

ORTHOPAEDIC ENVIRONMENT

An Analysis Offered By
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EXECUTIVE SUMMARY

The orthopaedic industry has proven to be both a hallmark for quality of care, as served by technology, as well as an investment rich opportunity for those so inclined. As the industry morphs out of its early growth stage and begins to “butt-heads” with entitlement expectations of our society, orthopaedic manufacturers will need to carefully choose development strategies.

With demographics that no longer just focus on the over 65 population, procedural interventions have segmented into markets identified by treatment specialties, such as; joint reconstruction, fracture management (trauma), spine and arthroscopy (sports medicine) . . . as well as the supporting science and technology of biologics and computer assisted surgery.

Having built a \$30 billion worldwide market on metals and plastic, change is inevitable as the future evolves to an earlier disease state under orthobiologics and minimal invasive interventions. Along with the speed of development, another major barrier to earlier stage treatment resides with diagnostics – or identifying the disease as it develops. Future barriers are on the horizon for margin retention via pricing, and the ability to implement new technology will become more difficult with economic influences demanding cost profiling. Finally, we will witness the major manufacturers struggle with business as usual, as government monitors become disenchanted with industry/surgeon relations.

As with other industries, orthopaedics had its round of major consolidations with the J&J/DePuy, Stryker/Howmedica and Zimmer/Centerpulse acquisitions. I would even suggest that the industry has now fretted-out a manageable number of competing companies (*5 majors with >\$1B in revenue*) and future activities will be geared to bolt-on acquisitions supporting new technology and advancing science. Currently, go-forward strategies have embraced one of two paths; (1) acquire/develop a footprint within each submarket that positions a company in all segments of the industry and hopefully allows for a platform to leverage this exposure, such as; Stryker & Zimmer for large companies, and Exactech as a smaller company. The other go-forward strategy is (2) niching out a profitable segment or two where a company can apply marketing and share muscle to dominate a particular area, such as in the larger companies of; S&N (*recon & arthroscopy*), Synthes (*trauma & spine*) and Medtronic (*spine*), while smaller companies are represented by Tonier (*shoulder*), Arthrocare (*sports medicine*) and about 100 others.

The new landscape will be a challenge for those large companies like Zimmer, having an interest in most of the submarkets, but struggling to convert vision and strategy to implementation. Under new leadership, Zimmer will need to segment its offerings, rather than blend them, seeking national momentum through positive industry exposure, rather than bundling at the street. Zimmer may well be the best positioned company in orthopaedics but they will need to do a better job of getting out in-front of the industry and leading with their announced strategies.

A MARKET and COMPANY REVIEW

THE ORTHOPAEDIC MARKET

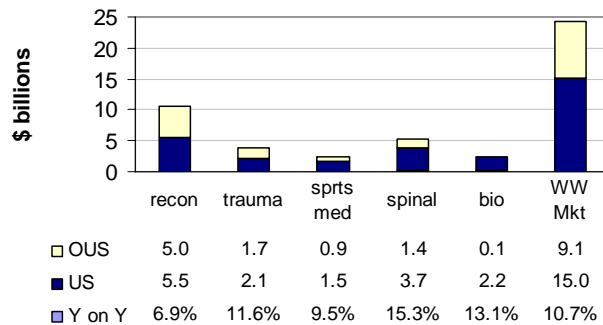
Any review of the orthopaedic market would require a baseline understanding from which to build on the information provided. Therefore I would offer the following PREMISE from which to begin:

- Lack of financial alignment within the Health Care System hinders collaboration among the stakeholders, while promoting price inelasticity.
- Stakeholders within this context include the following clinical and economic influences:
 - ✓ Orthopaedic surgeons – clinical
 - ✓ Hospital administration – economic
 - ✓ Government & following 3rd Party payers – economic
 - ✓ Mfg & selling channels - clinical
- The high profile expenses of medical devices & biologics continue to elude cost restructuring, nurture the rift between clinical and administrative functions, and increase the natural tension during the buying & selling process.
- Clinical liability and the entrepreneurial nature of the surgeon feeds the ongoing barriers existing between clinical and administrative factions.

Now on to orthopaedics . . . considered any musculoskeletal intervention as referenced to bone and soft tissue (*tendon & ligament*) repair . . . and in developed countries the primary cause of absence from work and the second most common reason for visiting a physician. Consuming an average of 3% of total gross domestic product in these countries, the treatment in the US alone approaches \$300 billion, and more than \$125 billion in developed countries outside the US.

Further to worldwide sales, 80% of total revenues are accounted for in US, Europe and Japan, even though these regions total less than 20% of the world's population. Absent from these figures are the peripheral products of power equipment, casting, soft goods, bracing gone growth stimulators, etc. as they account for less than 15% of the total revenues and a noticeably smaller margin.

2006 WW Ortho Mkt



A MARKET and COMPANY REVIEW

The largest five reconstructive device companies (*Zimmer, J&J/DePuy, Stryker, S&N and Biomet*) control more than 86% of total revenues for the past ten years with shares shifting one to the other based on introducing new technology, acquisitions or attracting competitive surgeons. **An interesting quirk is noted that three of these companies have their ww headquarters in Warsaw, IN)**

Demographics

Although devices manufacturers are most noted for their impact on reconstructive surgery (hips/knees), which are and have been the largest submarket of orthopaedics, it would be short sighted to focus only on this area. Clearly these companies and new entrants are segmenting their offerings based not just on low hanging profits, but on a compilation of demographics that go beyond the 65+ market.

Musculoskeletal Diagnoses Delineated By Age

	<u><25</u>	<u>25-44</u>	<u>45-64</u>	<u>65+</u>
Arthritis	2%	9%	33%	56%
Osteoporosis	0%	2%	22%	75%
Fractures	32%	19%	21%	29%
Back problems	9%	29%	35%	27%
Soft Tissue disorders	12%	24%	38%	26%
Dislocations	26%	26%	33%	15%
Sprains	32%	31%	24%	13%
Total Select Diagnoses	13%	23%	33%	31%

Exhibit 1
The Ortho FactBook 5th Edition

Obviously the aging world population is carrying the growth trends of traditional products, yet a review of the above problematic diagnoses opens up the market for those companies that are willing to diversify their offerings of orthopaedic interventions. Given the cost exposure of traditional hip and knee products, manufacturers are paying a great deal of attention to a vertical market exposure within the industry, as illustrated by joint replacements, which traditionally were focused on the 65+ group, now are carrying an array of products geared toward people over the age of 45.

Societal contributions to musculoskeletal interventions:

- the elderly (65+) expected to increase by three percent per year thru 2020
- increased physical activity of population at all ages
- increase in obesity (44% increase in number by 2015), identified as a major contributor to arthritis . . . with a 35% risk increase for every five kilograms of weight gain

A MARKET and COMPANY REVIEW

Submarkets

There are more than 150 diseases and conditions treated through the science of orthopaedics, with major categories of (1) joint replacement, (2) trauma, (3) arthroscopy, (4) spine and (5) peripheral markets. The latter is a compilation of new technologies, sciences and supporting products that are not only becoming financially visible, but “bell-weather” of future trends for the manufacturers.

Specialty products have evolved around the surgical techniques and innovative medicine taught within the orthopaedic environment. It is important to note that many of these areas are served by the same practitioner, most commonly in rural areas. However, in the larger markets (*SMSA's*) you will find surgeons with a focus in only one of these markets. In like manner, some companies have expanded, while others have focused their products only in; joint reconstruction, spine, arthroscopy (*sports medicine*), fracture management (*trauma*), orthobiologics, and more recently image guided surgery and robotics. Given the typical objective of ongoing growth and market/segment domination, a review of each area is pertinent to an understanding of a manufacturer's ability to leverage innovative technologies.

Reconstructive Surgery – *ww revenues of \$10.3 billion . . hips \$4.6 . . knees \$5.3 . . Shoulders \$0.4*

Supporting more than 2.3 million joint replacement procedures, this segment has long focused on hips (*initially*) and then knees (*a more complex procedure*) due to their large market potentials. As companies looked to “fill out their bags”, shoulder products were added, and subsequently small joints, including digits (*fingers & toes*), elbows, wrist, and ankles. On the clinical front, surgeons expanded their surgical treatments within joint reconstructive procedures, maturing to PRIMARY (*THA/TKA - total hip/knee arthroplasty*), PARTIAL (*part of the joint is replaced*) and REVISION (*17/20 yr life expectancy of procedure*). **Note: given the permutation of these products and the insatiable desire of the orthopaedic surgeon to customize his procedure, you may understand how the companies have been able to maintain margins through product evolution.**

Depending on disease state, bone density and new product technology, various approaches have been employed to support the refined needs of the patient . . .

cemented vs. cementless: *considers the use of polymethylmethacrylate (PMMA) to affix the implant versus porous coating to achieve a biological fixation, after several years of split preference . . . it appears the favored approach to bone healthy patients is cementless (60% share in US), with cemented used more for thin boned and revision cases*

resurfacing: *an effort to conserve bone during hip & knee arthroplasty has resulted in a procedural change for resecting a minimal amount of bone, such as removing just the surface of the femoral head in hip surgery, S&N's BHR product and Corin's Cormet (distributed by Stryker) are the only two currently approved in the US, with DePuy and Wright expected to enter the fray in 2008. Projections are now pegged at resurfacing representing up to 10% of the reconstructive market.*

A MARKET and COMPANY REVIEW

minimum invasive surgery (MIS): *more accurately refers to as less invasive . . . this approach intuitively refers to a smaller incision (2" - 5" vs. 8" or more) and has involved the use of refined instruments implanting standard constructs with minimal soft tissue disruption. Highly touted by Zimmer a couple of years back, this approach is now supported by all companies and although considered marketing hype by insiders, noted in 2006 are the 5,000 surgeons trained in this procedure and 7,000 instrument sets distributed. Note: look for a new line of implants specifically developed for MIS that will accommodate smaller portals, possibly assembled inside the body from modular components*

Industry material and designs have standardized with noted metallurgy exceptions used by companies to differentiate their quality and therefore pricing:

metal: titanium, cobalt chrome and stainless steel alloys are considered standard, with the exceptions:

S&N – Oxinium Zimmer's – Trabecular Biomet - Regenerex

ceramic: the smoothness of this material has led to a combination bearing with components use in combination with metal constructs, and as a coating that bonds to metal. Standard ceramic products:

Wright – Lineage Ceramic Exactech – Novation Ceramic AHS

plastic: traditionally the weakest component of the construct, ultra high molecular weight polyethylene (UHMWPE) now undergoes cross-linking via radiation with recent innovations noted:

Biomet's E-poly Liners Mako – Material X

design: innovative designs have also contributed to longer lasting implants in a younger more active patient population.

metal-on-metal (MoM): *utilizing new polishing techniques, now considered to promote less wear debris (osteolysis) and are now being combined with large headed systems*

DePuy – ULTAMET Zimmer – Metasul technology

ceramic-on-ceramic (CoC): *ceramic is considered a smoother surface and all companies are offering femoral heads for their metal systems*

Wright – Lineage Stryker – Trident System

mobile bearing knees (MBK): *to accommodate a wider range of motion, the femoral condyls rest on rotating platform or movable bearing that articulates with a twisting motion*

DePuy – LCS Zimmer – NextGen LCS-Flex

large diameter heads: *promoted to increase range of motion and lower risk of postoperative dislocation, most companies have added this to an ever expanding line of options*

DePuy – ASR-XL Wright – BFH technology Biomet – M2a-Magnum

resurfacing products: *more recent FDA approvals have been given to a bone conservation design that integrates the implant to healthy bone rather than press fitting them into the bone*

S&N – Birmingham Stryker - Cormet

gender specific: *Zimmer was first with their knee (GSK) and now developing a hip and ethic variations . . . although most companies (and industry gurus) considered this to be mostly marketing hype, Stryker has recently announced their first knee offering. On a similar path is Wright's tapered design (Advance Stature) to fit a smaller skeletal frame*

Note: almost all companies are at one stage or another of testing new material and approaches that are intended to establish "niche market ownership". Additionally this is a lucrative arena for new entrants to gain visibility and/or obtain early royalties from established distribution structures.

A MARKET and COMPANY REVIEW

A pictorial view of the constructs used in reconstructive joint surgery

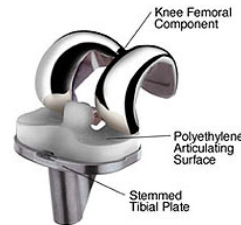
TOTAL HIP CONSTRUCT

- metal femoral stem
- metal femoral neck
- femoral ball (modular)
- plastic liner
- acetabular cup (metal shell)



TOTAL KNEE CONSTRUCT

- metal femoral stem
- metal tibial plate
- plastic liner
- plastic patella (if needed)
not shown



SHOULDER CONSTRUCT

- metal humeral stem
- humeral head
- plastic liner



Spinal Instrumentation *ww revenues of \$5.0 billion in . . . instrumentation . . . implants . . . biologics*

Back pain accounts for more hospitalizations than any other musculoskeletal condition, and is most often attributed to work-related disabilities. Some interesting figures in this arena involve; 1% of the US populations is chronically disabled because of back pain, and in some parts of Europe, 80% of workers suffer from back pain, while two in three Canadians will have at least one episode of back pain in their lifetime. Worldwide procedure volumes exceeded three million in 2006 and include fusion, discectomy, disc replacement, vertebroplasty/kyphoplasty and fracture repair. 2006 revenue saw a 15% increase in spine products (*excluding biologics*) exceeding \$5 billion.

A MARKET and COMPANY REVIEW



Outside of biologics, this is the fastest growing segment within orthopaedics, and the top four companies; Medtronic, J&J/DePuy, Synthes and Stryker, control 77% of 2006 sales. However interesting to note this share was down two percentage points year on year, as new entrants (*now totaling more than 100*) entered with differentiated or niche products.

The spinal column (*consisting of vertebrae*) is divided in three regions; cervical (*7 vertebrae*), thoracic (*12 vertebrae*) and lumbar (*5 vertebrae*). Discs act as shock absorbers a tough, outer layer (*annulus*) that ligaments attached to the vertebrae (*also called a slipped or ruptured*) disc the annulus, into the spinal canal through a tear or rupture and subsequently causes pain by pushing on the spinal nerve cord.



Located between each of the vertebrae in the spinal for the spinal bones. The discs are round and flat, with surrounds a jellylike material called the nucleus. Thick holding the pulpy disc material in place. A herniated is a fragment of the disc nucleus which is pushed out of

Given the high instance of disc repair, spinal fusion is/was the “gold standard” for procedurally relieving this back pain. It is worth noting that 75% of all spinal fusion is performed on people under the age of 65. Fusion is obtained by removing the disc and implanting a metal plate & screws for cervical applications and a hook and ladder system for lumbar applications. With this rigidity, metal cages (*packed with bone growth material*) are inserted between the facets as a platform for solid bone growth. The cages have been giving way to PEEK or other polymer spacers (*with radiolucency allowing an X-ray view of the fusion*) fulfilling the same purpose. Understandably fusion leads to some loss of motion depending on the vertebrae being fused.

With obvious negative factors connected with fusion surgery, most spine companies have targeted motion preserving technologies like artificial discs, nucleus replacement, dynamic stabilization, etc. Instead of removing the disc, these initiatives look to  replace it with a device that recreates the original movement from the natural disc. There are a couple of FDA approved lumbar products (*J&J/DePuy in 2004 and Synthes in 2006*) and a recently approved  cervical product by Medtronic. Anticipating heavy demand for this technology, these three have already implemented clinicals in the other regions and are joined by other companies with European and US trials, including; Abbott, Biomet, Orthofix, Globus, LDR, NuVasive, Scient’x, Stryker, Zimmer and others. **Note: you probably are noticing the similar growth cycle as experienced with joint reconstruction.**

Besides disc replacement, other non-fusion technology such as dynamic stabilization is clearly trending toward capturing a large share of the fusion procedures, with two of the more exciting technologies developed and currently marketed by Kyphon and St Francis Medical. Kyphoplasty is a term for Kyphon’s procedure of restoring the height within the spine bone and filling the void with cement. St. Francis created the X Stop which is a minimal invasive placement between the spinous process to restore height. These processes have been well supported by reimbursement, further contributing to their economic acceptance in the marketplace. **Note: at the end of 2006, Kyphon acquired St Francis for \$525+ million, and additional revenue based contingent payout of \$200 million . . . on less than \$100M in sales. Then last summer, Medtronic purchased Kyphon for \$3.9 billion on projected 2007 revenue of ~\$600 million. A clear indication of trending technology by the industry leader – Medtronic?**

A MARKET and COMPANY REVIEW

Sequence of clinical techniques:

1. *internal fixation - using either an anterior, posterior or lateral approach based on implants position to affix one vertebrae to another*
2. *biologic supplement - fusion was reinforced through cages, spacers, wedges and other devices that could carrying scaffolding products (BMP) to encourage bone growth*
3. *discectomy – removing or trimming a bulging disc so not to impinge on the spinal nerve*
4. *motion restoration – a movement to move away from affixing the vertebrae, and allow natural motion by implanting a moveable device*
5. *other non-fusion approaches -*
 - ✓ *facet arthroplasty is a device that affixes to the pedicle, replacing the facet yet restoring the motion normally allowed from the fact joint*
 - ✓ *nucleus replacement is a device filled with a gel, polyurethane or a matrix that polymerizes in situ, simulates the support structure of a disc*
 - ✓ *dynamic stabilization refers to innovative devices or techniques that are pedicle screw-based or interspinous that offer an alternative to spinal fusion by providing stability to affected spine segments but also motion and flexibility*



Sequence of technology:

- 1a *traditional products incorporate metal device hooks, supporting rods that affix one vertebrae to another*
- 2a *a variety of metal, PEEK polymer and resorbable materials were created to maintain height and carry collagen or other carriers that stimulated bone cell growth for rigidity*
- 3a *initial products that mechanically removed the disc, have given way to newer technologies in thermal energy (RF) ablation, with the newest identified as ArthroCare's Coblation (ablation without the heat)*
- 4a *moveable artificial disks were developed that affix to the end plates of the vertebrae and recreate similar motion to original construct*
- 5a *as noted above, a couple of the more exciting innovations have recently been purchased by Medtronic*
 - kyphoplasty – where orthopaedic balloons are used to lift the fractured bone and return it to the correct position, whereas the remaining cavity is filled with cement.*
 - Interspinous Process Decompression (IPD[®]) System – providing an interspinous process device placed minimally invasively between the spinous process of the vertebrae*

Note: this market is wide open for new technology as we find innovative ways to solve back pain. Characteristics of the spinal market appear to mirror the “wild & wooly” days of joint reconstruction, where there wasn't a lot of proof in the efficacy of products, rather if it was different (*perceived innovative*) and a logical approach, it was implemented. I would also speculate that the specialties for this area will become further blurred as the ortho spine docs perform MIS procedures and the neurological docs deal more in neuro wrap treatments.

A MARKET and COMPANY REVIEW

Arthroscopy *ww revenue of \$2.5 billion for equipment implants biologics*

Arthroscopy refers to the use of keyhole techniques for visualization, diagnosis and treatment of joint disorders . . . accurately considered as **minimal invasive surgery**. Not to be confused with the MIS techniques marketed by Zimmer (*see above in Recon section*), you will find 47% of US orthopaedic surgeons specialize in arthroscopy. Typically these procedures involve soft tissue repair, such as rotator cuff (*shoulder*), meniscectomies (*knee*), achilles tendon (*foot*), carpal tunnel (*hand*) and reattachment of ligaments & tendons (*all joints*).

Along with keyhole repair . . . mini-open and open surgery accounted for 15 million procedures in 2006, representing a 10% increase to \$2.5 billion in product revenue. Further analysis shows more than 3 million arthroscopic (*MIS*) procedures in the US alone and 2 million of these focused on the knee. The five largest companies in this orthopaedic submarket are; S&N, Stryker, Johnson & Johnson, ConMed (*Linvatec*) and Arthrex, which together capture more than 70% of the 2006 global arthroscopy/soft tissue repair sales. Their products include; scopes, cameras, instruments, soft tissue implants and repair kits. There are three major product categories to offer; arthroscopy equipment (*typically a capital expenditure*), soft tissue fixation and artificial ligament/tendon scaffolding. **Note: as of early 2007, none of the companies (*big or small*) that participated in this arena, carry a recognizable offering in all three categories . . . i.e. the top tier companies, S&N, Stryker and ConMed do not have a biologic portfolio, while and J&J/DePuy (Mitex) and Biomet offerings do not include the visualization and repair equipment**

Products –

arthroscopic equipment: *rigid scopes, cameras, image storage devices, fluid management, insufflators, power shavers, monitors, ,*



soft tissue repair: *suturing devices and anchors, handheld instruments, metal and resorbable tissue attachments (implants), plus innovative approaches to securing and/or tying sutures. Material used for metal fixation is generally titanium, while resorbable materials are variations of polymers with calcium carbonate and hydroxylapatite. Projections are, the resorbable products in sports medicine applications are use in more than half of all potential procedures.*



A MARKET and COMPANY REVIEW

tissue scaffolding: autographs, allographs, BMP, xenographs,



technology –

- Equipment to repair soft tissue involves either the mechanical resecting or the electro-surgical (*thermal energy via radio frequency*) to dissolve and remove bone and/or tissue. S&N, Stryker and Linvatec dominate the older mechanical resection market, while the RF subsegment include; ArthroCare, ConMed, Mitek S&N and Stryker. Newer technology includes ArthroCare's Coblation (lower temperature) and HydroCision's ultrahigh-pressure fluidjet technology.
- Visualization equipment for arthroscopy involves a "rigid" scope with an array of cameras, image capture & storage capabilities, and supporting equipment (*fluid management, insufflators, monitors, etc.*). Advance development is concern mostly in the software capabilities (i.e. high definition) or ability to integrate in future "state-of-the-art" operating rooms, such as Stryker's and S&N's offerings for a digital OR.
- Most of the technology in this market directed at affixing soft tissue is performed through metal, resorbable screws, or staples
- Biomaterials are the newest and fastest growing segment of orthopaedics with new applications announced every Quarter. Initially used as an acellular scaffold to encourage localized cellular growth, there is a great deal of work being done on importing bone and tissue cells within a protein matrix directed at speeding up the healing process.

Note: the clinical lines between Reconstructive surgery and Arthroscopic surgery become blurred as rural surgeons (*due to patient access*) are trained in both areas of treatment. As techniques in Recon further "less invasion" and products more modular and image guidance takes root . . . we may see the definition of these two specialties start to evaporate, as orthopaedics specialties trend toward earlier stage treatments under minimally invasive interventions.

A MARKET and COMPANY REVIEW

Fracture Management *ww revenues of \$3.8 billion in; . . . plates & screws. . . . fixators . . . BGS*

The continued aging of our population, characterized by osteoporosis (*decreased bone mass that increases susceptibility to fracture*) offers the projection of an average two fractures will incur in the lifetime of the more than six billion people worldwide . . . further extrapolated to over 50 million fractures each year, occurring for the most part to people under age 65. These events require medical treatment via the manipulation of the fractured bone such that it is returned to its proper position and alignment, in some cases non-surgically. The **non-surgical** application entails “bone growth stimulation (BGS)” supported by various technologies (*ultrasound, pulsed electromagnetic fields, etc.*) with global revenues of \$440 million, mostly in the US.

Surgical interventions are provided externally (*fixators*), or internally (*plates, screws, pins, wires, staples & intramedullary nails (IM)*) with \$3.3 billion in 2006 worldwide revenues contributing a 12% growth. Synthes is the dominant player with ~2.5 times the revenue of the next largest player, with the five largest companies (*Synthes, Stryker, S&N, J&J/DePuy and Zimmer*) controlling 77% of the total market. All five of the leading recon companies have products in this submarket, and their revenue ranges from \$624M for Stryker, to Biomet’s \$127M.

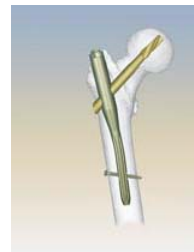
Product innovation has emerged from improvements to traditional products, as well as adaptations from products in other submarkets. An example of this is the *locking plate*, developed for cervical spine technology, and designed to prevent screw back-out. This product is now accountable for more than 60% of all plate and screw sales. Also sharing from design cross-over are intramedullary nails, small tubes that position broken bones from the inside of the bone structure.



EXTERNAL PRODUCTS - consisting of a rigid fixation scaffold that stabilize long bone breaks



INTERNAL PRODUCTS - consisting of plates & screws, intramedullary nails and a host of other products



A MARKET and COMPANY REVIEW

BONE GROWTH STIMULATORS - electrical or ultrasound stimulus to promote growth of bone cells



Note: companies with both recon and fracture management products have traditionally had trouble leveraging sales exposure, mostly due to average dollar sale and service support differences. Consequently I am not aware of a company that has capitalized on existing sales efforts, with the most recent example being Orthofix's acquisition of Blackstone Medical and subsequent product integration.

Peripheral Markets

There are specialized industries growing up around orthopaedics that are worth mentioning, not just from their quality of care impact, but also from their "bell-weather" position as indicators for future trends. Representing incremental improvements in the quality of care, these niches have emerged with new technologies supported by claims of better efficacy and faster recovery periods.

Orthobiologics - with noted double reporting in the spine submarket, ww revenue of ~\$4.0 billion is projected for this emerging market. As a subset of a much broader biologic science, orthobiologics refers to products that incorporate biology and/or biochemistry for the repair, replacement or regeneration of musculoskeletal structures, and include bone & soft tissue substitutes, allograft bone/tissue, tissue-engineered substances, growth factors/bone proteins, stem cells, etc. Given the broad definition of this category (from acellular implants to therapeutics focused on regenerative medicine), projected 2006 year on year growth of 13.5% is projected. The best evaluation I have seen considers three broad segments:

biomaterials projected at \$900+ million and focused on inorganic materials designed as structural scaffold or resorbable material. Products include bone cement, bone substitutes and embolic agents. Bone cement (roughly \$350M) has been considered under my Recon projections, and the synthetic material is mainly focused within the spine market.

protein therapeutics are amino acid-based molecules intended to react with the body's natural metabolism, promoting an intended cell signal that will ultimately involve some reaction to treat, stabilize or reverse a disease state. This market is about \$2.6 billion including viscoelastics, bone growth/healing factors and surgical hemostats. Viscoelastics are commercially used in "joint fluid therapy" with the lead product being Genzyme's Synvisc. Of the major orthopaedic companies, only S&N has a product offering (Supartz) in this field. Under bone growth/healing factors, the two most notable products are bone morphogenic protein (BMP) with Medtronic's Infuse (considered a blockbuster product as it approaches \$1B in sales) and the more recently approved Stryker's OP-1.

A MARKET and COMPANY REVIEW

Tissue-derived interventions are generated from biological structures such as human cadavers, animal tissue, or cell cultures from living donors and can be further classified as (1) sterilized tissue implants and (2) cell based therapeutics. With over \$1 billion in 2006 revenues these interventions include products like; machined bone, demineralized bone matrices (DBM), allograft bone and cell therapeutics. Sterilized tissue implants are currently in the “bags” of many orthopaedic companies as they look to fill-out their offering, resulting in a commodity level of margin for these products. The market for cell therapeutics includes platelet-rich plasma products also carried by a number of the orthopaedic companies. Further noted are a considerable number of focused players in this segment, mostly start-ups or early staged . . . as investors have been only too eager to support the next great “blockbuster”.

Note: the commercialization of these products have targeted on the spinal market, leaving those orthopaedic companies not heavily involved in spine (S&N, Biomet, and to a smaller extent Stryker) lagging in leverage from this emerging market.

Image Guided Surgery (IGS) – *I have broken out IGS from CAS to distinguish the evolution of this technology, via computed tomography, magnetic resonance, fluoroscopy, etc. In 2006 IGS was used in 10% of joint replacement procedures in Europe, with the highest penetration in Germany. This technology originally developed in the area of neurosurgery, soon expanded to the spine, and with a focus on MIS, is gaining momentum within the orthopaedic submarkets. Imitated as a preoperative surgical planning, templating and visualization software, navigation is now offered by a number of companies, lead by Medtronic Navigation and BrainLAB with 2,000 and 2,500 systems respectively installed in more than 65 countries. These software companies have collaborated with all of the major Recon companies providing them little advantage in the marketplace. Noted, is Zimmer’s recent acquisition of OrthoSoft, which undoubtedly will phase out of OrthoSoft’s relationship with 9 orthopaedic manufacturers.*

Computer Assisted Surgery (CAS) and Robotics - *most of the spin in this arena combines the area of CAS and Robotics, although in my mind there is a clear distinction in the amount of “assistance” provided through Robotics. Simply put, most of the current offering deal with instrument or implant alignment with the surgeon still providing the physical cutting and reaming. Notable exceptions are; MAKO Surgical which preoperatively plans, sizes, aligns components and then sculpts the bone according to virtual, volumetric templates through physician interaction (Haptic Guidance System (HGS)). This system is only FDA approved for uni knee procedures. Additionally Acrobot (development for Corin’s resurface hip) and Curexo Medical (open platform for hips & knees) have robotic cutting and reaming, but not FDA approved for the US. Note: I would be remiss in not mentioning Intuitive Surgical’s da Vinci System, which although not currently in the orthopaedic space, is the recognized leader in surgical robotics. With over 700 systems in place within the US, they are valued at 73 times 2008 earnings. Clearly their visibility and financial attraction will have continual impact for orthopaedic applications. The issue with adoption will be centered on a cost-benefit ratio for the hospitals.*

A MARKET and COMPANY REVIEW

OEM Suppliers – *supplying forging, casting, polishing, coating, machining, packaging, sterilizing, etc. for the orthopaedic manufacturers. Hundreds of companies provide products and services for the orthopaedic manufacturers, considered a \$2 billion market. Given their “upstream” services for implants and instrumentation, this market is a clear indicator of quarterly trends. There has been a great deal of industry consolidation during recent years as suppliers look to strategic acquisitions to leverage various positions with the orthopaedic manufacturers. The “bell-weather companies” to keep an eye on are; Symmetry, Acellent, and Paragon, with the new possibility of GreatBatch, the recent acquirer of Precimed.*

Note: the movement by suppliers and manufacturers alike, to locating production facilities to Ireland, Asia, Malaysia, China, Costa Rica and Mexico. Further highlighting the manufacturer’s exodus is the recent acquisition by Symmetry of DePuy’s manufacturing facility in New Bedford, MA. Additionally, S&N has announced the relocation of its Wound product production to China on the heels of the Endoscopy Division’s outsourcing their resection manufacturing and subsequent shut down of the Andover, MA facility.

Market Share and Size

2006 Worldwide Orthopaedic Market

(\$millions)

	<u>Recon</u>	<u>Fracture</u>	<u>Spt Med</u>	<u>Spine</u>	<u>Other</u>	<u>Total</u>
Aesculap	182	61	11	101	109	464
Biomet	1,096	127	57	105	404	1,789
DJO	0	0	0	0	413	413
J&J/DePuy	2,261	203	329	754	274	3,821
MDT/Kyphon/St Fran	0	0	0	2,139	869	3,008
Orthofix/Blackstone	0	96	79	145	0	320
S&N	1,183	331	519	27	176	2,236
Stryker	1,928	624	359	367	1,036	4,314
Synthes	0	1,575	0	607	210	2,392
Zimmer	<u>2,685</u>	<u>195</u>	<u>19</u>	<u>177</u>	<u>240</u>	<u>3,316</u>
<i>Total Top Ten</i>	<u>9,335</u>	<u>3,212</u>	<u>1,373</u>	<u>4,422</u>	<u>3,731</u>	<u>22,073</u>
<i>Total Others</i>	<u>1,199</u>	<u>574</u>	<u>1,024</u>	<u>619</u>	<u>3,431</u>	<u>6,847</u>
TOTAL MARKET	10,534	3,786	2,397	5,041	7,162	28,920

Pricing

First of all we should dispel any confusion between catalog list price (*typically highlighted by the economic buyer*) and selling price (*typically highlighted by the manufacturer*), along with strategy positioning of the major companies, versus those of secondary or niche companies. First of all let’s discuss what drops to the bottom line, with consideration to three factors; (1) volume, (2) price and (3) mix. The orthopaedic industry has been remarkable in its ability to maintain margins vis a vis the latter two. As recently as 15 years ago, little discounting was provided on implantable orthopaedic devices, and those given were masked by acknowledging previous years’ list price.

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As implants emerged on the radar screen of health care purchasing manager, discounting was slow to evolve due to the physician preference nature of the device, relations established between surgeons and manufacturers, and the fragmentation inherent in health care between the economic and clinical stakeholders. Over succeeding years, the manufacturers were able to significantly increase their year on year pricing to offset any discounts provided, while taking advantage of mix conversions to newer platform technologies . . . most notably; cementless fixation, advancement in metallurgy, combination products (*MoM, CoC, CoM, etc.*), minimal invasive instrumentation and biologics. Realizing that 78% to 85% gross margin was the norm just a decade ago, it is understandable that this margin as been maintained even though discounting is now approaching 40% - 45%.

Also of importance is the interest of the economic buyer to keep these products on the “radar screen”. There is a continual balance by the economic buyers of hospital margins and the administrative tension residing in their clinical relations. In recent years, CMS as announce yearly payment increases that have been favorable for orthopaedic products. This coupled with lower price increases from manufactures, has diverted some of the attention for lower prices. That said . . . the following factors are indicators of margin retention strategies from the manufacturers:

- *introduction of replacement products carrying incremental changes – mix change*
- *extent of product line extensions – mix change*
- *new technology launched with reimbursement support – financial benefit*
- *economic credentialing of new products – productivity benefit*
- *products targeting CMS reimbursement trends (i.e. severity weighting) – cost partnership*
- *heavily marketed clinical differentiation – quality of care benefit*

Channel Influences

Economic - *who makes the decision to buy/use a particular product and for what price? The answer lies within two types of individuals . . . the clinician (surgeon) and the economic buyer (for the most part, hospital purchasing). Historically the physician has made product decision and the hospital has applied its business prowess to achieve a fair price. As hospital procedure margins narrowed, purchasing has been charged to pursue more aggressive means in reducing supply costs (implants) . . . short of alienating staff surgeons.*

Hospital – obviously the hospital is working under operating margins that are too thin to ignore product supplies that absorb up to 50% of their procedure reimbursement. Look for purchasing departments to continue pressing for incremental reductions in their supply cost ratio to reimbursement, while underneath the radar.

IDN – an underlying premise to the consolidation of Health Systems is to advantage volume and exposure. Unfortunately this has not proven out with physician preference products and in fact, the larger the System, the more remote their influence over the surgeon. A much more effective model would be to pursue a contract or employer relation with the surgeons, such as a Kaiser or Mayo, or even Henry Ford.

GPO – historically physician preference contracting has not been successful due to the lack of influence exerted by the economic buyers on the surgeons. The GPO model works best with commodity products where price/volume is realized on both sides.

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Payer – the payer is the one entity that already has the capability to move market share based on their financial position with all stakeholders. Using a script type model, the payer could develop a contracting process that would reward standardization. **Note: I have worked with a national health plan considering putting together a contracting model for three of the stakeholders (hospital, surgeon & manufacturer) that promotes market share for reduced pricing. This effort was dropped in later stages and from my vantage point due to visibility issues and trade-offs of administrative risks with limited financial upside. The truth be known, I believe the visibility of their given their current profit structure had something to do with it as well.**

Distribution - *the “skill based” technology of orthopaedics has established the local sales force (referred to as a distributor agent) in a position of building long term relations with the surgeons. Although much has been said regarding the manufacturer’s financial ties with the surgeon the reality is there is a far more prevalent social relationship with the local distributor. So much so that it is widely understood when distributors change manufacturers, so do many of their surgeons. The independent nature of the sales force within joint reconstruction, (which by the way is shared with the independent nature of the orthopaedic surgeon), has always been problematic for companies to control sales practices and policies.*

Despite this relationship, when it comes to clinical issues, it is also widely accepted that it is not the sales force that carries a new concept banner, but rather a surgeon, for “surgeons will listen to surgeons”. This has promoted the historical use of training “get-aways” which are now on everyone’s radar screen.

On a final note: the larger companies venturing into the spinal market have attempted to use W-2 sales forces for better control, but have not seen the relational value from this strategy, leaving the industry with a hybrid of independent and employee sales management organizations.

Government Oversight - *the Department of Justice has recently negotiated settlements with the top five orthopaedic manufactures that resulted in \$311 million in settlement. With less than 2% of yearly revenue (the companies paid consultants an avg 1.4% of total revenue) one might considered this “chump change” amounting to little more than a slap on the hand. However, more concern should be regarded to the process and transparencies of the settlement. The Deferred Prosecution Agreements (DPA’s) require the firms to publish lists of their consultants and how much they are paid. Additionally companies are limited to a \$500/hr rate which could be problematic for some surgeon contracts. Hardly has the ink dried on this settlement, than the DOJ has again subpoenaed many of the top companies for information regarding surgeon relations outside of the US. Further, the DOJ has duplicated their subpoena activity with second level companies (i.e. Wright and Exactech) for information on their US surgeon relations.*

An issue that has been kicked around for a couple of years is “gainsharing” which has only been implemented for cardiology procedures. Gainsharing is sharing the cost savings from a standardization process, with the clinical decision maker. It is interesting to note that the DOJ has stated this concept violates Stark II laws, yet they are willing to ignore this under certain indications. Last year, HCA tried to obtain approval for orthopaedic products within its hospitals, but was denied. Never the less, its success in cardiology has encouraged hospital administration to pursue venues for many surgical interventions.

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Prediction of Future Market Strategies

Products –

Over all new products will be developed around minimal invasive procedures. In Recon this could lead to more modularity, with motion restoration a key ingredient and shoring up the weakest component of the construct (i.e. poly inserts for large joints). Therefore look for resorbable or easily removed implants for fracture management and motion restoration & cell based solutions for spine.

Gender specific strategies are being heavily marketed without concrete results. Given the fact that Stryker has announced its line of gender implants, without concrete value placed on Zimmer's two year old strategy would indicate a following effort. Also DePuy has just announced a design series for implants for India (ethnic based) that furthers a "me-too" acceptance by peers.

Procedures –

Procedures in all components are moving toward minimal invasive. This will be supported by robotics as the next offshoot of IGS systems. Look in 2008 for new FDA approvals for CAS and Robotic systems that further encourage new product development.

Orthobiologics is gaining momentum, notably without much by way of human trials. Both soft tissue repair and bone regeneration are targeted with scaffolds and protein enhancers and it is clear that cell & tissue regeneration is the way of the future. This should lead to a whole new bevy of carriers and instruments.

Pricing –

There will be continued price pressure from an industry where reimbursement is being redefined on a cost basis. Manufacturers will seek more comprehensive value added strategies to deflect price pressures, such as Zimmer's formulation of The Hospital Productivity Group.

The mix cycle has worked for the past 15 years and I see no reason for the manufacturers to move away from this strategy . . . therefore look for more product replacements and line extensions to create price disparity in products in the near term.

Government Intervention –

I have never been a big fan of gainsharing, as approved for cardiology. However, it appears the government is supportive for a better vehicle to tie together the financial interest of the hospitals and physicians. The next couple of years should see something similar to this approach, but less intensively administered and with better incentives.

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CMS has ruled for a 10.1% reduction in physician payments for 2008, however the drill down payments for orthopods will more likely be a 11.1% reduction for medicare payments with private carriers expected to follow suit. This continues ongoing statutory reductions of physician payments since 2002. Note: I have not heard whether or not Congress rescinded the ruling scheduled for hearing by year-end 2007.

The DOJ saga has not ended, but only started with subpoenas now submitted to second tier companies requesting details on their US surgeon relations. A number of the first tier companies, after settling with the DOJ, are now going through another round of investigations on their physician relationships outside of the US. The DOJ has clearly indicated they are going to send a message (control) to medical device companies.

Currently there is a Transparency Bill (S2221) before congress that will require medical device firms to report average and median prices of implantable devices to the government on a quarterly basis beginning January 1, 2009. This represents a significant risk and would clearly rekindle price pressure from the economic buyer if enacted.

Distribution Channels –

We have seen a gradual reduction in the importance of the sales agent's relationship with the surgeon. Notwithstanding last year's notoriety of Zimmer pirating agent distributors from both Biomet and DePuy (Biomet has filed suit against Zimmer), the industry continues to question the value of these relations given price pressure and access requirements for physician preference products.

As the older "mavericks" begin to retire and the "young bloods" begin to exercise their economic credentials, future distribution models will start transition to a W-2 platform and broader selling skills will be pursued beyond relation building.

During the past 15 years, both DePuy and Zimmer have tried to transition their sales forces to employed representatives with the result in both cases being a W-2 management structure. Although touted as premature, I would suggest it was evolutionary as the industry balances relational influence offset by economic impact.

Market Strategies –

Companies will continue to consolidate, looking to gain niche or technology positions by leveraging bolt-on acquisitions, as witnessed by Medtronic's acquisition of Kyphoplasty & X Stop and Orthofix's acquisition of Blackstone. Additionally look for better economic credentialing of new products as the larger companies counter lower prices from smaller competitors and are pressed by surgeons to help them cost justify their product usage.

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It has not been clear if the Direct-To-Consumer advertising has been effective, although the largest recon firms have invested in this strategy. However with surgeon relations strained from the recent DOJ requirements to publish financial relations, a DTC strategy could supplement local marketing efforts of surgeons and rebuild their loyalties.

It appears Orthopaedic companies will take a stronger position in the future toward conducting studies for biologic research in two major areas; (1) bone growth, and (2) tissue regeneration. Companies will look to products from these sciences to prop up falling margins. Additionally, combined products (drug & biologic combinations with metal & plastics) are being highlighted in most of the surgeon forums as manufacturers look to partner with start-ups having this focus.

The advancement of Image Guidance Surgery (IGS) along with robotics will narrow the perception of product differences and surgeon skill levels. Probably the biggest threat to orthopaedic companies comes from this area and some of them (Zimmer with OrthoSoft & Brigit and Stryker with eTrauma) are getting “out in front” of this movement through acquisitions.

*The Orthopaedic specialties of **Arthroscopy** and **Reconstructive Joints** will continue to come closer together through the focus of minimal invasive surgery . . . either by procedure, robotics, redesigned implants, orthobiologics . . . or all the above. Logically this would lead one to believe that those companies that have a foot in both camps are well positioned to leverage that kind of exposure.*

As of now, I have not seen this advantage being exploited by those companies that focus in both arenas (S&N and Stryker) either through lack of vision . . . lack of management skill . . . or, as of yet there has not been a compelling need. However, look to the horizon for strategic changes in leveraging this advantage.

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ZIMMER - A COMPANY VIEW

Current Positioning in the Marketplace

My familiarity with Zimmer only dates back to 1993 when they were owned by Bristol Meyers Squibb. Zimmer was the industry leader, vertically integrated with Hall's Surgical (*powered instruments*) and Linvatec (*arthroscopy/sports medicine*) and possessing one of the broadest lines of products available in the industry. The next seven years proved to be tumultuous for Zimmer as BMS sold off their two largest vertical companies and they lost market share and ranking through complacency and inactivity in a consolidating industry. In 2001 Zimmer was spun off to an IPO, allowing Ray Elliott (*now a seasoned ortho executive with Zimmer for 5 years*) to lead its turn around, resulting in revenue growth from 2001 of just over \$1B to \$3.8B (*includes acquisitions*) projected in 2007. Ray has not sat still since going public, as can be seen by major announcements:

- 2000 - Bristol-Myers Squibb announces plans to divest Zimmer.
- 2001 - spun off from Bristol-Myers Squibb, on August 7th
- 2001 - First Zimmer® *Minimally Invasive Solutions™ (MIS™) 2-Incision™* Hip Replacement Procedure performed
- 2003 - acquires Centerpulse AG, and with the acquisition, Zimmer also expands into the spinal and dental markets
- 2003 - announces its intention to acquire Implex Corporation, previously marketing their *Trabecular Metal* Technology.
- 2003 - opens The Zimmer Institute, a state-of-the-art training facility to advance surgeon skills
- 2004 - completes acquisition of Implex Corp.
- 2004 - launches the *Minimally Invasive Solutions™*
- 2005 - introduces electromagnetic computer navigation technology for *MIS* knee replacement
- 2005 - acquires ww distribution rights for genetically engineered xenogeneic tissues from Revivicor, Inc.
- 2005 - launches the *iNav™** Portable Electromagnetic Navigation System, offered through Medtronic partnership
- 2006 - launches the *Gender Solutions™* Knee Implant, to address the unique needs of women patients.
- 2006 - FDA approval of Neocartilage, a tissue-engineered living tissue graft being developed with ISTO Technologies
- 2006 - acquires rights for *Zimmer® BRIGIT™* Bone Resection Instrument; BRIGIT
- 2007 – announces agreement to acquire Endius, a leader in minimally invasive spinal surgery
- 2007 – announces agreement with Regeneration Technologies to distribute new allograft paste implant
- 2007 – announces agreement with Tutogen to distribute biological products
- 2007 - announces agreement to purchase OrthoSoft a major leader in computer assisted surgery
- 2007 - receives FDA approval to market mobile bearing knee

With 7,000 employees, 130K orthopaedic sku's and a market cap of \$15B Zimmer has recaptured its market dominance in joint reconstruction (*#1 overall and in both hips & knees, #2 in extremities*) . . . # 5 in fracture management . . . and # 6 in spine.

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Positions within Orthopaedic Submarkets

Revenue Snapshot

Five Year Review

	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007E</u>
Hip	645	1,080	1,140	1,189	1,289
Knee	801	1,195	1,368	1,461	1,619
Extremity	n/a	15	65	78	103
Recon	1,446	2,290	2,573	2,728	3,011
Spine	34	135	161	177	192
Fracture	152	172	180	196	202
Ortho Implant	1,632	2,597	2,914	3,101	3,405
Surgical Products	193	216	226	215	230
Dental	n/a	36	148	179	216
Total Revenue	1,825	2,849	3,288	3,495	3,851
YoY Growth		30.2%*	10.2%	6.4%	10.2%

* reflecting Centerpulse acquisition

Reconstructive Surgery – *there is little question regarding Zimmer’s breathe and depth in product line and with the momentum of the Gender Specific Knee (GSK) and recent FDA approval of a mobile bearing knee, they are well position for the next few years. Zimmer sets the benchmark for the larger recon manufacturer by accommodating and embracing various surgical philosophies and patient requirements. The one exception to this has been Zimmer’s lack of position to take advantage of the “resurface” movement, which although only projected to grow to 10% of the market, leaves a hole in their bag that needs filling.*

Zimmer is better prepared than the other majors, with the notable exception of S&N (oxinium), to take advantage of a premium material (trabecular) and although competitors have jumped on the bandwagon with MIS procedures, Zimmer is advancing beyond instruments & technique to modular implants through their Kinectiv technology.

Along with Biomet, Zimmer has signed a co-licensing agreement to market the vitamin E treated poly liner. The intention of this product is to hinder the oxidation process, which is the “Achilles heel” of the plastic component of reconstructive joint implant.

During the past couple of years, Zimmer has renewed its focus on extremities, specifically shoulders. With a greater than 25% growth in 2007, they are #2 market share leader with 17% of the market. Unfortunately the worldwide revenues of this market are only \$400 million.

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Spinal – last year they had a change in leadership within this Division and as mentioned in the intro, have made a recent acquisition (Endius) to gain some momentum. With only 3% of the ww market, Zimmer is woefully lagging with their product offering. From “comments on the street” it appears the technology they purchased from Centerpulse was not as competitive as one would like and it appears the recent acquisition of Endius is to shore up that offering. From a product line basis, it would appear that their Dynesys product is doing well, however projected year on year growth of 8.5% is significantly below the 15+% market growth as they lose share in 2007.

Arthroscopy/Sports Medicine – other than some resorbable screws there is no worthwhile offering in this area, although I understand they have contracts with their former Divisions (Hall and Linvatec), I have heard nothing to this advantage in over a year.

Note: I would consider this to be a serious hole in Zimmer’s strategy for market dominance, and inconsistent with their minimum invasive surgery strategy.

Fracture Management – in a \$3.3 billion market growing at 10%, Zimmer’s 6% share with a projected 0.6 share point loss in 2007 reflects the lack of attention over the years. Historically recon companies have shunned this market (except for Howmedica) however now S&N (which was not a large player back then) and Stryker (through its Howmedica acquisition) have provided a separate sale focus to counter the low average sku sale and time consuming service. Now with a consolidated industry and everyone looking for new strategies to leverage, Zimmer will need to decide how they want to play in this market. Should Zimmer want to aggressively grow in trauma (currently #5) they should learn from Synthes and S&N by spinning off a sales force that concentrates only this market segment.

Peripheral Markets – some comments on the peripheral markets involving either innovative technology or expanded science, that in one form or another support the orthopaedic submarkets.

Orthobiologics – with press releases, joint ventures and technology acquisitions, Zimmer is aligning itself to future sciences that will enhance the bags of each of its Divisions. At this point it is difficult to sort through their overall strategy and to experience any results from all the activity released in the media. Suffice it to say that they appear to have some type of game plan, but school is still out.

ISG/CAS & Robotics – in 2005 Zimmer joint ventured with Medtronic in their stealth technology, supporting the iNav and AxiEM products for Minimally Invasive Solutions Procedures and Technologies. Although they acquired Brigit Bone Resection in a 2006 acquisition from Med Tech, there are no revenue expectations until 2008. And last year Zimmer acquired OrthoSoft bringing procedural and implant planning to their Program. Along with CAS is Zimmer’s recent announcement of their Ice Cube Instruments, an obvious extension of their manufacturing and CAS offering, combining sterilization to disposable cutting guides. I suspect Zimmer does not have a clear integration plan for their CAS products as they are in search for an integration strategist in this area look for change in their support of iNav and AxiEM with Medtronics.

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Pricing – historically Zimmer has been among the stronger of the companies to use their physician relationship to hold pricing. Over the years, a common strategy of the larger companies is to negotiate “vanilla” contracts with the regional and national buyers, while driving performance base contracting at the local level. Zimmer has written a number of these price contracts and is very good at installing “outliers” for their broad line and new technology, resulting in higher pricing and margins for those products.

Zimmer has some repair work to do with HCA, the largest for profit US chain of hospitals. A couple of years ago, there was a difference of opinion between the two organizations on achievement of contract requirements and it ended up being played out in the media. The result was an embarrassing retraction by HCA and higher implant pricing not only for Zimmer, but the other contracted vendors as well.

Government Oversight - Deferred Prosecution Agreement (DPA) indicated Zimmer clearly had the most physician consultants with 753 . . . almost double #2 DePuy although Zimmer’s \$86M paid was on \$12M more than DePuy’s Consulting payments. For this Zimmer paid \$170M . . . 2X DePuy’s fine. Zimmer has provided the following Surgeon Payment Disclosure on the reported \$86 million paid in 2007 through 10 months:

- 74% Product Royalties
- 11% Consulting
- 10% Research & Clinical
- 4% Education & Other
- 1% Travel and Expense

Early comments that Zimmer (and some others) have now started to reduce these agreements and given their large exposure, it is reasonable to believe they have more risk than the other manufacturers. Additionally there is a great deal of “buzz” within the industry on the DOJ requirements for suppliers to publish individual physician consulting amounts and the negative backlash resulting from physician comparison. I am a skeptic of this opinion . . . and would rather believe that Zimmer will use this as an opportunity to strategically prune their contracts.

Further Zimmer is one of a handful of top tier companies that the DOJ has now gone back to for information on payments to physician outside of the US. Along with Biomet, S&N, Stryker and Medtronic . . . Zimmer will be responding to this probe on possible violations of the Foreign Corrupt Practices Act.

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Market Strategies – *Zimmer has the industry image of a large company that cannot get things done quickly. They are considered very strong in their marketing, but successful commercialization of many new ventures do not seem to be realized in their financials. Not only in the financials, but it is also difficult to see the results of these efforts from a field perspective as well.*

I particularly like the creation of their Hospital Productivity Group, where they have merged a 2006 acquisition of Human Motion Institute with expertise in developing programs to increase the profitability of hospital procedures. Although this has great potential in price positioning of products, we have not see effective utilization of this advantage through 2007.

Zimmer has expanded their Direct to Consumer advertising to support their Gender Solution and MIS strategies. All four major companies have ventured down this road, and all are guarded on quantifying the success of this strategy.

As mentioned in the CAS section, Zimmer is building a presence in this arena and appears to be further down the road than other major orthopaedic companies.

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How does Zimmer stack up

Strengths – *Zimmer is a marketing powerhouse and has the experience and where-with-all to drive positioning strategies anywhere in the world . . . possessing a complete line of products within the core business (joint reconstruction) there appears to be no offering where they can not meet a surgeon's interest . . . has the most comprehensive value added support in the industry, which will require leadership to effectively position their image . . . middle management team has been stable and in place the longest of major orthopaedic manufacturers*

Weakness - *school is out on the new CEO (David Dvorak) and whether he can fill the shoes of Ray Elliott (or drive the company for that matter) . . . don't see their dental segment (obtained via Centerpulse acquisition) as a strategic fit except in manufacturing . . . there is no exposure in the sports medicine arena although they have a foot in the spinal market, it is weak at best and will require further acquisition to gain the momentum in this fast growing industry*

Opportunities – *with Ray Elliott now retired, Zimmer has the ability to reposition its relationship with the hospital sector. Dave Dvorak can rebuild their image with the economic buyers as supported by health care economics. . . how to use the Zimmer Institute in lieu of recent set backs last month's FDA approval of their mobile bearing knee (this could be huge, given the distribution muscle of the only two companies - Zimmer & DePuy - with approved MBK product) neutralize supply chain via their health economics area look for Zimmer to advantage their experience in market segmentation (gender solution) with ethnic offerings*

Threats – *the DOJ is not through with controlling the surgeon relations within the medical devices sector . . . clearly price pressure will continue in their market space . . . legislative interest for medical device price transparency . . . the continued decline of both autonomy and income for orthopaedic surgeons*

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Conclusion on Zimmer's future Outlook

As reviewed, Zimmer is not only the overall revenue leader in orthopaedics, but the share leader in its largest segment . . joint reconstruction. With a position in every major segment (except sports medicine) Zimmer has the opportunity to foster innovation for cross-market support.

Unfortunately Zimmer has been losing market share in recent year which may very well reflect the Bill Elliott (*recently retired CEO*) control area, where all decisions flowed through Warsaw and maybe a reflection of bygone Bristol Myers Squibb days. This may have served Zimmer well approaching an IPO, clearly the company is in a different mode now. David Dvorak (*new CEO*) would seem to have an open door to take the pieces Bill E has acquired and build some synergy without combining them. This would be affective through a service and product portfolio that supports all submarkets:

- *multiple ventures in orthobiologics*
- *developing the CAS/Robotic IP and assets*
- *expanded marketing of MIS from education to advertising*
- *targeting the resources, data and intellect assembled via Motion Institute & Health Economics*
- *the relational and exposure advantage of the Zimmer Institute*

Segments of their strategy has been impressiveminimal invasive solutions gender solutions orthobiologics CAS however each seems to lack the staying power so far, either through premature launch or lack of a well thought out strategy, either near or far term. At times it appears Zimmer has moved forward more defensively than offensively.

There is more to be said regarding the DOJ investigations regarding the DPA and the rationale for Zimmer's heavy fines. Additionally we need to stay tuned for the newly launched investigations on their surgeon relations outside of the US. However, my take on this is more from the opportunity side Zimmer has now had a look at what the other majors are paying for surgeon relations, vies a vie their own exposure. It would be believable that this situation can be used to "right-size" their portfolio of surgeon consultants and royalties and use the government as the "fall guy".

And area of intense scrutiny over past years has been the inelasticity of pricing and resulting contribution to margin. I would look for more of the same in the near term with prices remaining flat, with consideration to the evolvement of physician preference influence. This said, the mix element will continue to drive margins as Zimmer highlights technology through new products introductions, i.e. the Natural-Knee & LPS-Flex, VerSys Epoch Hip, Cyclone Cervical Plate System and DeNovo NT natural tissue graft. Also believe Bill E strategy for Human Motion Institute will blend with Zimmer's long term discounting strategy and create a powerful economic profile for the hospitals.

Regarding Zimmer's financial position, I believe there are those who are in a better position than I to evaluate their positioning of eliminating provisions requiring an 80% (*"super-majority"*) vote and authorization of \$1 Billion to repurchase shares of stock. For my part, Zimmer now needs to show the vision and commitment to drive the economic influences, along with the clinical

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Various Web Sites

The Institute for Orthopaedics
8401 Chagrin Road
Suite 18
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www.theorthopeople.com

SLACK Incorporated
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