on the Reconstructive and Trauma product segments.

Current Business Environment

- People over the age of 65 represent 60% of the 13 million people with osteoarthritis of the knee and hip.
- The number of people greater than 65 years of age is expected to grow from 41 million in 2010 to 61 million in 2025.
- Medicare and Medicaid account for approximately 57% of all hip and knee replacement reimbursements.
- Hospital profit margins have been squeezed by the disparity between the rising cost of implants and the government reimbursement rates.
 - From 1991 to 2009 the average price of a Hip implant device has grown at an average 6.9% CAGR, while the reimbursement rates to hospitals have risen by an average 1.5% CAGR.
- Economic inequality has frustrated physicians as commissions paid to implant sales people have increased while reimbursement payments to surgeons have declined.



- Healthcare reform is a government priority and focuses on reducing costs and continued reduction in government reimbursement.
- Since 1984 when the U.S. government passed the Hatch / Waxman Act the number of generic drug prescriptions as a percentage of all drug prescriptions written has increased from 19% in 1984 to **72% in 2009** and the % of brand name prescriptions written have decreased from 81% to 28%, respectively.



- In 2007, the Federal Department of Justice (DoJ) established a "Deferred Prosecution Agreement" with five major OEM's that imposed restrictions and guidelines regarding the appropriate consulting relationships between physicians and device manufacturers. This agreement was established after \$320M dollars in fines were levied against the OEM's for improper relationships with surgeons.

Business Opportunity / Thesis

- Healthcare consumers and government agencies are demanding lower cost products and procedures.
- The Brand name industry leaders in the US orthopaedic implant market have excessive cost and profit structures that are vulnerable to lower cost alternatives, like the generic drug industry:
 - For example, in 2007 the average cost of a generic prescription drug was 71% less than the average cost of a brand name prescription drug.
- No significant low cost producers compete in the US market for reconstructive or trauma orthopaedic implants.
- All of the industry leaders out-source a significant portion of their implant and instrument manufacturing to third party contract manufacturers.
- Doctors are key decision makers in choosing the implant brand that is used, and leading surgeons agree that reconstructive and trauma implants have become a commodity/generic technology.
- Majority of current reconstructive and trauma products are based upon designs over 20 years old and are without patent protection.

The Covenant Solution

Covenant Orthopaedic Solutions, LLC, will be the industry leader in providing high quality, high customer service and low cost orthopaedic implants and instrumentation. The Covenant business plan will:

- Emulate the **GENERIC PHARMACEUTICAL INDUSTRY** model in the Orthopaedic Implant Industry, Covenant will pass on to the customer the value of commodity pricing using FDA approved technology that is no longer patent protected.
 - Penetrate the market using third party manufacturing in the U.S., positioned as the **LOW COST** provider of **HIGH QUALITY ORTHOPAEDIC IMPLANTS**.
- Address industry criticism regarding **TRANSPARENCY**
 - Disclosing clinical outcomes of competing products to patients and physicians
 - For Example: establish a U.S. focused **CLINICAL REGISTRY (database)** that is similar to the European Registry.
- Be the **CUSTOMER FOCUSED** implant company meeting the needs of the patient, the clinical institution and surgeon by reducing market channel selling and distribution costs.
- Promote **PHYSICIAN LEADERSHIP** in the movement to value based orthopaedic care.

Covenant Management Advantage

Covenant has the depth of executive leadership in both domestic and international product design and manufacturing that uniquely equips them for this challenge. With 50+ years of device experience that ranges from QA/QC to market development, sales, and operations management, the management team is well positioned to take advantage of the current market conditions and execute the business plan necessary for this bold business start-up.

The Founder and President of Covenant was the President and Managing Director of Sandvik Medical Solutions. This global operating division was a \$100+ million dollar International medical device contract manufacturer. As President of Doncasters Medical Technologies, he restructured the division into a “pure play” medical business, growing sales revenue from \$30M to +\$100M, before orchestrating the sale of Doncaster’s Medical to Sandvik in 2007. Prior to joining Doncasters he was Group Director of global implant manufacturing for Smith &

Nephew. Mr. Birdsong held several executive management positions over his 21 year career with Smith & Nephew. During his extensive career Mr. Birdsong was a key leader in launching new products and improving operational performance. He led the implementation of innovative approaches to personnel motivation, performance measurement, and enhanced manufacturing processes.

The Senior VP of Product Development and Regulatory has served 5+ years as the Vice President of Design for a Spinal start-up company and has over 20 years of experience at a top 5 OEM. During his tenure at this OEM, he provided progressive leadership within trauma product development, and specialized in intellectual property rights (IPR) management and regulatory affairs.

The third member of the management team has extensive market and administration experience with Smith & Nephew and executive experience with a major hospital system.

The Customer Development and care team member is an executive with 20+ years of diverse healthcare experience including developing and implementing Sales and Customer service organizations. He is highly successful at working with market channels and partners.

The CFO is an accomplished executive with over 25 years of financial and operational experience in Fortune 500 and private equity owned businesses. He served as the CFO and COO for True Temper Sports, Inc., a \$100M manufacturer and distributor of golf equipment. He successfully organized and executed two separate private equity transactions. He also opened True Temper’s Greenfield operation in China. Prior to joining True Temper he held various financial roles with Emerson Electric Co.

The headquarters and operations will be located in the Memphis, TN area where four major OEM’s are located, thus enabling the group to attract additional industry related talent.