



Warsaw, Indiana:
The Orthopedics Capital of the World

**An overview, analysis and blueprint
for future industry and community growth**

September 2009

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I. Executive Summary

With support from the Lilly Endowment, BioCrossroads (CICP Foundation, Inc.) has developed a detailed study of Indiana's remarkable achievements and potential for growth in the global orthopedic device sector. The following report draws heavily upon research by the Battelle Technology Partnership Practice – both a 2001 study and an update to that work completed in 2009. In addition, a community study which included a number of in-depth interviews and facilitated discussions with key business and community leaders in the Warsaw region, and input from distinguished orthopedic surgeons, were also utilized in the creation of this report. The integration of all of this information and research has resulted in a picture of a currently robust, respected and globally competitive orthopedics device cluster in Warsaw, Indiana. The report underscores the value of this cluster for the region and for the entire state's long term economic competitiveness and identifies some emerging challenges to the industry. Finally, and most importantly, the process of putting this report together has resulted in a number of insights about opportunities within Warsaw and across north central Indiana which, if strategically pursued, will further ensure the long-term sustainability and enhance the growth of this immensely productive sector.

The principal findings include:

I. The Current Environment in the Warsaw Cluster: A World-Class Asset Benefiting All of Indiana

A. The Warsaw, Indiana orthopedic device cluster is one of the most concentrated centers of economic activity anywhere in the United States. Three of the world's five leading orthopedic device companies began in Warsaw and remain there today. A major spinal implant manufacturing facility owned by Medtronic Corporation is also based in Warsaw. All of these companies are supported by dozens of Warsaw-based suppliers and contract manufacturers. Collectively, these enterprises earn more than \$11 billion in annual revenues, representing better than a 50% market share in the United States, and more than a 33% market share in the world.

B. The Warsaw cluster retains a strong competitive position in orthopedics because of its concentration of headquartered companies, highly skilled employees and significant levels of profitability, despite efforts by other regions – for example, Memphis – to compete for orthopedic headquarters, global suppliers, and talent. The proximity of Zimmer, Biomet and DePuy, as well as the multiple contiguous companies securely rooted in Warsaw, has allowed the sector to retain its leadership position. The markets for orthopedic devices are strong and growing, due to the industry-favorable demographics of an aging baby boomer generation. Additionally, the long history and strong technologies at the base of the Warsaw cluster have resulted not only in a stable core of companies, but in the emergence of new, highly entrepreneurial companies in the orthopedic space, such as OrthoPediatrics and Paragon Medical, all with a strong determination to have a "Warsaw address".

C. The global reach and connectivity of the Warsaw-based orthopedics sector is not well understood outside the orthopedics industry itself. The companies in Warsaw thrive in a worldwide network of customers, suppliers, surgeons and R&D activities, all of which represent a critical source of intelligence about markets, technological trends and regulatory issues of

relevance to the industry. These networks and relationships are of value, not only to the Warsaw cluster, but to the entire state of Indiana.

D. Even in Indiana, the Warsaw orthopedics cluster is perceived primarily as a strong manufacturing hub, when, in fact, it is also a growing center of innovation and R&D activity. Zimmer alone has 800 researchers working in Warsaw, and there are currently more than 30 sponsored research partnerships with institutions such as Purdue and Notre Dame. In addition, with an extremely small population base, Warsaw companies have generated publications and patents far in excess of what would be expected. The average patenting rate in the United States is five per 10,000 people; in Indiana it is 13, and in Warsaw, it is 32. This growing interest in R&D and innovation within the Warsaw orthopedics cluster merits recognition and continued support to stimulate even more aggressive growth.

II. *Emerging Challenges Confronting the Warsaw Orthopedics Cluster*

A. Despite its enormous achievements and its great value to the state of Indiana, the Warsaw orthopedics device cluster is facing significant challenges, most of which are externally driven. These include:

- Increased federal regulatory and compliance scrutiny of the medical device industry,
- Rising cost pressures,
- Significant education and training shortfalls in the orthopedic workforce,
- Difficulties in attracting and retaining senior engineering and management talent,
- The absence of a full array of locally accessible industry support services,
- Travel, shipping and other logistical transportation infrastructure challenges, and
- An increasing need among newer and smaller orthopedic companies in the sector to have access to innovative research, new technologies, and the capital required for commercialization.

B. Until recently, the Warsaw community also lacked any form of organized and integrative leadership expressly focused on the future of the industry and its opportunities, the challenges facing its sustainability, and the support it needs from the broader region. While connected to national trade and interest groups, the Warsaw orthopedics sector itself has not been organized locally, much less regionally, to work together to address local needs and long-term sustainability challenges.

C. The tremendous success of this sector, its development opportunistically rather than strategically in a relatively remote locale, and a widespread lack of appreciation of the impact of the industry and this region to the economy of the state, could result in a number of unintended threats to the vitality of the Warsaw orthopedics cluster. This is specifically true given the array of external challenges facing the industry as a whole.

III. *What Warsaw Can Do, Moving Forward*

A. In recent years, the Warsaw-based orthopedics companies have begun to collaborate on what are essentially precompetitive or non-competitive issues, such as workforce education and training, as well as the promotion of cultural and social amenities important to employees at all of their companies. There have been compelling examples of collaborative planning and investment totaling more than \$6 million in shared facilities for education and technical development purposes at both Grace College and Ivy Tech Community College. These emerging conversations and shared investments indicate that the Warsaw-based companies are recognizing shared interests that can collaboratively drive shared solutions.

B. Interviews with business and community leadership across Warsaw indicate a growing desire for a strategically organized effort that should be anchored in Warsaw, directed by a coalition of Warsaw community and cluster leaders, focused on what needs to be done to strengthen this cluster, and frankly, determined to increase the visibility and respect that Warsaw commands with neighboring Indiana communities and with State government, given the significant economic strength the Warsaw orthopedics sector represents.

C. A number of key leaders from both industry and the community have been identified and/or have expressed a personal willingness to take the steps necessary to develop a more formally organized platform through which a clearer definition of the opportunities and challenges facing Warsaw can be addressed. Such a platform could also be the base from which a better understanding and strategic utilization of the leverageable assets of benefit to Warsaw from neighboring communities such as Fort Wayne – which has housing and business services not available in Warsaw – and South Bend – which has university, research and medical centers not available in Warsaw – could serve to extend Warsaw’s vitality and sustainability.

D. There is a genuine openness to and enthusiasm for creating a business league, along the lines of the Central Indiana Corporate Partnership in Indianapolis and surrounding counties, that could build on emerging collaborations and further organize the Warsaw community through a strategic initiative. Such a business league could move quickly beyond “just talk” to focus on an integrated set of educational, workforce, cultural, communication, branding, logistical and entrepreneurial initiatives that would advance the orthopedics sector and the Warsaw community which calls that sector “home”.

E. As a complement to such a business league, there may also be an opportunity to establish a center of research, testing and education, building on, but also extending beyond, sponsored research partnerships and educational investments the companies in the cluster have already made. Such a center could potentially be college and university led, and provide a platform for engineering, business, regulatory and other technical support services responsive to widely acknowledged orthopedics sector needs. This center could also serve as a site for workforce skills and practitioner development, statewide college and university engagement and internships, compliance and regulatory training and pre-clinical testing services.

The following report will show that the Warsaw-based orthopedics sector represents a significant force globally – one that both needs and merits support to realize expanding opportunities and address the many challenges facing the region and the industry as a whole. Contiguous regions across north central Indiana have an enormous stake in the success of Warsaw’s orthopedics cluster, as does the state as a whole. This is an opportune time for a significant investment to be made in the development of community leadership platforms that can advance both the interests of the Warsaw-based orthopedics sector and the economic and social needs of surrounding regions as well. A secure and growing future for this remarkable “industry-within-a-community” in north central Indiana represents one of the best possible ways to strengthen the position of the entire state of Indiana as a global leader in the health and life sciences.

II. Study Overview

Building upon an important regional economic development assessment by Battelle Technology Partnership Practice, originally conducted in 2001 and further updated for this report, BioCrossroads has organized a variety of meetings and assessments with industry executives, college and university administrators and faculty, orthopedic surgeons, government officials, and economic and community development officials to provide a deeper understanding of the opportunities and challenges for the Warsaw orthopedic cluster in the context of its region and the entire state of Indiana. Quickly determining that the Warsaw-based orthopedics device sector truly is a shining star on Indiana's economic landscape, BioCrossroads believes it is important to know what leaders of the Warsaw cluster see as the major challenges and opportunities for sustainability and growth. To this end, BioCrossroads, working closely with Grace College, arranged a series of roundtable discussions and Warsaw focused one-on-one discussion sessions facilitated by an international expert in community and economic growth, Dr. Mary Walshok, a Professor of Sociology at the University of California, San Diego, and a principal in Global CONNECT at UC-San Diego. Extending over three days and evenings in late 2008, the discussions drew upon a broad cross-section of nearly 80 participants from Warsaw's community, industry, government, civic, educational and not-for-profit leadership. The meetings provided candid and pivotal insight, and formed the basis for many of the findings and recommendations set forth in Section VI of this report.

These visits and conversations in the winter of 2008, for purposes of this report, have been significantly augmented by the important data about the Warsaw cluster furnished by the original and updated Battelle studies. In addition, to assure fidelity to what we heard through the roundtables and interviews, we previewed, discussed and further refined preliminary findings and recommendations through a follow-up series of facilitated dinner conversations in mid-April 2009 with the same group of Warsaw-based participants. In addition, BioCrossroads requested further background research by the team at UC-San Diego, and solicited expert practitioner recommendations for specific industry support services from orthopedic surgeons such as Dr. Rick Sasso. All of this input provides the underpinnings for the report which follows, as well as the conclusions of BioCrossroads, summarized at the end of the report.

This report begins with a brief overview of Warsaw as the orthopedics capital of the world, relying heavily on the updated Battelle study and additional recent data provided by the UC-San Diego team. It also shares a variety of qualitative insights and opinions, based on the visits and roundtables conducted in the winter of 2008 and spring of 2009. The report further includes a summation of some of the recent challenges facing the orthopedics industry as a whole, which may have profound implications for the future of the cluster in Warsaw.

In this overview, it is important to reiterate how robust the Warsaw "micropolitan" area is, based on the Battelle studies' comparative assessment. Warsaw is home to orthopedics sector companies that collectively make it the 15th largest area employer in medical devices in the country, with a jobs concentration that is "off the charts" at 52 times the national average. Put another way, with more than 6,700 jobs in the region, and growth rates since 2001 averaging nearly 40% for medical device companies and their strategic suppliers, Warsaw's orthopedics cluster is the economic engine that drives much of the north central Indiana economy. With respect to the findings highlighted in Section V, the Global CONNECT effort explored the evolution of Warsaw's orthopedics sector through entrepreneurial leaders that have developed a diverse and uniquely comprehensive set of industry

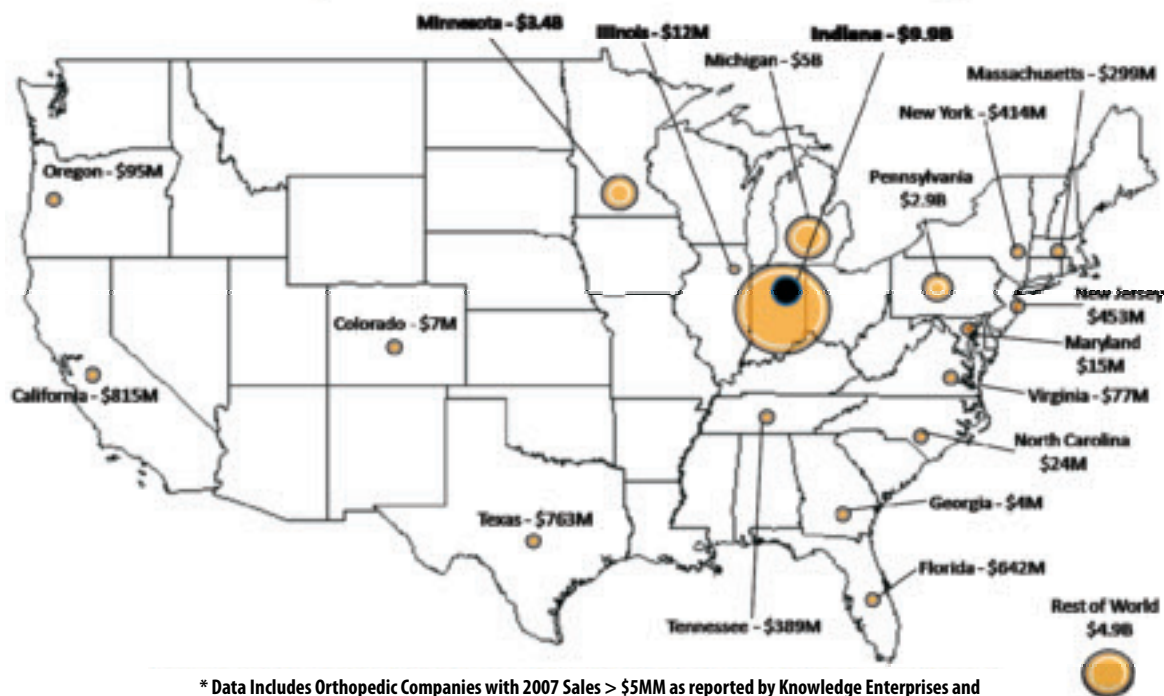
assets that today are positioned to be strategically leveraged across the region and across the State. Building on Battelle's impressive quantitative data for this sector, Global CONNECT's more qualitative research revealed the powerful "sense of place" that exists among the leadership within the industry and across numerous entrepreneurs and business people who have returned to Warsaw because of the values and quality of life they see in the region. Among this leadership group there was universal acknowledgement of the power of the Warsaw "brand" in the highly competitive orthopedic industry. Nonetheless, Global CONNECT identified specific challenges facing the industry and community alike, and these include such things as access to continuous innovation, a changing regulatory and reimbursement environment, and the limits inherent in Warsaw's remote geography.

BioCrossroads has drawn upon all of this diverse material to conclude with some preliminary recommendations addressing the challenges and opportunities facing the key stakeholders in Warsaw's orthopedics industry. Those recommendations include building more strategically focused efforts and leadership groups through which important issues related to innovation, education, transportation infrastructure and quality of life can be addressed. These issues are all critical to the long-term sustainability of this distinctive center of global economic activity.

III. The Big Picture: Warsaw, Indiana - Capital of the World's Orthopedics Industry

Warsaw, Indiana, is the undisputed capital of today's global orthopedic device industry (*Wall Street Journal*, October 26, 2006). The world's first modern orthopedic device company (producing custom-fitted leg braces) was founded in Warsaw in 1895 by a visionary inventor and marketer Revra DePuy. Continuing innovation and entrepreneurship within the region ultimately led to dominance of the market, and today three of the world's five largest orthopedic manufacturers (DePuy, Inc.; Zimmer, Inc.; and Biomet, Inc.) are headquartered in Warsaw. In addition, the world's largest spinal implant manufacturing facility (Medtronic Sofamor Danek, Inc.) is located in Warsaw, employing 650 skilled workers. As the modern orthopedics industry evolved, a true cluster of more than 20 orthopedic device manufacturers, suppliers and technical service providers capable of delivering the entire value chain of innovation and production has developed in the Warsaw region as well. Research by BioCrossroads

One-Third of the \$32 billion Global Orthopedic Industry is Headquartered in Warsaw, IN



* Data Includes Orthopedic Companies with 2007 Sales > \$5MM as reported by Knowledge Enterprises and Independent research conducted by BioCrossroads

indicates that nearly one-third of the world's \$32.5 billion orthopedic device sector, including 60% of the global hip and knee replacement market, is now based there. The result is a deeply integrated and highly profitable industry concentrated in a compact geography, sharing and supporting a specialized regional economy that draws upon a concentrated pool of talent, training and resources to advance global competitiveness. According to a recent article in the *Chicago Tribune* ("Indiana Town Thrives as

Orthopedic Manufacturing Capital," March 8, 2009), approximately 6,500 skilled Hoosiers - nearly half the town's population - are employed in the Warsaw orthopedics industry.

Warsaw not only has the most concentrated share of the global orthopedics industry, but also features three varied business models competing for market share. DePuy, the oldest of the three major manufacturers, is today a wholly owned subsidiary of Johnson & Johnson. Being held under the umbrella of a global pharmaceutical company offers unique opportunities and challenges as cost becomes increasingly important and orthopedics companies begin to test a global supply chain model in some ways reminiscent of the pharmaceutical industry. Zimmer, also a public company, is independently traded and has sought to build a global enterprise with worldwide reach from an expanding Warsaw base. Biomet, another global company, is owned by private equity investors typically focused on achieving early value-driven return to public company status, and appears to be increasing its near-term focus on research and development rather than physical expansion of manufacturing operations.

Short-Term Considerations and Longer Range Forecasts

The orthopedic industry is fiercely competitive as a rule, and this competition is intensified within a geography as compact as Warsaw. Major participants have historically resisted collaboration. The current spotlight brought by US Department of Justice investigations on the physician consultation practices of the "Big 3" Warsaw companies (and others) only intensifies the isolation of these companies from one another. Further, the nature of innovation and product development within the industry does not encourage collaboration. Unlike the pharmaceutical industry, where both new classes of therapeutic candidates and sweeping new approaches to therapeutic solutions are the norm, the orthopedic industry is focused on the treatment of a finite number of applications – the majority of which are hip, knee and spine related – often through continuous but relatively minor product differentiation and improvement. In large measure, the company that will gain market share is the company that is able to navigate the regulatory environment most efficiently and be first to market.

Orthopedics companies are currently in a period of record profitability projected to be sustained or increased for a decade to come. The June 2008 *Annual Report of The Institute for Orthopaedics* reports the value of the US orthopedic market to be \$19.8 billion and the global market to be \$32.5 billion. These figures represent sales of reconstructive devices, fracture repair, arthroscopy/soft tissue repair, spinal implants, orthobiologics and all other products. While the orthopedics device companies, including Zimmer, Biomet and DePuy, have not been immune from the more recent overall economic market turmoil of late 2008 and early 2009 and reported profits have decreased, the sector continues to be a strong and outsized performer. The global orthopedics market increased by 9% to approximately \$35 billion in 2008 and through the first quarter of 2009, sales results reported by the trade publication *OrthoWorld* show increases of 7% at both Biomet and DePuy, and a slight decrease of 1.5% at Zimmer, compared to sales for the same period in 2008.

Presenting at the 2009 OMTEC conference in June, Shirley Englehardt, Founding Partner of Knowledge Ventures, LLC offered a comprehensive and largely optimistic overview of the orthopedics industry. While there has been a slowing in semi-elective procedures such as hip and knee replacements, trauma, sports medicine and spine segments have continued to see nearly 10% growth over the same period in 2008. Hips, knees and biologics grew 5% during that period, compared to 8% in FY 2008. Growth, even at current rates represents significant economic impact, translating into billions of dollars for the global orthopedics industry - roughly equivalent to the size of one of the "Big 3" companies' annual sales. Compared to the performance of the overall national economy, which saw a 5.5% annualized decline in gross domestic product during the first quarter of 2009, the orthopedics market is weathering the storm

quite well. Economic pressures, as well as the unknown impact of national healthcare reform, comparative effectiveness measures, and a potential implant registry will all impact the future of the orthopedics industry.

Still, the major variables driving procedures and sales volumes lend strong support for a long-term optimistic outlook. Industry growth rates are projected to hold stable in the near term and to accelerate in the future, especially as the country's baby boomer generation lives longer, embraces more active lifestyles and approaches the average age for knee and hip implants. The *Chicago Tribune* recently reported ("Indiana Town Thrives as Orthopedic Manufacturing Capital," March 8, 2009) that the number of hip replacements increased 87% from 2000 to 2006 and cited a report from the American Academy of Orthopaedic Surgeons predicting a doubling of knee and hip replacements by 2016. Another recent article in *Barron's* ("Knee-Deep in Profits," June 16, 2008) concluded that, based on the demographic factors noted above, today's stock value in Zimmer, DePuy and Stryker, representing two-thirds of the \$10 billion artificial hip and knee market, is understated, with each of these companies poised to enjoy significant long-term growth.

IV. “Kosciusko County’s Health and Biomedical Industry: Economic Analysis” by Battelle Technology Partnership Practice, May 2009

Introduction

Battelle’s Technology Partnership Practice first examined the health and biomedical sector in Kosciusko County, Indiana in a study released in February 2001.¹ At that time, Battelle was commissioned for a strategy that was broad in scope and sought to create a “road map” or technology strategy specific to the strength in the region’s health industry and related manufacturers. Today, Battelle has been engaged by BioCrossroads to update the definition of this sector specifically for Kosciusko County and to conduct an economic analysis of where the industry stands including current strengths, recent trends, and opportunities for growth into the future.

The economic analysis presented here revisits the definition of the health and biomedical industry first presented in the 2001 report and defined under the old Federal Standard Industrial Classification (SIC) system which has since been replaced by the North American Industrial Classification System (NAICS). In addition to this change in fundamental industry coding, Battelle has re-examined the industry as it stands today and updated the industries to reflect not only those core bioscience or biomedical industry components but also the highly interrelated key supplier industries in the region. By implementing a broad definition, regional stakeholders can more effectively position the entire cluster of industries and companies for continued success.

Although the challenging economic situation in 2009 is impacting industries worldwide, the prospects for the health and biomedical sector going forward are relatively bright given the robust job growth and ongoing R&D efforts in healthcare and the biosciences. While the analysis in this report shows employment trends only through 2007, it reveals a regional and national health and biomedical sector with very strong momentum as it entered the recession.

Key findings in this analysis include the following:

- Kosciusko County has a large, highly specialized, and growing health and biomedical industry employment base that employs more than 10,000 workers and accounts for one in three private sector County jobs.
- The region’s health and biomedical sector is clearly driving the 7% growth in the overall private sector through 2007. With total job growth of 39%, County health and biomedical firms lifted the local economy adding 2,800 jobs since 2001.
- Medical devices and equipment remains Kosciusko County’s largest and most specialized subsector of the industry and has driven job growth by increasing an already large job base by 39% since 2001 to nearly 6,000 jobs today.

¹ *Sustaining Kosciusko County’s Health and Biomedical Industry for the 21st Century*, Prepared for Kosciusko Development, Inc. and Indiana Health Industry Forum. Battelle Technology Partnership Practice, February 2001

- Kosciusko County measures up nationally as a leading regional medical device center. When compared with the larger Metropolitan Statistical Areas analyzed nationally in Battelle’s biennial state by state industry analysis for the Biotechnology Industry Organization (BIO), the Warsaw, IN Micropolitan Area would rank as the 15th largest employer in medical devices and equipment.²
- Strategic supplier relationships for the medical device sector are substantial in the region. Kosciusko County firms employ more than 700 in strategic medical device supplier industries, a figure that has grown since 2001 by 200 jobs or 40%.

Defining the Health and Biomedical Industry

In updating the definition of Kosciusko County’s health and biomedical industry, Battelle used the following approach:

- Assessed current employment data at the six-digit level of NAICS detail for Kosciusko County in areas highly related to healthcare and biomedical, mapping previously used SIC codes to the new NAICS structure;
- Reviewed the national IMPLAN Input-Output impact model to identify supplier industries with particular attention to those most critical to medical device manufacturing concentrated in Kosciusko County;
- Used companies identified in Warsaw and Kosciusko County in the Indiana Health Industry Map and additional company databases to verify key NAICS supplier industries.

These focused industry research steps led to a definition of the health and biomedical industry made up of 57 detailed industries spanning 11 major subsectors of the broader industry. This NAICS-based definition is presented in Table 1.

Firms and establishments included in this definition span the biosciences from core life sciences R&D activities to pharmaceuticals manufacturing and the traditional regional strengths in the production of medical devices and equipment. In addition, the industry includes the array of regional health services including hospitals, outpatient care, and veterinary services. The “strategic medical device supplier industries” have been identified and grouped to track their current economic position as well as recent trends.

² See Battelle-BIO, *Technology, Talent, and Capital: State Bioscience Initiatives 2008* (<http://bio.org/local/battelle2008/>)

Table 1. Health and Biomedical Industry Definition

NAICS Code	NAICS Title	NAICS Code	NAICS Title
Medical Devices & Equipment		Ambulatory Health Care Services	
334510	Electromedical & Electrotherapeutic Apparatus Mfg.	621610	Home Health Care Services
334516	Analytical Laboratory Instrument Mfg.	621910	Ambulance Services
334517	Irradiation Apparatus Mfg.	621991	Blood & Organ Banks
339112	Surgical & Medical Instrument Mfg.	621999	All Other Miscellaneous Ambulatory Health Care Services
339113	Surgical Appliance & Supplies Mfg.	Doctor/Health Practitioner Offices	
339114	Dental Equipment & Supplies Mfg.	621111	Offices of Physicians (except Mental Health Specialists)
339115	Ophthalmic Goods Mfg.	621112	Offices of Physicians, Mental Health Specialists
339116	Dental Laboratories	621210	Offices of Dentists
Strategic Medical Device Supplier Industries		621310	Offices of Chiropractors
331512	Steel Investment Foundries	621320	Offices of Optometrists
332322	Sheet Metal Work Mfg.	621330	Offices of Mental Health Practitioners (except Physicians)
332710	Machine Shops	621340	Offices of Phys., Occupational & Speech Therapists, & Audiologists
332811	Metal Heat Treating	621391	Offices of Podiatrists
332812	Metal Coating, Engraving & Allied Services to Manufacturers	621399	Offices of All Other Miscellaneous Health Practitioners
332813	Electroplating, Plating, Polishing, Anodizing, & Coloring	Health Industry Wholesale	
541330	Engineering Services	423450	Medical, Dental, & Hospital Equip. & Supplies Merchant Wholesalers
541512	Computer Systems Design Services	423460	Ophthalmic Goods Merchant Wholesalers
Drugs & Pharmaceuticals		424210	Drugs & Druggists' Sundries Merchant Wholesalers
325411	Medicinal & Botanical Mfg.	Hospitals	
325412	Pharmaceutical Preparation Mfg.	622110	General Medical & Surgical Hospitals
325413	In-Vitro Diagnostic Substance Mfg.	622210	Psychiatric & Substance Abuse Hospitals
325414	Biological Product (except Diagnostic) Mfg.	622310	Specialty Hospitals
Personal Care Facilities		Outpatient Medical Care Centers	
623110	Nursing Care Facilities	621410	Family Planning Centers
623210	Residential Mental Retardation Facilities	621420	Outpatient Mental Health & Substance Abuse Centers
623220	Residential Mental Health & Substance Abuse Facilities	621491	HMO Medical Centers
623311	Continuing Care Retirement Communities	621492	Kidney Dialysis Centers
623312	Homes for the Elderly	621493	Freestanding Ambulatory Surgical & Emergency Centers
623990	Other Residential Care Facilities	621498	All Other Outpatient Care Centers
Research, Testing, & Medical Labs		Veterinary Services	
541380	Testing Laboratories*	541940	Veterinary Services
541710	R&D in the Physical, Engineering, & Life Sciences*		
621511	Medical Laboratories		
621512	Diagnostic Imaging Centers		

*Data for these industries (NAICS 541380 and 541710) include only the shares involved in life sciences activities.

The following includes an employment analysis of the health and biomedical industry base in Kosciusko County, including its current position and recent trends relative to US. The analysis makes comparisons with the national sector in order to provide context for the relative performance of the region.

Labor market data in this analysis (employment, establishments, and wages) are for 2007, the most current annual data available.³ Industry trends are examined over the seven years from 2001 through 2007. The North American Industry Classification System (NAICS) is the official Federal government system for classifying establishments and their activities into the appropriate sectors. NAICS industries at the most detailed (six-digit) level were selected for this analysis and together make up the major sectors and subsectors.

³ For detailed information on the employment data used in this analysis, see the Appendix.

The Health and Biomedical Industry

Kosciusko County has a large, specialized, and growing health and biomedical industry employment base. Combined, the 11 industry subsectors employ more than 10,000 workers in 2007 or one in three private sector County jobs across 176 individual business establishments. Since 2001, county health and biomedical firms have increased both their establishment and employment levels by 5.3% and 38.8%, respectively (see Table 2).⁴

Kosciusko County has grown its Health & Biomedical employment base by 39% since 2001 compared with 15% for both Indiana and the US.

Employment concentration is a useful way to gauge a state or county's degree of specialization in a given industry or cluster of industries. Location Quotients (LQs) measure the degree of job concentration within the region relative to the nation.⁵ A county LQ greater than 1.0 is said to have a greater concentration than the national average. When the LQ is significantly above average, 1.20 or greater, the county is said to have a "specialization" in the industry.

In 2007, the concentration of jobs in the overall health and biomedical industry was more than twice the national average, yielding a highly specialized LQ of 2.16 for Kosciusko County. Within the regional industry are four major subsectors considered to be regional specializations of their own—medical devices and equipment (LQ is 51.86); health industry wholesale (LQ is 3.41); drugs and pharmaceuticals (LQ is 2.12); and strategic medical device suppliers (LQ is 1.25). One should use caution, however, in characterizing the County's drugs and pharmaceuticals sector as a specialized industry as there are fewer than 200 total jobs and the LQ is based on the relatively modest size of the County's private sector which stands at just 32,106 jobs in total.

Table 2. Kosciusko County employment metrics, 2007

Industry & Subsectors	2007 Establishments	Percent Change Estab, '01-07	2007 Employment	Percent Change Empl, '01-07	2007 Location Quotient
Kosciusko County, IN					
Total Private Sector	1,796	7.5%	32,106	7.1%	1.00
Total Health & Biomedical Industry	176	5.3%	10,095	38.8%	2.16
Medical Devices & Equipment	16	-20.0%	5,979	38.7%	51.86
Hospitals	1	-91.1%	1,106	10.1%	0.88
Personal Care Facilities	18	28.6%	762	23.7%	0.92
Strategic Medical Device Supplier Industries	42	9.0%	724	40.2%	1.25
Doctor/Health Practitioner Offices	59	3.5%	523	14.2%	0.52
Health Industry Wholesale	17	46.9%	404	394.5%	3.41
Ambulatory Health Care Services	4	66.7%	234	199.7%	0.73
Drugs & Pharmaceuticals	1	71.4%	176	17500.0%	2.12
Veterinary Services	10	0.0%	88	25.7%	1.07
Outpatient Medical Care Centers	7	337.5%	78	-43.1%	0.54
Research, Testing, & Medical Laboratories	1	218.5%	22	6487.6%	0.17

Source: Battelle analysis of Bureau of Labor Statistics, QCEW data from the Minnesota IMPLAN Group.

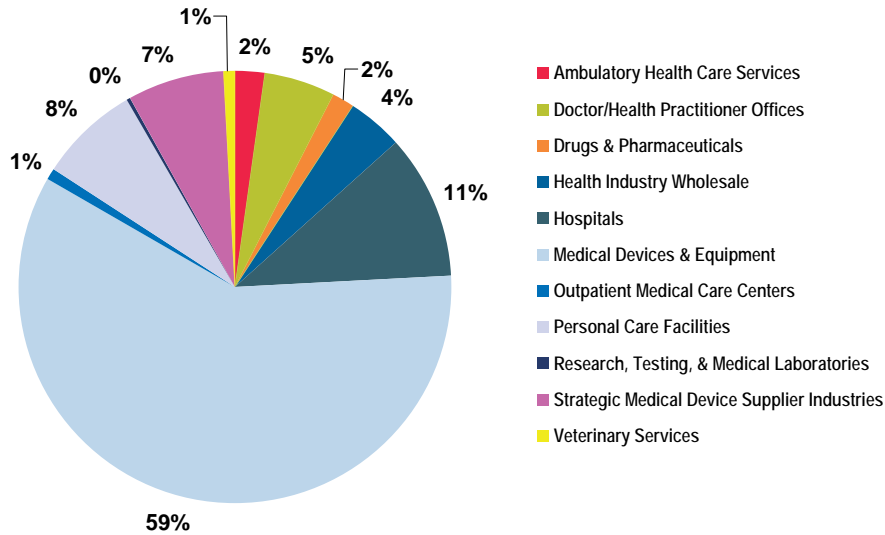
⁴ A version of Table 2 is included in the Appendix for both Indiana and the US for reference and comparison.

⁵ Location quotients (LQs) are a standard measure of the concentration of a particular industry in a region relative to the nation. The LQ is the share of total state or regional employment in the particular industry divided by the share of total industry employment in the nation. An LQ greater than 1.0 for a particular industry indicates that the region has a greater relative concentration, whereas an LQ less than 1.0 signifies a relative underrepresentation. An LQ greater than 1.20 denotes employment concentration significantly above the national average. In this analysis, regional specializations are defined by LQs of 1.20 or greater.



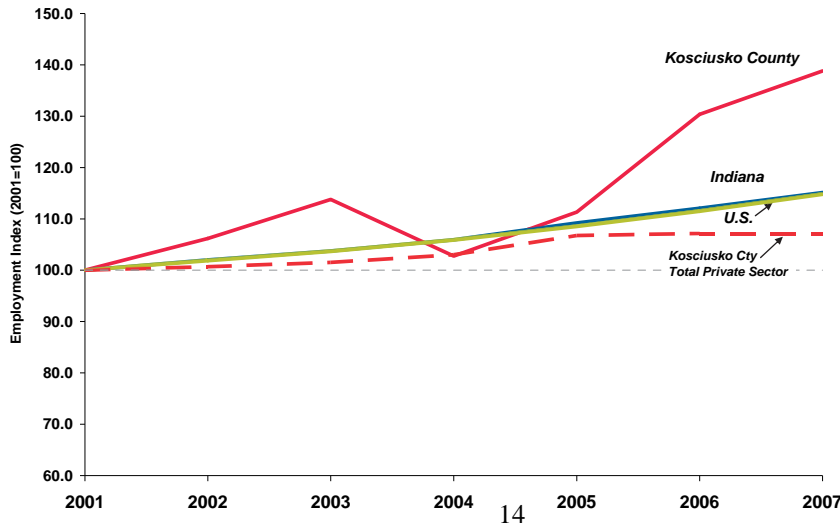
The pie chart below presents the employment composition of the health and biomedical industry in Kosciusko County in 2007. **The chart shows the regional dominance and overall importance to the regional economy of the nearly 6,000 jobs in the medical device sector which accounts for 59% of the industry overall.** Employment in hospitals is next largest at 11% followed by personal care facilities (8%) and the strategic suppliers for the device sector (7%). By comparison, the same pie charts for Indiana and the US show a much more similar, varied industry in terms of the employment distribution. These additional pie charts are shown in the Appendix.

Figure 1. Employment Composition of the Health and Biomedical Industry in Kosciusko County, 2007



The nearly 40% employment growth of the overall sector since 2001 is especially impressive compared with the trends seen in Indiana overall and in the national sector during this same period. Nationally, the health and biomedical industry grew by a strong 14.8%, and Indiana grew by 15.1%, but the sector in Kosciusko County grew by more than twice these rates (see Figure 2). Area firms have added over 2,800 jobs since 2001, driven primarily by the large medical device sector. In addition, the remarkable strength of the region's health and biomedical sector is further driven by the additional jobs added in ten of the 11 total industry subsectors since 2001.

Figure 2. Health and Biomedical Industry Employment Growth, Kosciusko County, Indiana, and the US, 2001-07





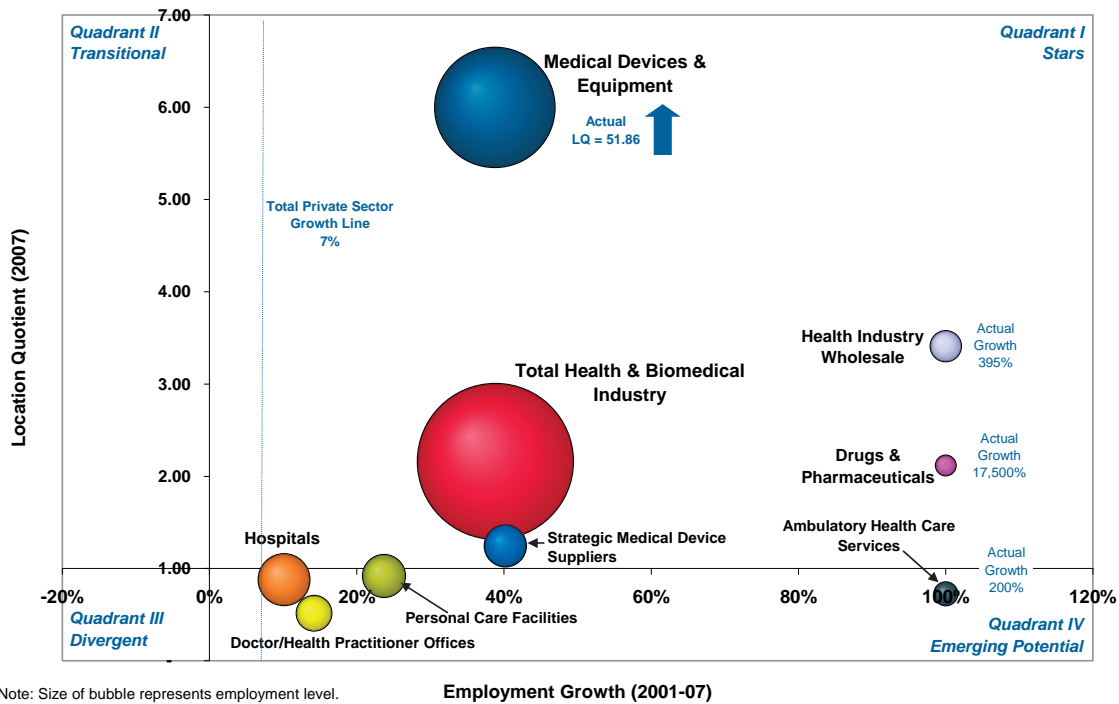
Major Health and Biomedical Subsectors

To fully understand the underlying composition, niche strengths, and recent trends driving the County’s health and biomedical industry, it is critical to examine the 11 major subsectors that combine to form the diverse and dynamic overall sector.

The nature and composition of a state or region’s bioscience sector can vary dramatically based upon regional strengths and economic characteristics such as the presence of local academic research institutions, the availability of venture capital dollars, the regional talent base, and historical industry strengths. Based upon these and other characteristics, clusters of interrelated entities can form niches within the regional health and biomedical sector that shed light upon what that region does best and where emerging areas of opportunity lie.

The bubble chart in Figure 3 provides a useful snapshot of three key employment variables that track recent performance—employment size (size of bubble), relative employment concentration (LQ), and recent employment growth (2001 to 2007). The quadrants in which the bubbles lie provide insight into the relative performance of each industry subsector and allow for a general characterization based upon these variables.

Figure 3. Kosciusko County Health and Biomedical Industry Subsectors, Degree of Specialization, Employment Growth, and Size, 2007



Note: Size of bubble represents employment level.

Note: data not shown for 3 local industries with fewer than 100 jobs in 2007—veterinary services; outpatient medical care; and research, testing, & medical labs.

Source: Battelle analysis of Bureau of Labor Statistics, QCEW data from the Minnesota IMPLAN Group.

Overall, the health and biomedical industry has experienced strong employment growth since 2001 and has a specialized concentration of jobs relative to the national average (LQ is 2.16). This places the red sector bubble squarely in the regional “stars” quadrant in the bubble chart and identifies a specialized and growing industry cluster overall. The health and biomedical sector in Kosciusko County is clearly

driving the 7% growth in the overall private sector through 2007. ***With total job growth of 39%, County health and biomedical firms have outpaced the total private sector across the board—every subsector has outpaced the private sector (7% growth) during the six-year period.***

Kosciusko County's large, growing, and highly specialized medical device and equipment sector can be considered mature and a regional "star." Medical devices and equipment has a rich history in and around Warsaw, Indiana and continues to be the primary health and biomedical subsector. This sector is critical to the region's economy and is clearly driving the overall regional health and biomedical industry. Accounting for nearly 6,000 jobs and 59% of health and biomedical employment, the subsector has a location quotient that is literally "off the charts" (the blue subsector bubble had to be placed lower than the actual LQ which exceeds 50 and would distort the entire bubble chart). In Kosciusko County, this sector has a relative concentration of jobs more than 50 times that for the national average (LQ is 51.86). County establishments numbered 16 in 2007 a level that has remained relatively steady though slightly lower than the 20 recorded in 2001.

Medical Device Firms Headquartered in Kosciusko County (examples):

- **Zimmer, Inc** (Warsaw, IN): headquarters, manufacturing and R&D facilities, and distribution center; manufactures joint replacements for knees and hips; spinal care; and a range of trauma, dental implant, and orthopedic surgical products
- **DePuy Orthopaedics, Inc.** (Warsaw, IN): century old firm was first commercial orthopedics firm in the US; produces orthopedic products for hips, knees, and extremities and related supplies and products
- **Biomet** (Warsaw, IN): manufactures musculoskeletal products from reconstructive (orthopedic joint replacement, bone cement, dental implants) to fixation and spinal products (spinal stimulation, hardware, and orthobiologics)

there are several manufacturing firms spanning industries such as machine shops, metal coating and heat treating, steel investment foundries, and services firms in engineering and computer systems design. Together, these industries have been grouped in order to track and characterize the key role of “strategic medical device supplier industries.”

In 2007, Kosciusko County firms employed more than 700 in strategic medical device supplier industries, a figure that has grown since 2001 by 200 jobs or 40%. The region has a specialized concentration of jobs, with an LQ of 1.25. These County firms are primarily in manufacturing with a small share providing services. When combined with the regional medical device firms they supply, the County is home to 6,700 jobs in this group of interrelated device industries.

MedCast, located in Warsaw, uses an investment metal casting process for precision medical implants and instrumentation to supply the medical device sector. Precision casting tools and techniques are combined with advanced materials and metals to produce hips and knees, staples, and other medical implants.

A third specialized subsector in Kosciusko County is health industry wholesale. With 17 establishments employing 400 County workers, industry firms are engaged in medical, dental, and hospital equipment and supplies wholesales. Though the employment level is somewhat modest, the medical wholesale industry is highly concentrated in Kosciusko County relative to other regions around the country—the industry LQ is 3.41 or nearly three and a half times the average concentration of jobs. These establishments distribute the professional medical equipment, instruments, and supplies manufactured locally and may or may not be part of the manufacturing company.

The County’s hospitals sector consists of one establishment, Kosciusko Community Hospital in Warsaw, employing approximately 1,100.⁶ Hospitals play a vital role in delivery of health services and apply the technology and products developed in the other subsectors of the broader health and biomedical industry. County hospital employment has remained steady in recent years, rising by 10% since 2001.

Personal care facilities span a range of residential care arrangements and serve multiple groups from the elderly in nursing care to the mentally ill. In Kosciusko County, the subsector from an industry employment perspective is almost entirely within nursing homes. County nursing homes employ more than 600 in 2007 within eight individual establishments.

Prior to 2007, Kosciusko County had no employment in the drugs and pharmaceuticals subsector. At that time, the region added an establishment with nearly 200 jobs, and given the relatively modest size of the County, immediately boosted the location quotient to 2.12. Jobs in the drugs and pharmaceuticals subsector typically are well-paid and range from R&D activities in a laboratory setting to highly skilled manufacturing in production facilities.

Key Detailed Industry Drivers

While analysis of the 11 major subsectors of the health and biomedical industry provide insight into the regional strengths and niches of the sector, delving further into the detailed, six-digit NAICS industries that drive these subsectors is often very useful for identifying key drivers at the micro level.

Using a minimum employment threshold of 150 County jobs, the presence of at least two establishments and a requirement that the industry be a regional specialization (LQ greater than 1.20),

⁶ BLS does not disclose the data for industries with only one or a few establishments for confidentiality purposes. Data from IMPLAN estimate these “non-disclosed” estimates and in this case estimates 1,100 County jobs for 2007. This differs from the Kosciusko Community Hospital website which reports a current figure of 890 (see <http://www.kch.com/>).

this analysis identified five detailed industries that are key to the industry as local drivers and niche strengths:

- Detailed County industries with a large and specialized employment base:
 - Medical Devices:
 - **Surgical Appliance and Supplies Manufacturing** (5,597 jobs; LQ is 203.13)
 - **Surgical and Medical Instruments Manufacturing** (382 jobs; LQ is 12.26)
 - Personal Care Facilities:
 - **Nursing Care Facilities** (639 jobs; LQ is 1.42)
 - Health Industry Wholesale:
 - **Medical, Dental, and Hospital Equipment and Supplies Wholesalers** (396 jobs; LQ is 7.52)
 - Strategic Medical Device Suppliers:
 - **Electroplating, Plating, Polishing, Anodizing, and Coloring** (169 jobs; LQ is 8.34)

Industry Wage Analysis

Comparisons of annual wages by industry provide insight into the relative demand for and supply of workers within a regional labor market. Specifically, wage premiums paid to workers in industries like the health and biomedical sector signal the strong demand for highly-skilled and well-educated workers that drive the high-value commercialization in the sector. ***Similar to the wage relationships seen nationally, the Kosciusko County health and biomedical sector pays average wages to its workers well above those earned by their counterparts in the rest of the private sector.***

In 2007, Kosciusko County health and biomedical workers earned, on average, just over \$66,000 per year. This compares to \$41,725 for the average County private sector worker (see Table 3). The wage premium earned by these regional health and biomedical workers, at \$24,500 (or 59% more) exceeds that earned by workers in the national industry at \$5,900 (or 13% more).

Workers in the health industry wholesale subsector earn, by far, the highest average wages in the County, more than \$127,000 annually. Employees of the County's niche strength and largest employer, medical device production, earn more than \$81,000 per year, on average, compared with the US average wage of \$64,000. In general, County workers providing health services (in hospitals, personal care facilities, ambulatory services) earn much less, on average, than their counterparts in the biomedical manufacturing subsectors. This wage relationship also holds true nationally.

Table 3. Average Annual Wages for Kosciusko County Health and Biomedical and other Industries, 2007

Industry	Avg. Annual Wages, 2007
Health Industry Wholesale	\$ 127,451
Wholesale Trade	\$ 86,970
Medical Devices & Equipment	\$ 81,470
Total Health & Biomedical Industry	\$ 66,253
Drugs & Pharmaceuticals	\$ 61,272
Management of Companies and Enterprises	\$ 61,083
Research, Testing, & Medical Laboratories	\$ 48,813
Doctor/Health Practitioner Offices	\$ 46,854
Finance and Insurance	\$ 41,888
Total Private Sector	\$ 41,725
Outpatient Medical Care Centers	\$ 40,786
Information	\$ 37,590
Strategic Medical Device Supplier Industries	\$ 36,825
Construction	\$ 33,276
Hospitals	\$ 32,726
Professional, Scientific, and Technical Services	\$ 32,546
Ambulatory Health Care Services	\$ 26,644
Personal Care Facilities	\$ 25,985
Veterinary Services	\$ 21,125
Retail Trade	\$ 20,860
Arts, Entertainment, and Recreation	\$ 18,636

Source: Battelle analysis of Bureau of Labor Statistics, QCEW data from the Minnesota IMPLAN Group.

Note: Subsectors of the health and biomedical industry are indicated in blue, bolded font.

Conclusion

Kosciusko County, Indiana, as of 2007, has positioned itself as a major regional medical device center. This regional specialization has led to a strong and still developing cluster of strategic medical device suppliers and wholesalers spanning a range of industries and has bolstered the broader health and biomedical industry. A sizable regional network of related healthcare service providers has developed within the County. While a severe recession began in late 2007 and continues today, it is clear that Kosciusko County had positioned itself well with strong momentum through 2007. At the core of its globally traded opportunities is the orthopedics cluster in Warsaw about which the following section provides significantly more detail.

V. Taking a Closer Look at Warsaw's Distinctive Characteristics and Challenges: Analysis by UC-San Diego Global CONNECT

According to a recent *Newsweek* magazine overview of major economic and political trends in the United States, the state of Indiana had one of the largest decreases in middle class citizens due in large part to the massive layoffs in traditional industries such as automotive manufacturing.⁷ In the 1950's, states such as Indiana were magnets for workers and homes to high wage industries, whereas today these states have a net loss in college graduates remaining in the state and an increasingly low-wage economy. In a century where knowledge and advanced technology-based industries and professional services such as finance, legal, general business and consulting are growth sectors, states such as Indiana run the risk of falling further behind.

Despite national and state-level indicators that paint an overall dreary picture, data on specific regions within Indiana point to more promising current economic activity and to opportunities for potential growth. Such is the case with the orthopedic device cluster centered in Warsaw in north central Indiana. The Warsaw cluster currently has a 60% share of the \$11 billion global market for hip and knee implants;⁸ it represents advanced manufacturing and well paid jobs across a variety of competencies; it is in an industry where demand is growing; it has national and global links, partnerships and platforms; and it is profitable.

Nonetheless, the cluster receives little attention in conversations or reports asking where future economic prosperity might lie in the state of Indiana. Further, the cluster is not sufficiently celebrated as an example of American inventiveness, entrepreneurship and competitiveness in the national conversation about re-engaging economies across the country to enhance prosperity for all. In short, the Warsaw orthopedic cluster in Indiana is a current and potential economic asset which has been neither supported nor leveraged to the extent it merits. As a standalone cluster, it is very impressive. Were its global assets to be more strategically leveraged and its muscularity better aligned with the equally robust pharmaceutical assets of the state, in areas of possible convergence such as biologics, Indiana might be better able to bridge into a stronger economic position in the 21st Century economy.

The 2001 study by the Battelle Technology Partnership Practice on Kosciusko County's health industry, summarized in the preceding section, identifies many strengths and promising opportunities for the region's medical device industry. However, the report also notes many challenges, including a lack of amenities that provide an attractive quality of life for employees, the need for collaboration among the major firms on issues where they may mutually benefit, workforce training gaps, and the ability of the industry to adapt to emerging technologies.⁹

The following section builds upon the findings of the Battelle report as they pertain to the orthopedic device industry and explores what may be motivating regional stakeholders to become more strategic

⁷ Newsweek, January 26, 2009, Vol. CLIII, No. 4.

⁸ Knowledge Enterprises, "The Orthopaedic Industry Annual Report", Institute for Orthopaedics, 2007. Figures based upon reported sales for Zimmer, DePuy Orthopaedics, and Biomet.

⁹ Battelle Memorial Institute, *Sustaining Kosciusko County's Health and Biomedical Industry for the 21st Century*, Prepared for the Indiana Health Industry Forum and Kosciusko Development, Inc., 2001.

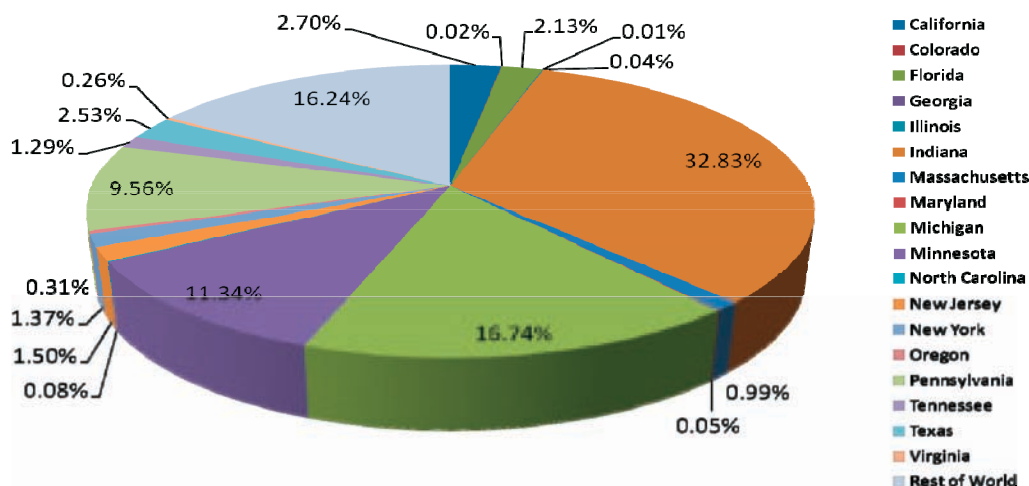
vis-à-vis sustaining and strengthening both the orthopedics cluster and the broader community moving forward. These discussions 1) revisit the assets this cluster represents, many of which have not been well understood or articulated; 2) describe the regulatory and technological trends affecting this cluster; 3) highlight the unique talent and infrastructure challenges the cluster faces due to its rural Indiana location; and 4) offer some observations and recommendations about how to catalyze the civic as well as economic interests of the region moving forward, in a strategic effort to assure continued growth and competitiveness. The primary purpose of these sections is to elucidate the civic and community challenges and opportunities related to assuring growth, beyond simple sustainability, in the Warsaw cluster. Much of this portion of the report was generated utilizing direct input from industry, business, governmental, and educational stakeholders. Information was gathered during a three-day visit to the Warsaw region in mid-December 2008. Several roundtable discussions were held to foster discussion surrounding the topics of this report and many more individual and small group meetings were held as well.

Several common themes emerged during these discussions. Issues ranging from workforce development, talent recruitment and retention and transportation infrastructure to educational, civic and cultural amenities were frequently raised. Select comments from stakeholders that were reinforced during many of the discussions with industry and community leadership have been incorporated into the following sections of this report.

Warsaw’s Orthopedic Strengths

A variety of reports by major economic consulting firms have described the major characteristics of the orthopedics cluster in Warsaw. As noted earlier, the combined revenue of Warsaw-headquartered Zimmer, DePuy, and Biomet constitutes nearly a one-third share (\$9.9 billion) of the \$32.5 billion global market for orthopedic devices, based upon 2007 sales.¹⁰ Figure 1 shows the percent market share by firm location. In the mid-term, prospects for market growth remain positive as baby boomers retire and increasingly look to repair or replace damaged joints with implants.

Figure 1 Percent Share of the Global Orthopedic Device Market by Location¹¹



¹⁰ Knowledge Enterprises. *op.cit.*

¹¹ Data includes Orthopedic Companies with 2007 Sales > \$5MM as reported by Knowledge Enterprises and independent research conducted by BioCrossroads.

This vibrant industry and its global reputation were built over time, beginning with the founding of DePuy in 1895. DePuy's success was the spark that fed the growth of an ecosystem of new companies, including Zimmer in 1926, Biomet in 1977, and a wide range of suppliers and business support providers that serve the larger firms. These developments provided continued momentum that has solidified the cluster's strong competitive position. The Warsaw region is now home to many of the key elements of the supply chain - discovery, research and development, product development, contract manufacturing, and packaging. Further, the cluster is now also the center of a global industry, with subsidiaries, customers, research centers, and strategic partners throughout the world. Combined, these activities all feed back into further reinforcing Warsaw's brand as *the* preferred location for innovative orthopedic device companies.

It is important to understand at a more granular level the nature of the assets in the cluster with a particular eye on undervalued and under leveraged assets, vis-à-vis the continued competitiveness of the cluster, growing prosperity in the region and even enhancing the well being of the entire state of Indiana. Obvious assets of the cluster are its global "brand" and reputation; the quality of its products; its market dominance; its long history of continuous adaptation and diversification; and its relationships with surgeons and healthcare providers around the world. Its less obvious leveragable assets include its growing national and international sites and partnerships which provide early access to market trends, regulatory changes and new developments in R&D; its small, but growing, locally anchored innovation and entrepreneurship experience and resources; its ready-to-serve education and training resources; and its yet-to-be-explored regional links to Fort Wayne and South Bend, which could provide some of the lifestyle and infrastructure needed for this growing, increasingly talent based industry.

The Warsaw Cluster: Headquarters of a Global Industry

The Warsaw region has developed a reputation as the "orthopedic capital of the world" due to the presence of several of the largest orthopedic medical device companies in the world. The devices produced by these companies and a surrounding network of contract manufacturers and suppliers include knee, hip, spine and other implants; braces, tools and instruments, as well as cases and trays. These firms rely on advanced science and engineering capabilities to produce products that are safe, effective, and durable. The knowledge required to meet such high standards includes an in-depth understanding of human anatomy, biomechanics, materials science, advanced machining techniques, surgical procedures, and the regulatory constraints on product designs. Additionally, the companies are actively aware of recent advances in tissue engineering and regenerative medicine. Although the new science of regenerative medicine seems to many to have mainly long term implications, all agree the next generation of orthopedic devices will likely include more biologic components, such as tissue regenerated from embryonic stem cells or adult stem cells, growth factors, and extracellular matrix. In order to maintain their leadership position, companies in the cluster have developed a wide-ranging network that extends far beyond the immediate Warsaw region. This national and international network of sales, manufacturing, R&D locations, and interactions with orthopedic surgeons connects Warsaw's companies to markets and innovative technologies, which can provide critical intelligence regarding market opportunities, regulatory issues, and new product development. Product lines and the companies' ability to innovate also have been improved through a strategy of targeted acquisitions throughout the US and abroad. Figures 2, 3, 4 and 5 show the various domestic and international geographic locations of firms based in the Warsaw region.

Figure 2 Domestic Locations of Warsaw, Indiana Based Device Companies*



*Maps created by UCSD GIS Lab using location information provided by Global CONNECT.

Figure 3 International Locations of Warsaw, Indiana Based Device Companies



Several of the larger original equipment manufacturer (OEM) firms in the Warsaw region are now multinational, or part of a larger multinational enterprise. For instance, Biomet has 58 office locations in 32 countries, representing the largest portion of the cluster's linkages (Figure 4).¹² DePuy Orthopaedics

¹² See <http://www.biomet.com/corporate/locations.cfm>.

is now a subsidiary of Johnson & Johnson, and therefore has access to the parent company's global network. DePuy's European headquarters are located in the United Kingdom, where it also has a ten-year collaboration with the University of Leeds to develop new materials and implant designs.¹³ Zimmer has offices in seven regions in the US and a European headquarters in Switzerland. Further, it has developed research partnerships with universities and companies in Kansas, Missouri, and Ohio.¹⁴ While Medtronic Spinal & Biologics' Warsaw facility largely interacts with its divisional parent in Memphis, Tennessee,¹⁵ it is also part of one of the world's largest medical device companies with offices in 11 different countries.¹⁶

Figure 4 Biomet National and International Locations



Contract Manufacturing

The Warsaw region's orthopedic medical device cluster also includes many contract manufacturers that fill a valuable niche in the supply chain for the larger OEM companies. Suppliers deliberately locate in Warsaw not only to be near their primary customers for logistical reasons, but to also take advantage of the knowledge base that exists in a geographically concentrated area and to leverage the region's global reputation for leadership in this industry. These firms are often an excellent source of information on market and technology trends. Firms such as DeGood, Micropulse, Paragon Medical, and Symmetry Medical deliver high quality implants, instruments, and components based upon the specifications provided by their clients. In addition to providing relatively straightforward manufacturing capabilities, several of these firms have moved up the value chain by also offering co-development and design services. With their own advanced engineering skills, these contract manufacturers also support innovation in the region by assisting clients with concept development and modeling, prototype development, testing and analysis, and even project management.

¹³ See http://www.yorkshirecic.com/view.asp?content_id=300&parent_id=232.

¹⁴ See <http://www.zimmer.com/z/ctl/op/global/action/1/id/10167/template/CP/navid/10104>.

¹⁵ Demetrakakes, Pam, "Plant is the backbone of spinal implant business: Medtronic's Sofamor-Danek facility packages up to 20,000 screws and other spinal implant components daily – one at a time." *Food & Drug Packaging*, May 1, 2007. See http://findarticles.com/p/articles/mi_m0UQX/is_4_71/ai_n27272899?tag=rel.res1.

¹⁶ See <http://www.medtronic.com/about-medtronic/locations/index.htm>.

Like the OEM companies, a few of the Warsaw region's contract manufacturers have built their own distributed networks via office locations throughout the US and internationally. This allows them to tap into specialized engineering and manufacturing skills while also being embedded in emerging markets, thereby augmenting their capacity within Warsaw. Examples include Paragon Medical, which has four US locations as well as facilities in Switzerland and China;¹⁷ Sroufe Healthcare Products now has a subsidiary that manufactures products in Vietnam;¹⁸ and Symmetry Medical, which has nine US locations, three of which are designated as Design and Development Centers (DDC), and six overseas offices, including one DDC in the UK (Figure 5).¹⁹

Figure 5 Symmetry Medical National and International Locations



R&D and Innovation Capacity in the Warsaw Region

The orthopedic companies in Warsaw primarily position themselves as traditional manufacturers. They are clearly much more than that. For instance, both Zimmer and Biomet's global R&D headquarters are in Warsaw. In fact, 800 of Zimmer's 1,500 researchers are locally based. This is complemented by a number of strategic R&D partnerships and acquisitions outside of the region. Nonetheless, during in-person meetings, company executives tended to understate their corporate capacity, R&D assets, and the potential value their innovative capabilities may bring to other industries within the state. Data on patent applications, sponsored research agreements, and scientific journal publications indicate that innovation is taking place within the region itself.

The number of patent applications and number of publications in scientific journals can serve as proxy indicators of innovative activity. From 2006 to 2008, 579 patent applications were submitted by

¹⁷ See <http://www.paragonmedical.com/locations.html>.

¹⁸ See http://www.sroufe.com/oem_services.htm.

¹⁹ See <http://www.symmetrymedical.com/About/SymmetryMap.aspx>.

inventors in Kosciusko County; approximately 475 of them related to orthopedic devices and procedures. During the same time period, the entire state of Indiana submitted 8,500 applications. Kosciusko County filed **76** applications per 10,000 people, while the state average was **13**, and the US average was **five**. Using only this one measure, one might say Kosciusko County is **over 15 times more innovative than the US as a whole, and five times more innovative than the rest of Indiana.**²⁰

Warsaw's performance with patent applications is particularly notable given the lack of a research university located in the immediate area. However, firms are working with researchers at the University of Notre Dame, Purdue University and Indiana University. From 2000 to 2008, orthopedic companies sponsored 11 research projects at Notre Dame and 14 projects at Purdue. Research areas included biomaterials, minimally invasive surgery, gene therapy, and modeling among others. Zimmer was the most active, supporting 11 projects between the two universities.²¹ During the roundtable discussions held in Warsaw, industry executives stated that co-op programs have also been established with the three universities.

While the outcomes of industrial research are often proprietary and therefore unpublished, from 2006 to 2008, three Warsaw-based research units published 11 articles in scientific journals. Biomet and Zimmer both published five articles and DePuy Orthopaedics published one.²² Although small in number, the articles do cover a wide range of topics, including surgical techniques, polymer materials, testing of joint implants, tissue engineering, and bone graft material.

Ready-to-Serve Education and Training Resources

Two local educational resources relevant to the cluster are Grace College and Ivy Tech Community College. Grace College, under the leadership of President Ron Manahan, was singled out in nearly every interview and roundtable as an essential and evolving resource in the success of the cluster. It appears to be a highly trusted "honest broker" institution in an environment of companies which, for the most part, see one another as competitors even though they understand the idea that the cluster and its overall robustness is what enables their individual success. Grace is universally perceived as a critical resource and catalyst, not only by orthopedic companies, but by civic leaders and the business community. Grace's leaders can get people in the room, they deliver on promises and they aspire to be an enabler of civic development and economic prosperity. In our interviews, Grace College was valued for a range of services and initiatives seen as benefiting the cluster and the region's quality of life. These include such things as establishing a 56,000 square foot facility for community events and conventions, the Orthopedic Capital Center, in partnership with Biomet, DePuy Orthopaedics, Paragon Medical, Symmetry Medical and Zimmer. These companies have contributed \$3.25 million towards construction costs.²³ Grace College also supports the region's cultural development through its involvement with the Warsaw Symphony Orchestra and its own Masterworks Festival, and its science, technology, engineering, and mathematics (STEM) initiatives are helping to boost science education in the region.

Ivy Tech is another valuable asset which has now established an advanced training site in Warsaw with \$2.8 million in private support to assure that the equipment and curriculum needed to train technical people is in place. Focused on the kinds of advanced manufacturing and technical skills critical to the

²⁰ United States Patent and Trademark Office database: <ftp://ftp.uspto.gov/pub/patdata>. Per capita patent rates determined using US Census Bureau population estimates. See <http://www.census.gov/popest/estimates.php>.

²¹ Data on industry sponsored research projects at the University of Notre Dame and Purdue University provided to Global CONNECT by BioCrossroads.

²² Data returned from the PubMed database: See <http://www.pubmed.gov>.

²³ See <http://www.grace.edu/alumni/orthopedic/>.

industry, the college is purchasing equipment and leasing space required for delivering new training programs. However, Ivy Tech is concerned about the reliability of state matching funds and the influx of unemployed recreational vehicle and auto workers from neighboring towns such as Elkhart, who often do not come with the basic educational foundation needed to be successfully trained in advanced manufacturing. It is imperative that Ivy Tech develop programs collaboratively with the orthopedic industry, in order to assure that the standards and competitive skills essential to the workers they need are addressed. This means collaboration in curriculum development, potentially using industry practitioners as faculty and the development of clearly defined criteria for admission and graduation from training programs. It is not clear whether this has yet been achieved. Indeed, the current facilities and curriculum do not appear to match the “state of the art” needs of the global companies in Warsaw.

The region’s geographic proximity to both South Bend and Fort Wayne also could be turned to advantage, as campuses of globally recognized institutions (Notre Dame, Indiana University and Purdue University) are located in these other cities, even though they are not yet deeply connected to the Warsaw cluster. Indiana University has the second largest medical school in the US with satellite campuses in South Bend and Fort Wayne and all three offer leading science programs which represent a variety of basic and clinical research activities of potential value to the cluster and a pipeline of technical and scientific graduates, as well as business school graduates for whom careers in the cluster would be an attractive option. However, to tap into these resources requires industrial collaboration in the region, as well as agreed upon strategic initiatives. There is no current organization in the region which is providing the vision and leadership that could enable partnerships with these research universities.

Innovation and Entrepreneurship Assets: The Micropulse Example

Micropulse and its founder Brian Emerick represent the quintessential American business success story. Beginning in his garage in 1988, Emerick grew Micropulse into a leading contract manufacturer for most of the major orthopedic medical device companies across the US, including Warsaw-based Biomet, DePuy, and Zimmer. With approximately 150 employees, Micropulse produces implants, tools, instruments, sterilization cases and trays, and also offers product design, preproduction planning, and program management services to its clients.

Interestingly, Emerick did not begin his career in medical devices. He started out as a Tool & Die Maker in 1979 at a large shop in Fort Wayne doing work for the automotive and electronics industry, while taking night classes at Indiana University-Purdue University Fort Wayne (IPFW) in mechanical engineering. Shortly after starting his business, he began doing a lot of new product development prototyping for a small spine company in Winona Lake called Warsaw Orthopaedics, today's Medtronic Spine & Biologics. Although Micropulse took on plenty of projects outside the orthopedic industry throughout the 1990s, seeing the brightest opportunity in the orthopedic area, he decided to transition fully into medical devices. Under Emerick's leadership, Micropulse was built by focusing on cutting-edge niche products. Over the years, the company grew organically on a foundation of integrity and a long-term strategy of reinvesting profits back into the company. As an example, the company recently expanded its facility space by 47,000 square feet and has added over \$6 million in equipment to better accommodate future business. Recognizing the need for improving his personal leadership skills, Emerick has completed a Bachelor's in marketing from Indiana Wesleyan and an MBA from Notre Dame in the last five years. He stated, "In order to be the best leader for Micropulse, I either needed to raise my game or hire my replacement. Since I love what I do, I decided to seek further education and training."

In addition to building a successful contract manufacturing business, Emerick has become a strong supporter of local innovation and entrepreneurship by working with several startup companies, entrepreneurs, surgeons, and universities. Beginning with DVO Extremity Solutions, Emerick has directly invested in and served as an advisor or board member for eight startup companies in the Warsaw region in recent years. For some of those that he invests his own money in, he offers space within Micropulse to help incubate the company, while also providing the startup with access to support services such as capital raising, accounting, legal, regulatory, product design, prototyping, manufacturing, and even distribution. Four startups are currently incubated within Micropulse; one is located in Purdue University's research park, with the others located in Warsaw. Emerick saw DVO through a successful acquisition by an outside company, and is also involved with VOT Arthroscopic Solutions, BioSpine, DelPalma Orthopaedics, S-Med, Argent Technologies, Nanovis, and OrthoPediactrics.

Emerick invests in new ideas that typically come from surgeons, universities, and people who have worked for some of the larger, established device companies in the Warsaw region, and who desire to leave the large corporate environment. Emerick helps assemble the right team of management, surgeons, sales and marketing, engineers, and strategic investors. He also keeps an eye on possible strategic partnerships with larger companies, who in turn may be looking for attractive future acquisitions.

With Micropulse still his core business, Emerick is working towards a quadruple bottom line by incubating and advising new startups. Besides seeking a return on his financial investment, he is also growing the innovative orthopedic medical device industry in north central Indiana, increasing Micropulse's future customer base, and helping cultivate the next generation of successful entrepreneurs.

Industry Challenges and Pressures

The Changing Policy Environment for the Orthopedic Industry and Implications for the Dominant Technologies in the Warsaw Cluster

Not all orthopedic devices are federally regulated, and many companies manufacture or distribute both regulated devices such as surgically implantable devices, and unregulated devices such as external knee braces, orthotic shoe inserts, and the like. The path to profitability for regulated devices is obviously more complex, and companies producing regulated devices must continually monitor the changing Federal policy environment and the reimbursement policies of payers.

Changing US Food and Drug Administration (FDA) Approval Environment

According to some experts,²⁴ the main driver of increased cost to regulated orthopedic device manufacturers is the increased stringency of the regulatory climate at the FDA, beginning in the 1990s, when the agency's increasingly risk-averse climate, engendered by missteps with high-profile drugs, caused both a slow-down in approvals and stricter testing requirements. The FDA's Center for Devices and Radiological Health (CDRH) points out that the increased complexity of the devices means increased amounts of information that must be evaluated in a safety and efficacy determination.

Low risk Class I devices such as surgical scalpels or reading glasses, and Class II devices such as hearing aids or bone cement receive quick clearance. Class III devices such as implanted orthopedic devices, artificial heart valves, and pacemakers are the most complex and potentially pose the greatest risk to patients. Congress originally allowed those Class III devices "substantially similar" to devices already on the market be given minimal reviews, but with the caveat that the FDA should set a deadline and write rules for demonstrating rigorous testing of Class III devices before approval. Recently the US Government Accountability Office (GAO) issued a report critical of the FDA pointing out that the promises the FDA made 14 years ago to fix its system for approving complex medical devices have yet to be acted upon,²⁵ and that most Class III devices receive only cursory review. The GAO recommended that for a subset of Class III device types,²⁶ the FDA issued new regulations, requiring the devices to undergo full Pre-Market Approvals (PMAs) or reclassifying them to a lower class of device. The Department of Health and Human Services agreed with the recommendation.

A non-governmental watchdog group, Project on Government Oversight (POGO), also issued its report, "The FDA's Deadly Gamble with the Safety of Medical Devices".²⁷ The report is critical of the fact that in 2006 the FDA's CDRH decided not to enforce the regulation requiring preclinical testing of devices to be used in humans be done in conformance with the FDA's Good Laboratory Practices (GLP) regulations.

These critical reports will increase the pressure to require full PMAs of new joint implant devices – a process that will require extensive testing on the part of the manufacturer, and an approval process that will be much lengthier, and the requirement that preclinical testing be done in conformance with GLP. The FDA states that the PMA full scientific and regulatory review to evaluate safety and efficacy for the

²⁴ Katsnelson, Alla, "Biotech's Hidden Stepsister", *The Scientist*, Oct 2008 p 33-37.

²⁵ United States Government Accountability Office, "Medical Devices: FDA Should Take Steps to Ensure that High-Risk Device Types are Approved Through the Most Stringent Premarket Review Process", GAO-09-109, January 19, 2009. See <http://www.gao.gov/new.items/d09190.pdf>.

²⁶ Class III orthopedic devices noted in this subset were metal-on-metal hip implants and pedicle screws (anchor points for spinal fusion).

²⁷ Project on Government Oversight, "The FDA's Deadly Gamble with the Safety of Medical Devices", February 19, 2009. See <http://www.pogo.org/pogo-files/reports/public-health/safety-of-medical-devices/ph-fda-20090218.html>.

intended use is intended to take 180 days. However, the FDA itself admits that the review time is normally longer.²⁸ The longer a patented device is held up from approval, the more revenue is lost, due both to the expiration of the patent, but also the fact that reimbursement approvals for regulated devices depend on FDA approval, and there is essentially no market for a device without a reimbursement code.

However, the industry will strongly resist any changes to the PMA requirement, and, given that the leadership of the FDA is in flux with the change of presidential administrations, it is unclear what the FDA's position on this issue will be going forward. The uncertainty in these issues, which could have major financial and time-to-market impacts for the industry, adds to the Warsaw cluster's business risk.

Reimbursement Environment

To be sold, a new device, whether regulated by the FDA or not, must gain a place on the list of acceptable devices and procedures maintained by the payer paying for the procedure. With healthcare costs being a perpetual problem and political hot-button, it is becoming increasingly difficult to convince payers, the largest of which is the US Government's Centers for Medicare and Medicaid Services (CMS) but also includes all private insurers, to cover new procedures or products for an indication when there are already existing solutions. According to Mir Imran, who runs InCube Labs and InCube Ventures, a California med-tech incubator and venture fund, respectively, device companies rarely achieve reimbursement in less than a year *after* FDA approval, and often the approval takes closer to five years.²⁹ Bill Starling, a partner of VC firm Synergy Life Sciences Partners, states "CMS has no incentive to approve anything unless there's a huge amount of data."³⁰ Without data, no reimbursement code is given; without a reimbursement code, a surgeon is effectively prevented from implanting the device; and without usage data, no code can be assigned: a classic chicken-and-egg dilemma.

Increased Scrutiny of Surgeon Networks

Innovation in product design largely comes from the industry's extensive network of surgeons in the US and overseas. This network is built through traditional sales and distribution relationships. It has also been built proactively through training centers set up by the manufacturers themselves. For instance, Medtronic's Bakken Education Centers allow medical professionals to learn more about the company's products and receive training on how to use them. The centers also provide the opportunity for the company to receive feedback from their end users. There are twenty-two centers located throughout the world, seven of which are in the US.³¹ In 2003, Zimmer launched the Zimmer Institute in Warsaw to train surgeons on minimally invasive joint replacement techniques. It also serves as a test bed for new ideas, such as the company's "O.R. of the Future" initiative. In addition to the 15,000 square foot facility in Warsaw, Zimmer is working with hospitals and educational institutes to deliver Zimmer courses around the world.³²

The brief Medtronic and Zimmer examples presented here only hint at the full extent of the surgeon networks that Warsaw orthopedic device companies have created. However, it should be noted that questions have been raised regarding the way in which these networks function, particularly around the issue of financial inducements offered by the companies to surgeons who use their products. As a

²⁸ FDA, "Device Advice", <http://www.fda.gov/cdrh/devadvice/pma/>

²⁹ Katsnelson, A., *op.cit.*

³⁰ *Ibid.*

³¹ See <http://www.medtronic.com/about-medtronic/locations/index.htm>.

³² See <http://www.zimmer.com/z/ctl/op/global/action/1/id/265/template/MP/navid/266>.

result, in September 2007 five orthopedic device firms, including Biomet, DePuy Orthopaedics, and Zimmer, entered into five-year Corporate Integrity Agreements with the US Department of Health and Human Services' Office of Inspector General which requires the companies to enact reforms and undergo federal monitoring.³³ These agreements place restrictions on consulting contracts companies have with physicians. Companies must now disclose the names of all physician consultants and the amount of compensation for each. Companies must also conduct a needs assessment to determine what a reasonable demand is for product-development consultants and educational consulting services. Physicians must disclose all of their financial arrangements with these companies to their patients. Whether the new constraints will have large-scale unintended consequences on the ability to develop new design improvements remains to be seen. However, some effects have already been noted. For instance, Zimmer reported in its Q3 2008 financial results that disruptions caused by the transition to a new model of collaborating with surgeon consultants have had a negative impact on operating revenues.³⁴ One financial article indicated that as a result, Zimmer's stock price dropped to six-year lows.³⁵ These Corporate Integrity Agreements may result in the need for a broader focus on innovation strategies and resources.

Current safe harbor guidelines limiting surgeon ownership of orthopedic device companies to 40% could affect how innovative startup companies are established. The ownership limitation means that there will now be a 60% equity gap which has to be filled by other types of investors, such as non-surgeon angel investors and venture capitalists, both of which are becoming increasingly difficult to access. The implications of these two developments need to be better understood if the region is to continue to be an industry and innovation leader.

Patent Regulations

Recent proposed changes to the patent system suggested by the United States Patent and Trademark Office³⁶ would make it much more difficult to file more than one amendment to a patent application. Since devices are designed iteratively, and often continuous improvements adjusting an original design are made during testing, being able to amend a holder's existing patent application would be the more appropriate step, rather than claiming a novel invention and beginning the patent application process anew.

In addition, the bar for determining whether an invention is "obvious" has gotten higher. Both changes raise legal costs and as importantly, cause longer time lags in the granting of a patent. Patentability issues affect both regulated and non-regulated orthopedic devices.

Evolution of Technology

The holy grail of biomedicine would be the successful replacement of failing or poorly functioning organs, cartilage, bone, and entire joints with those regrown from the body's own cells. The tissue engineering world of the 1980s and 1990s had the goal of growing replacement organs. Today's regenerative medicine has the more modest and achievable goal of developing therapies that will induce the body to heal itself. Progress toward this goal is being made in many research institutions, through the use of adult stem cells or embryonic stem cells, as well as with conventional cell culture

³³ See <http://www.usdoj.gov/usao/nj/press/files/pdf/hips0927.rel.pdf>.

³⁴ Zimmer Holdings Q3 2008 Financial results.

³⁵ CNN Money, "Orthopedics Firms to Lose Oversight, Keep Payment Controls," February 11, 2009.

³⁶ Federal Register, Vol. 71, No. 1, Tuesday, January 3, 2006, pp 48-61. Proposed Rules, Patent and Trademark Office, 37 CFR Part 1 [Docket No.: 2005-P-066]

beginning with already-differentiated cells of the desired type. Stem cell research directed toward replacing whole organs, although showing great promise, is still in its infancy. Much remains to be learned in order to reliably guide stem cells to differentiate into the desired lineage, and to provide the necessary environment to allow them to form fully functional entire organs.

Many research groups are now growing artificial tissue in the laboratory, some with success in coaxing adult or embryonic stem cells to differentiate correctly, to populate a carefully designed three-dimensional scaffold and demonstrate some organ functionality. For example, MIT has demonstrated the production of human cartilage, and its successful implantation into immunocompromised mice. (Immunocompromised mice are used to avoid rejection of human tissue.)

Biologics and tissue regeneration products require cell culture and tissue culture facilities; bioreactors instead of the machining, casting, forging, and polymer forming technologies required for conventional orthopedic devices. Existing orthopedic device companies will need to acquire or build entirely new manufacturing facilities in order to accommodate orthobiologics.

Orthobiologics sales will also require a sales force with advanced technical training completely different from that for conventional devices. Surgeons likewise will need training in a new field having little overlap in subject matter with conventional implantable devices.

Pressure to Institute a Joint Implant Registry

Currently the United States does not track the success record of joint implant surgeries, although many other countries (e.g. UK, Canada, Scandinavian countries, Australia) and some HMOs (e.g. Kaiser-Permanente) do. Joint implant registries, depending on the detail of the data collected, allow surgeons, providers and payers to track the revision rate (repair surgery required within one year) for individual devices, and in some cases, for individual surgeons. Although the American Academy of Orthopaedic Surgeons strongly supports such a registry and states that everyone would benefit from such a registry which would in effect add valuable quality control,³⁷ the AAOS also recognizes the medical/legal and other obstacles to establishing such a registry in the US, such as, Health Insurance Portability and Accountability Act (HIPAA) compliance requiring patient record privacy and security; reluctance of surgeons to be tracked individually; reluctance of device manufacturers to have successful devices downgraded by comparison to slightly better ones; and the cost to providers of providing data to such a system.

Warsaw device manufacturers naturally have a concern that the implementation of such a registry, if required, might affect the market for those devices that appear to have a poorer revision history than others.

Implications for the Orthopedic Device Cluster in Warsaw

Orthopedic device companies face the prospect of more time, money, and innovation being required just to maintain current market position. Added to this are the difficulties of gaining speedy FDA approval for a new device; getting the device classed as a Class II (less risk, therefore lower safety requirements) rather than Class III (viewed as most risky to patients); and achieving a reimbursement code that allows a sufficient profit margin within a reasonable time lag. These are problems shared by all regulated device developers and manufacturers. However, the companies feel that their strategies for optimizing the path to FDA approval, and the path to reimbursement success, are an important part

³⁷ Hayashi, Annie, "Building a national joint replacement registry", <http://www.aaos.org/news/aaosnow/mar08/cover2.asp>

of their intellectual property. Therefore, they do not wish to discuss common problems or strategies for solution with their competitors. The orthopedic companies instead depend on their trade association for any coordinated actions such as lobbying the FDA, interacting with payer groups and the like.

The orthopedics industry, whose history in Warsaw dates back to 1895 and Revra DePuy's company founding, followed by Justin Zimmer establishing his company in 1926, and then in 1977 with the founding of Biomet, has been characterized throughout as a machining, casting, forging and polymer forming manufacturing business. Were new technologies to take hold, particularly with regular breakthroughs in new biomedical research and regenerative medicine, the Warsaw cluster could find itself challenged by new competitors or even threatened by radical breakthrough technologies. Research on the history of innovation suggests that often robust clusters with large global markets, such as typewriters, mainframe computers and automobiles, ignore at their peril the breakthrough innovation that could change the nature of the marketplace for their products.

The Warsaw cluster is perhaps better positioned than the industry as a whole to anticipate and integrate a variety of the scientific and technological developments on the horizon. Some Warsaw companies, such as Biomet, Zimmer, and Schwartz BioMedical among others, have been conducting exploratory work on biologics and tissue engineering. There have been some questions about how well the industry as a whole is prepared to shift to a very different technology base. Not only will different types of facilities and equipment be required to produce next generation devices that incorporate biologics, but those manufacturing products in the industry will need a vastly different set of skills, more akin to specialty fermentation than to specialty machining. However, since there are many hurdles to be faced before tissue regeneration products are ready for trial in humans, and since the regulatory path is expected to take five years at a minimum for stem cell products,³⁸ the conventional orthopedic device industry has time to adapt to a gradual shift. According to an executive in a tissue engineering firm, because there have been no "blockbuster" products to-date in the cell therapy, tissue engineering or gene therapy space, the investment necessary to bring these products to market is currently not available. It is likely, therefore, that biologics will only gradually gain some fraction of the overall orthopedic device market, while at the same time, the market continues to grow due to aging baby boomers' staying active well into their retirement years. In addition, some experts feel that conventional orthopedic devices will be engineered to incorporate more biologics, such as integrating ligament regenerating capability with a conventional metal and polymer replacement joint, or including time-released anti-inflammatories into device materials.³⁹ One tissue engineering company CEO, when asked in 1998 to predict when engineered cartilage would become commonly available, opined that it would be available in ten years. When asked the same question in 2008, the executive mentioned her previous prediction and again predicted successful product production would occur ten years in the future. Clearly the alert orthopedics company making careful preparations now will have time to morph itself appropriately for the future.

Continued creative thought about aspects of these kinds of constraints on innovative development that might be amenable to cooperation and collaboration is still worthy of vigorous pursuit.

³⁸ Robert Lanza, CEO of Advanced Cell Technology, a stem cell biotech company, as quoted by CNN Money's author Aaron Smith, Oct. 31, 2007.

³⁹ P. Rejto. Computational Chemistry, Pfizer La Jolla, private communication.

Challenges Facing the Warsaw Cluster

Talent Attraction and Retention

The Warsaw cluster has benefited from decades of talent which has been cultivated locally or has returned to the region, with experience and networks which enhance the industry. For this cadre, small town Indiana and a closely knit local industry is a big part of why they work there. However, increasingly, the engineering, marketing and manufacturing know-how required in this globally positioned sector requires people who crave more economic and cultural amenities than the Warsaw region can offer. This may include people who have professional spouses who also need jobs, people who are single and desire diversion, or people whose religion or ethnic backgrounds can make them feel isolated.

In our interviews, an executive from one of the orthopedics companies mentioned the challenges of recruiting and retaining employees in Warsaw, and the frequent loss of talented young and single professionals who are not from the area.

Others stressed the need to address how to assure the quality of life that professionals need in order to keep and attract the best senior level talent.

Several community and business leaders cited the lack of cultural and recreational amenities that inhibit attraction and retention efforts. “Community assets aren’t developed here,” said one roundtable participant.

“...The lack of things to do in the community makes it difficult for [recruited] people to stay in the area for very long,” according to a senior leader at an orthopedics company.

Still, some noted that a local symphony performs concerts year-round and a greenway trail system has made positive strides in addressing some of these concerns. There does seem to be support among all of the groups that were interviewed to organize additional opportunities to bring more diverse activities to the community, such as a farmer’s market.

The need for more preK-12 educational options was cited often as a concern for the community. There is only one school system in Warsaw, leaving no choice for parents. Many participants in the discussions mentioned that Warsaw workers, especially in leadership roles, live in South Bend or Fort Wayne, due to the additional school choices, extra-curricular school programs, child care availability and university-related programs.

According to some participants, many parents drive children as far as Purdue’s campus in West Lafayette (a two-hour drive) in order to participate in educational enrichment programs. A few suggested that Purdue and Grace College could collaborate and create similar programs for Warsaw area elementary school children.

Equally important is the constant need for a pipeline of technicians, machinists and manufacturing workers in the industry. Internal training programs enhanced by Ivy Tech developments are promising (and there was a 37% increase in enrollment in Ivy Tech’s Warsaw training facility in 2008), but there is much to suggest that the K-12 pipeline and a large share of recently unemployed auto workers lack many of the habits and learning capacities the industry needs.

The investments that industry is making in Ivy Tech and industry engagements with Grace College speak to the orthopedic companies’ shared concerns about these challenges. A better articulation of the K-12,

community college, and university education paths into the industry might be helpful, and a model already exists: In 2008, several stakeholders in the Indianapolis region came together to propose the establishment of a charter school to better prepare high school students for the architecture, construction, and engineering industries. As envisioned, the Indiana Architecture, Construction, and Engineering (ACE) Academy brings together local government, labor groups, the building industry, and Ivy Tech to deliver this new training program.⁴⁰ A parallel orthopedics initiative in north central Indiana could enhance the pipeline of talent for this cluster.

An expanded sense of regionalism also could help with talent issues on multiple fronts. A more strategic alignment with other communities could help address some of the lifestyle issues faced by some potential employees. Enhanced transportation infrastructure, even shuttles, could support an easier flow of workers and residents across the region, so that the distinctive assets of disparate communities could be enjoyed by all.

Diversified Economic Base

North central Indiana has not fully benefited in the financial, business services and residential or commercial real estate sectors from the robust orthopedics cluster anchored in Warsaw, in part because of its self containment, but also because of its reliance on Chicago and other urban centers for such services. Similarly, certain kinds of suppliers/services purchased at a distance could be more localized, such as sterilization facilities and testing facilities for regulatory compliance. As a result, critical components of an integrated economic cluster are missing; components which could mean more high-wage jobs in the region, i.e. technicians, accountants, attorneys, marketing professionals, etc. There has been little serious discussion in civic organizations or economic development forums of the value of supporting growth in these sorts of services. Based on the experience of other regions with strong tech industries, the growth of a supportive business service sector would be good for the overall well being of the region, as well as the continuing competitiveness of the orthopedic cluster. Interviews revealed a potential interest in creating incentives/momentum to accomplish this.

Geographic Challenges

Warsaw is isolated geographically – a fact that creates unique challenges to supporting a majority of the world’s orthopedic industry. Throughout the interviews and roundtable discussions, transportation issues and the remote locale of Warsaw often were cited as a challenge for conducting global business. Transportation and logistics are crucial to moving people and products throughout the globe on a timeline that is often determined by operating room schedules, and not by the time the last FedEx shipment can go out. Additionally, business and leisure travel for the thousands of highly-skilled employees in this region is more difficult than in competing specialized orthopedics regions.

The large orthopedic manufacturers have state-of-the-art surgeon training facilities that are impeded by the lack of commercial air access, especially since surgeons have limited time because of their need to be on-site at their hospitals and their busy operating schedules.

One of the local supplier companies holds its Board of Directors meetings in Chicago in order to avoid the expensive and cumbersome travel to Warsaw. It is also difficult for company leadership to travel to facilities around the globe from Warsaw. It may not be feasible to add direct air service to a local municipal airport, but attention should be paid to alternative forms of transportation to enable efficient travel from this robust economic center to regional transit hubs.

⁴⁰ See <http://www.indianaaceacademy.org>.

Timely distribution of products also is crucial to the success of the orthopedic industry. Vehicular access for cargo and the lack of air cargo service (even via small planes) at the Warsaw municipal airport is a concern identified by both industry and civic leadership. Specifically, a leader at one of the supplier companies mentioned that they cannot ship a product with next-day delivery after 3 pm.

The challenges of Warsaw's location aren't limited to airline travel. One company executive said that he often brings in a candidate for an engineering position, makes a job offer, and then has to tell the prospective employee that his or her new home will be a one-hour drive to the airport, mall, and closest auto dealership. Far too often, such factors become deal breakers for successful recruitments.

Seeing a different side, the president of a Warsaw business noted the people in Warsaw "can live in splendid isolation" *because* they have access to Fort Wayne and its shopping and airport as well as to South Bend with the amenities of Notre Dame and its television stations.

Summary Observations on the Warsaw Orthopedics Cluster

The Warsaw orthopedics cluster has evolved over time, drawing upon the vision and entrepreneurship of its early founders, DePuy and Zimmer. It propelled into global dominance by innovations in technology over the course of the 1970s and 1980s, experiencing growth in demand, as well as achieving a critical mass of design and manufacturing talent over the past decade. This sector has the potential for continued innovation, adaptation and growth if it can manage the shifting regulatory and reimbursement environment, all the while continuing to serve existing customers. The cluster must also be prepared to adapt to and adopt the results of biomedical research that will gradually transform the industry in the coming years.

Untapped Regional Assets

Warsaw, the community of Winona Lake, and the surrounding rural countryside all represent assets to a wide array of people both inside and around the orthopedics industry. An unusual number of principals and leaders within the established companies, the supplier networks and entrepreneurial enterprises are native Hoosiers who have either returned to the region after work experience elsewhere or have never left the state. Pride of place, an affirmation of small town values, and an appreciation of the lakes, farms and open space across the region was expressed by a surprising range of people. In an era of freeway traffic, often anomic suburbs and impersonal commercial and public services, people seem to feel Warsaw represents a real alternative. Such strong attachment to the region is clearly valuable for the attraction and retention of qualified talent for local industry, including the orthopedics cluster. However, this sentiment does not appear to be promoted among the strengths of the region.

Warsaw could look to its contiguous communities such as South Bend and Fort Wayne to augment many of the amenities it is lacking. The need for educational enrichment opportunities for children, more diverse arts and cultural events, a wider array of shopping and dining options, more varied housing stock could all be realized if Warsaw, the unchallenged economic hub and driver of industrial growth in the larger region, could find ways to align with and leverage nearby communities with complementary assets. Fort Wayne, for example, may not be able to duplicate the robust orthopedics cluster in and around Warsaw, but its housing industry, commercial developers, business service providers and food and entertainment industries could benefit from the employment growth in Warsaw. This may be the moment in time for Warsaw to enhance its critical economic leadership position with a civic and regional development initiative focused on broader issues relevant to improving the quality of life throughout north central Indiana. To do this, it must first achieve consensus within the industry that this is an essential and worthwhile effort for the companies as well as the region. Secondly, Warsaw

must then identify a platform from which to operate a potential “business collaborative” or “civic league” under the auspices of an honest broker institution, such as a regional foundation. Finally, it must work collaboratively with its historical regional competitors – South Bend and Fort Wayne – turning them into regional allies through mutually beneficial civic engagement initiatives. Warsaw needs to “drive” an effort such as this, but it needs to be genuinely inclusive in order to maximize the cross-regional benefits.

The Need for More Collaborative Strategies

While Warsaw companies belong to nationally significant trade associations and policy focused organizations, they have not formally coalesced and have rarely been regarded by regional or state economic development forces as a key asset in a growing prosperity strategy. This needs to change. During the past few decades, the United States has witnessed the decline of its steel, textile, and more recently, automotive industries. Other examples could be listed. However, the incredibly negative consequences in these three examples provided here were due, in part, to economies based on single product industries, a reliance on a narrow range of technologies, and a resistance to recognize global trends. Greater collaboration among the leaders in those industries to address their shared challenges might have mitigated some of the impacts that resulted in enormous economic loss. Greater collaboration between leaders in Indiana’s pharmaceutical industry and the orthopedic device cluster may also bear good fruit.

Given the clear value everyone in the Warsaw region places on the strong international brand of the place, the importance of the small town Indiana environment to the cluster’s talent development and attraction, and the increasingly large global footprint the companies are building, it would be a shame to lose position due to a lack of attention to the issues and developments. To an outsider, it is surprising how little collective attention, both within the cluster and across the region, has been given to the challenges and opportunities ahead.

Economic development professionals and elected officials may underestimate the richness of this industry, seeing it as simply another manufacturing sector. In reality, it represents a wide range of relationships and sophisticated knowledge about where a growing marketplace demand – healthcare – is going. It also represents design, manufacturing, regulatory and marketing know-how which is globally connected and responsive.

The problem is compounded by the competitive attitude among the individual companies. The companies, operating in similar marketplaces, have been reluctant to share information about R&D developments, marketing strategies or design issues for fear it will disadvantage their products. However, there are examples of collaborative efforts on what are considered pre-competitive common concerns. A good example is the significant time and resources companies have contributed to both Grace College and Ivy Tech for facilities, equipment and curriculum development essential to recruiting, educating and training the workforce they need. These efforts paradoxically have received little if any public support from either regional or state coffers.

Bringing together key stakeholders from the orthopedics industry, government, and education and training providers via a collaborative league or organization focused on the prosperity of the region and the importance of the orthopedics cluster to that prosperity, could be a highly positive move for the entire region. Such an organization would be positioned to:

- a) identify opportunities and issues shaping the regional cluster;

- b) mobilize resources to support cluster growth needs, such as industrial facilities, workforce education and training support, K-12 educational activities, cultural, commercial and recreational resources important to employees, etc.;
- c) further strengthen the brand and reputation of the region through joint efforts;
- d) seriously look at a strategy which embraces a wider geography than Warsaw, in order to address lifestyle issues and support activities enhancing the cluster's continued competitiveness;
- e) guide a regranting function to channel external foundation and philanthropic resources into local community-based organizations focused on regional innovation, economic growth and an improved quality of life throughout the region. Regranting through a local organization enables the development of local stakeholders and a more informed process for distributing funds that are responsive to local needs and have the promise of being effective. Such regranting activities could also increase the community's desire to understand, engage with, and support the agenda of a collaborative regional development organization;
- f) offer coaching and mentoring for new, innovative orthopedic start-up firms to connect them to the critical market intelligence, funding, and other business support services they need in order to be successful. There are a variety of incubators and start-up support programs across the United States and within the state of Indiana which could be relevant here; and
- g) establish metrics for social and economic returns on both investment and involvement to properly assess the success of the organization and its impact on the community.

These goals cannot be accomplished without an honest assessment of the enablers and barriers to collaboration a) within the cluster, b) between the cluster and the Warsaw community and c) across the larger regional geography of Warsaw, Fort Wayne and South Bend. To accomplish this would require a substantial, but necessary, investment of resources to create an institutional platform initially working in concert with an established and trusted community partner such as the Kosciusko County Community Foundation (KCCF), through which priorities, activities, alliance building and resource development could be agreed upon and implemented.

VI. Recommendations for Sustaining and Growing Indiana’s Warsaw-Based Orthopedics Device Cluster

It is clear the economic vitality of Warsaw and north central Indiana depends heavily upon the continued success of the orthopedics device industry. Because of this region’s concentrated industry base, there are a great number of opportunities and challenges. At the epicenter of a global and expanding industry, the Warsaw community should come together in a new way to organize a formal support structure that bolsters that industry’s advantages and addresses its concerns. Building on the strengths that were so clearly defined in Battelle’s report and the observations and recommendations from Mary Walshok’s community interviews and the UC-San Diego Global CONNECT study (see “The Need for More Collaborative Strategies” in the previous section), BioCrossroads has developed a series of recommendations. These recommendations, taken together or in selected components, are intended to provide a diversified action plan for community stakeholders, supported in appropriate measure by outside experts, advisers and investments.



OrthoWorx

The introduction to this report referenced a business league, further discussed in the Global Connect study, which could serve as the platform from which to brand, engage, promote and support the orthopedics assets within the region. Such an initiative would also be designed to engage the broader business and community assets directly and indirectly reliant on the vitality of the orthopedics sector. Properly deployed, such a business league could take the lead in defining the best opportunities and then driving economic growth across north central Indiana. It should first address the issues facing Warsaw’s important economic needs as well as identify relevant assets and opportunities in the larger regional economy. Much as BioCrossroads has become the supporting brand of the broader life sciences assets within Indiana, a business league advancing a new brand (such as "OrthoWorx"), could specifically “capture” the presence and potential of the Warsaw-based orthopedics industry and the community that supports it.

Based in Warsaw but regionally focused, an OrthoWorx initiative could serve as the hub to seek definition, support and, ultimately, investment in addressing the biggest concerns and embracing the best non-competitive, non-proprietary opportunities for the orthopedics industry and the north central Indiana economy. Building upon active listening and further direct conversations with representatives of the orthopedics industry, business, community and civic leaders within the Warsaw region, BioCrossroads has identified an early possible “action agenda” for an appropriately empowered group of business and community leaders organized as the OrthoWorx regional business league. The recommendations comprising this potential “action agenda” are each described briefly below, and are intended to provide a helpful initial and illustrative focus for OrthoWorx. Undoubtedly, some of these ideas are better than others. Some are more feasible than others. And many other ideas will doubtlessly arise through the league’s independent deliberations. What is important is the establishment of a credible, highly consultative, participatory, and strongly supported branded community initiative – soon. An organization such as OrthoWorx is in the best position to judge the opportunities and challenges for this sector and this region – as well as to translate those opportunities into action. Equally important will be the cultivation of energetic participation from member

organizations and the recruitment of a strong professional team, including a full-time CEO/Executive Director, to lead the organization and prioritize its work.

BioCrossroads is prepared to work with key community and industry leadership to launch the OrthoWorx business league as an early priority. To that end, BioCrossroads has developed and trademarked an "OrthoWorx" brand and reserved appropriate domain names for an eventual website, as a placeholder. In consultation with community leaders, BioCrossroads has further assembled the following preliminary agenda of six efforts for the initiative to pursue.

(A) Branding and Awareness

Spreading the word and generating awareness about the newly-formed OrthoWorx is an important early component in the development of the organization. The OrthoWorx name needs to resonate within Warsaw and beyond. Warsaw deserves a strong brand to identify the community broadly as *the* orthopedics capital of the world, and OrthoWorx can provide formal definition to the reality that has developed over the past 115 years through a host of public relations and marketing activities that BioCrossroads could potentially help the organization implement. Extending beyond Warsaw, OrthoWorx could leverage the broader assets of north central Indiana and serve as a bridge linking the civic, cultural and business strengths of the entire region while appropriately identifying the orthopedics sector anchored in Warsaw as the core economic driver.

The name "OrthoWorx" brings together "ortho", the strength of local industry and heart of the community, with "worx" which encompasses the actual work of creating the orthopedics products as well as the idea of people "operating together" and "having an effect or influence" – definitions of work and the ethic essential for work to yield results. OrthoWorx's tag line of "finding strength in people" demonstrates the goal of creating a robust organization that can support the community's strong industry presence, enhance its business climate and grow its educational, cultural and recreational amenities.

Early efforts in branding and awareness will be focused on defining and otherwise preparing the OrthoWorx brand and educating broad public audiences about the particular capabilities and resources of the north central Indiana region. This definitional stage could include activities such as hosting an annual orthopedics-focused educational conference targeted to industry, university, and workforce development stakeholders throughout the state and beyond. Similarly, a web site could be established providing access to the data in this report, as well as study findings and materials developed in the areas of community enhancement, education, talent and workforce development, transportation and logistics, technical support services and research as described in the sections below. Following this initial stage of definition and preparation, it is reasonable to conclude that the focus of the branding and awareness initiative could mature to include promotion of specific assets and capabilities identified by these early efforts.

(B) Community Enhancement

Cultural and recreational amenities including a farmer's market, child care, adult education, youth education, access to extracurricular children's activities such as music and art classes, and options for child care and pre-schools are crucial to the overall vitality of the region and can enhance or inhibit the industry's ability to recruit and retain talent. An actual or perceived lack of amenities can act as an impediment to recruiting and retaining the top talent (and the talented families in which those individuals reside) and is essential to the long-term success of the orthopedics sector. Warsaw, as the industry center, with its small population and relatively isolated geography cannot support all of the

amenities that may be desirable. However, by embracing a larger regional approach involving, for example, Fort Wayne and South Bend and surrounding counties, OrthoWorx can work to inventory and promote a broader set of amenities collaboratively. Analyses can also be conducted to identify gaps in entertainment, civic and cultural programs and determine what additional amenities could be supported. Partnerships between Warsaw and contiguous cities could bring additional cultural opportunities to the area. Focused relationships with organizations such as The Fort Wayne Dance Collective, South Bend's HealthWorks Kids' Museum or the Snite Museum of Art could result in traveling exhibits and performances in Warsaw. Grace College, building on the base of its existing programs such as the Young Musicians Workshop, could serve as a natural link and host to such educational and cultural exhibits. By taking this more regional approach, a greater set of amenities could initially be both more feasible and more visible, with a greater chance of sustainability by reaching a broader audience.

(C) Education

A comprehensive K-16 educational strategy should be a strong, initial focus of OrthoWorx. Crucial to both talent development and community enhancement, a robust set of educational options and opportunities should be developed in Warsaw and north central Indiana. While these opportunities may not be designed specifically with the orthopedics sector in mind, strong core curriculum in science, technology, engineering and mathematics (STEM) disciplines undoubtedly produces better prepared students equipped with skill-sets applicable to a wealth of career possibilities. Over the course of our research, many community and industry stakeholders spoke with pride to us and our consultants about the best-in-class facilities of Warsaw's school system, but also identified the need to strengthen the current educational curriculum and add programs to better prepare students for an evolving economic landscape as well as future educational pursuits. Grace College and Ivy Tech could be looked to as local resources to partner with and leverage as they develop and expand their own curricula. The State of Indiana I-STEM Resource Network should be leveraged to enhance competencies in STEM education.

Building upon the community's recent collaborative efforts with Grace College and Ivy Tech, specific orthopedics-related curriculum and educational path initiatives could guide a larger number of high school students and graduates toward pursuing a job or degree in the industry. For example, Grace College's Orthopedics Scholars Institute, a competitive extracurricular internship and mentoring program aimed at preparing business students for careers within the orthopedics industry, could be leveraged to bring Grace's orthopedic focused managerial strengths to a wider, and younger, student population. In the case of Ivy Tech, furthermore, better preparation for a career as a CNC machinist, a biomechanical engineer, or a project manager, through a tailored curriculum developing these competencies, could give north central Indiana students (and their potential employers) a significant advantage in a globally competitive marketplace. Overall, Indiana has a distinct, diversified, and specialized set of educational assets that can prepare the future orthopedics' workforce. The scientific and engineering expertise of Indiana University's School of Medicine, Purdue and Notre Dame; the orthopedic-focused business programs at Grace College; and the vocational and technical skills provided by Ivy Tech should be independently and collaboratively leveraged to provide a ready workforce for this crucial industry.

OrthoWorx could develop a strategy to better leverage these strengths and additionally could provide an in-depth analysis of the overarching public education system in Kosciusko County, resulting in a benchmark to comparable communities throughout the state, regionally and nationwide. Specific deficiencies could be identified and options presented to advance the educational curriculum and implement new models of instruction to ensure that students within the system are gaining the skills necessary to seek employment with the major employers in the region or otherwise becoming adequately prepared to continue their educational pursuits. In any such effort, statewide governmental

resources should be assessed and local, state and national educational expertise should be utilized to determine shortfalls and identify focus areas for enhanced educational opportunity.

Specific educational options that have been pursued in other regions of the state could be explored. These include charter schools and New Tech High Schools - both of which are aimed at tailoring curriculum and programs to the needs of the ever changing educational landscape - as well as private educational options. Recently, the Rochester, Indiana Community School Corporation launched the Zebra New Tech High School, which will soon encompass all 9th and 10th grade students within the Rochester Community School Corporation. New Tech High Schools are based on a project-based learning educational model originally developed in San Diego, CA and now replicated nationally, motivated by concerns over a lack of skilled local employees, students' dissatisfaction over being insufficiently prepared for technologically advanced jobs and the overall community's frustration with the quality of public education generally. A successful track record has led to an increased number of New Tech High Schools in Indiana and nationwide. Most recently, Fort Wayne announced a significant investment aimed at enhancing STEM education at the K-12 level through the development of New Tech High Schools and the expansion of project-based learning.

(D) Talent and Workforce Development

A common need throughout the Warsaw-based orthopedics sector is access to skilled employees. In conversations with industry leaders, BioCrossroads consistently identified a need for trained machinists as a top priority. Ivy Tech's Orthopedic Advanced Manufacturing Training Center in Warsaw begins to address the companies' workforce needs, but a more collaborative engagement including industry, government and education could improve the pipeline of participants, bolster the resources – and enhance current results.

The human resources and manufacturing operations divisions of the various Warsaw-based orthopedics companies should be more actively engaged with Ivy Tech and other direct sources of talent (such as Indiana's research universities for scientific and engineering talent and Grace College for orthopedic-focused business and management preparation) to develop curriculum and provide more directed guidance on specifically needed skills for development. By increasing the direct involvement of the end-user in the training equation, newly trained employees have a greater probability of meeting company needs more rapidly.

Indiana's Department of Workforce Development should also be engaged by OrthoWorx to assist in identifying gaps in training programs and work to secure qualified programs for those training dollars that may be available from state and federal sources. As Indiana's manufacturing industries overall see declines in other sectors, such as recreational vehicles and automobile production, OrthoWorx's talent and workforce development initiative could help identify potentially transferable skills across industries and set standards for retraining displaced workers to transition into the orthopedics sector to meet increasing demands for a skilled manufacturing workforce.

Building upon, and in addition to, the orthopedics focused research competencies described in detail below, a statewide college and university engagement strategy could be developed from a local center to further leverage the broad range of relevant skills being developed by Indiana students. Institutions such as (but not limited to) Rose-Hulman Institute of Technology and Valparaiso University could provide valuable engineering talent. Similarly, programs could be developed leveraging the model created by Grace College's orthopedics scholars internship program to capture talent and leverage the expertise developed at the statewide network of colleges and universities.

(E) Transportation and Logistics

For Indiana’s orthopedics industry, concentration in a relatively remote locale presents certain challenges with regard to transportation and logistics. Manufacturing, shipping and distribution are at the core of the Warsaw companies’ operations and represent a significant driver of efficiency and cost. To remain competitive with other regions hosting orthopedics manufacturing and operations functions, north central Indiana, in close consultation with the State of Indiana, must work to implement a comprehensive transportation and logistics strategy to enhance the efficiency of transport, shipping and distribution routes to and from the region.

Among other actions, OrthoWorx could engage an expert team to analyze the regional transportation system linking the companies’ manufacturing and distribution facilities most efficiently to the ultimate destination for their products. The Indiana Department of Transportation (INDOT) would need to be the external focal point for this effort as a partner in analyzing and recommending potential upgrades within the region. Deficiencies in local and regional infrastructure assets should be reviewed in close collaboration with state and local officials through an appropriate lens focused on the major scale of the orthopedics sector and opportunity, rather than its modest geographic setting. Traditional population metrics used to guide official decisions regarding infrastructure requirements do not provide an accurate assessment relative to the economic concentration that a region like Warsaw represents.

Transportation of customers and employees, as well as products, is also critical to the success of the orthopedics sector. Ensuring that connectivity to regional transit hubs such as Chicago and Indianapolis is as seamless as possible, whether through links via highway, air or alternative forms of transportation, is an issue appropriate for exploration formulation and action through a broad group of parties convened by OrthoWorx. An initial step suggested by both corporate and community stakeholders, would be to test the business case for regularly scheduled shuttle flights between Warsaw and Chicago’s O’Hare airport. In our experience, airlines are open to discussions for additional routes where an economic case can be made. This is a manageable and tangible task that would require the large corporate players to come together to share information regarding numbers of employees traveling to and through Chicago on a daily, weekly, monthly and annual basis and demonstrate unified support for this additional transit option. Traditionally, many companies here have struggled with similar challenges in transportation and logistics and each has attempted to solve problems independently. With OrthoWorx serving as a facilitating organization in support of the industry and region as a whole, efforts should be able to be coordinated and energy focused on one set of common goals.

(F) Technical Support Services

Over the course of our research, it became apparent that while the orthopedics assets in north central Indiana are deep and singularly comprehensive, there remain several specific supporting services and facilities that are needed but not readily accessible in the region. The development of some or all of these services, described in more detail below, could leverage existing strengths and enhance the efficiency and productivity of the orthopedics sector on an industry-wide, “pre-competitive” basis. BioCrossroads has not determined whether sufficient demand exists within Warsaw, north central Indiana or Indiana generally to support any or all of these services as ongoing, self-sustaining enterprises. Accordingly, we recommend that OrthoWorx conduct or sponsor appropriate diligence and/or business planning activities on each to ascertain market potential.

Orthopedic Implant Sterilization Facility

The sterilization of orthopedic implants is a sophisticated process that contributes significantly to both cost and overall production time for orthopedics manufacturers. Each implant that comes off the

assembly line must be packaged and sterilized prior to shipment to the end user. Over the course of our interviews, orthopedics industry leaders commented frequently about the lack of a local facility that could provide proximate, timely, FDA-compliant sterilization services. Currently, the closest commercial facilities for these services are located in central Illinois and central Ohio, which requires companies like Biomet, Zimmer and DePuy to make constant shipments of products from Warsaw to an out-of-state sterilization facility and back. As cost pressures in the industry intensify, and the price of gasoline for such shipments continues to rise, the timing appears optimal to determine the business case for developing an FDA-certifiable sterilization facility within Indiana's borders, and far closer to Warsaw.

As a first step, a demand analysis should be conducted to determine the volume of implants from Warsaw companies that are currently being sterilized in remote locations. Among other alternatives, current out-of-state sterilization service providers such as Steris (Mentor, OH) should be engaged to determine whether a local outpost of a high quality service provider might be sustainable in the region and therefore represent an attractive business proposition for the parent company. OrthoWorx could serve as the facilitator of this analysis and work collaboratively with the Indiana Economic Development Corporation to determine the overall feasibility of developing or relocating such a facility closer to its Warsaw customer base.

Orthopedic Surgeon Training Facility

Surgeons are the “delivery mechanism” for the devices produced by the Warsaw-based orthopedics industry, and constant and skilled training and education are critical components to the industry's overall success. Comprehensive training programs are often mandated by the FDA for new procedures, devices and tools. The heightened scrutiny brought on by the recent deferred prosecution agreements between the Department of Justice and the major orthopedics device manufacturers makes transparency in company–physician relationships critical. An independent training facility, operated by a third party and accessible to all surgeons and device manufacturers, could add to the transparency of those relationships and assuage fears of impropriety – perceived or otherwise. A brief review by Dr. Rick Sasso, for example, resulted in a very interesting idea for such a facility with an approach, which he described as follows:

“Education is critical to the orthopedic industry. Surgeon training is a vital step in the release of a new device or technique. Orthopedic manufacturers require modern training facilities in order to teach the proper use of their products and the FDA many times requires surgeons complete a comprehensive training program before using new technology. The modern surgical training facility includes a cadaver laboratory with complete operating room set-up including microscopes, fluoroscopy, and image navigation technology. Video and audio connection to an in-house auditorium is essential for moderators to ask and answer questions from participants in the auditorium in real-time. Interactive technology is also necessary for live feeds from operating rooms and auditoriums around the world. This facility should be attached to a very nice hotel for the participants and faculty members to stay and this hotel should also be able to provide catering services to the training auditorium. This facility needs to be very easy to access from a large international airport so that time-strapped surgeons waste the least amount of time traveling.”

State-of-the-art training facilities are required to utilize surgeon and company time efficiently, and proximity to a major, readily accessible transit hub is ideally preferred by surgeons undergoing such training. Our work in this area leads us to at least a preliminary conclusion that significant demand exists for additional, accessible and modern training facilities that include cadaver laboratories with operating rooms offering imaging technology, audio video and conferencing capabilities and adjacent lodging facilities. OrthoWorx could again be tasked with spearheading an early effort to further analyze

this opportunity and coordinate the needs of both surgeons and the companies around a possible business case for facility development.

As again summarized by Dr. Sasso, “An independent biomechanical testing facility will benefit and serve all orthopedic interests in the state. Manufacturers need an independent laboratory to conduct many diverse loading tests as mandated by the FDA prior to approval of their devices. There are a limited number of testing facilities in this country that can provide these types of services. Product approval is often times delayed while waiting for critical biomechanical testing. An orthopedic-focused independent biomechanics lab will help our state’s orthopedic manufacturers drive their products to market faster and benefit our state economy. This facility can also serve the innovative surgeons and researchers of Indiana with early stage design, product development, and proof-of-concept validation.”

Independent Biomechanical Testing Facility

Biomechanical testing facilities conduct a multitude of diverse load tests to determine strength and durability of orthopedic devices. Large orthopedics manufacturers have internal laboratories that are utilized during product development, but the FDA requires independent testing of implants prior to granting product approval. There are today a limited number of independent facilities [outside Indiana] that serve the major orthopedics manufacturers as well as the small but growing number of orthopedics startups within the region. However, our research indicates that the Warsaw-based orthopedics market might support the development of one or more additional, readily accessible testing facilities providing authorized, expert and efficient testing services to cut times and control costs by collecting data for FDA submission more rapidly.

Once again, these findings are preliminary. An early initiative of OrthoWorx should be to facilitate the conduct of thorough diligence to determine the possible business case for locating or developing such a facility in the Warsaw region.

Preclinical Testing Facility

Similar to the benefits of developing the type of biomechanical testing facility described above, the addition of a pre-clinical animal testing facility would provide the Warsaw orthopedics sector with a dedicated resource to gather critical data mandated by the FDA. As the FDA data requirements for submissions continue to increase, there are only a few animal testing facilities equipped to provide quality data quickly and cost effectively. Safety and durability testing is anticipated to increase in the future, as suggested in Dr. Sasso’s report:

A pre-clinical orthopedic animal testing facility would not only provide a positive impact to the orthopedic industry in our state but also to all companies that must produce FDA mandated pre-clinical animal data for their products. There are very few facilities that can provide this type of research data, while at the same time, the FDA is increasing the amount of animal data necessary for PMA applications. As technology is advancing, we will need more animal examination of wear debris in motion-sparing devices, biologic evaluation of gene therapies, and histological study of resorbable technology.”

Purdue’s School of Veterinary Medicine, working closely with Purdue’s biomedical engineering department, is at the forefront of the utilization of animal models in orthopedics product research and development. OrthoWorx could provide a valuable and early service by partnering with Purdue to assess the feasibility of developing a sustainable preclinical testing facility that would provide a “pre-competitive advantage” for all of Warsaw’s orthopedics companies through greater accessibility and enhanced attention to their requirements.

IN-OrthoNet (Orthopedics Research Institute)

The Warsaw-based orthopedic companies all support active research programs and dedicate significant resources to the development of new technologies. A traditional way to expand the depth of the companies' research bench comes through sponsored research agreements with research universities. As evidenced in the Global CONNECT findings, collaborations of this type are already occurring regularly between Indiana's research universities and specific companies in the orthopedics sector. These relationships are also increasingly common developments between orthopedics companies and institutions around the globe. The existing structure of collaboration appears to be meeting the current innovation partnering needs of the industry.

BioCrossroads has opened a dialogue with the biomedical engineering departments of both Purdue University and the University of Notre Dame through Dr. George Wodicka and Dr. Peter Kilpatrick, their respective departmental leaders, to understand how the existing relationships work and to explore ways to support and expand their individual capabilities through formalized inter-university collaboration. This discussion has given rise to a proposal for a translational orthopedic research institute aimed at creating a link among researchers, clinicians, entrepreneurs and industry operating in an independent environment. An important question moving forward is whether the Warsaw cluster would find such a more formalized structure useful to their competitiveness.

The proposed Indiana Orthopedics Innovation Network (IN-OrthoNet) is the brainchild of Dr. Wodicka and Dr. Kilpatrick. Geared toward maintaining Indiana's competitive advantage in orthopedics, IN-OrthoNet is conceived as an effective means to stimulate new discoveries and translation in promising areas of new technology such as regenerative medicine, orthobiologics, bionanotechnology, biosensors, pharmacogenomics, proteomics and bioinformatics, while bolstering the industry generally by providing expertise to the growing sector of entrepreneurial-driven small and medium-sized new product companies. The overarching structure of the institute is yet to be determined, but would likely seek a credentialed industry expert to lead the centralized staff. The institute would serve as a point of organization for the substantial research, clinical and industry resources already focused on innovation within each participating university, and seek to connect these valuable resources to one another. The institute could also support a standalone infrastructure with core facilities dedicated to translational research working with start-ups and corporations that may lack appropriate expertise or wish to partner with the institute as a fee-for-service provider.

IN-OrthoNet could complement, or be incorporated into the initiatives of OrthoWorx as a potential consumer of services that support the industry and quite possibly the provider of pre-clinical services and biomechanical testing outlined as industry support enterprises as well as house the surgeon training facility (see the discussion of the "Technical Support Services" under subsection (F) above). Indiana's network of orthopedic surgeons and clinics such as the Indiana Spine Group and OrthoIndy could be tapped to ensure that IN-OrthoNet research is targeted to improve health outcomes for Indiana's orthopedic patients. IN-OrthoNet could also be a resource for the talent and workforce development component of OrthoWorx. For example, the existing and expanding regulatory and compliance expertise at Purdue could be integrated into the institute to provide a crucial training service to employees throughout Warsaw's orthopedic companies as well as provide guidance to entrepreneurial companies seeking to commercialize a product. Indiana's active and expanding venture and private equity landscape, including the Indiana Future Fund and Indiana Seed Fund, might also be explored in appropriate cases to assist in commercialization of promising new technologies. Through IN-OrthoNet, the strong entrepreneurial traditions and talent in the Warsaw region could be more effectively focused and tapped to build new companies around innovation.

IN-OrthoNet would not look to replace sponsored research agreements among the universities and companies, but instead would leverage a more collaborative structure to enhance Indiana's collective academic depth in orthopedics. The aggregation of university resources and expertise in orthopedics is aimed to set Indiana apart from its competitors and afford a competitive advantage for research universities pursuing federal funding and future industry relationships. While the large orthopedics manufacturers may very well not be the immediate customer of IN-OrthoNet, the advancing of an orthopedic research focus within Indiana's research universities would establish the basis for a longer-range, deliberate strategy to create a best-in-class partnership with those companies as industry dynamics shift, new challenges are defined and a collaborative approach among companies becomes necessary to provide solutions to widely shared industry problems. With an industry-acknowledged shift to biologics, biomaterials and regenerative medicine on the horizon – admittedly, a horizon at an undetermined distance – the types of challenges that drive collaborative research among the industry leaders may occur again. IN-OrthoNet will organize, develop and leverage Indiana's orthopedic research strengths to allow the orthopedics industry to look within and have proximate partners to help forge the future path to orthopedic solutions.

Appendix I: Data and Methodology, Battelle Economic Analysis

The economic analysis in this report examines data for Kosciusko County, Indiana, the state of Indiana and the nation and corresponding trends in the health and biomedical industry from 2001 to 2007. For employment analysis, Battelle used the Bureau of Labor Statistics (BLS) Quarterly Census of Employment and Wages (QCEW) data. The QCEW data (formerly known as the ES-202 program) provide the most current, detailed industry employment, establishment, and wage figures available at both a national and subnational level.⁴¹ Battelle receives an enhanced version of these state and county data from a private vendor, the Minnesota IMPLAN Group, Inc.

The QCEW program is a cooperative program involving BLS and the State Employment Security Agencies (SESAs). The QCEW program produces a comprehensive tabulation of employment and wage information for workers covered by state unemployment insurance (UI) laws and federal workers covered by the Unemployment Compensation for Federal Employees (UCFE) program. Publicly available files include data on the number of establishments, monthly employment, and quarterly wages, by NAICS (North American Industry Classification System) industry, by county, and by ownership sector, for the entire United States. These data are aggregated to annual levels, to higher industry levels (NAICS industry groups, sectors, and supersectors), and to higher geographic levels (national, state, and metropolitan statistical area [MSA]).⁴²

Since 2001, the QCEW has been producing and publishing data according to the NAICS. Federal statistical agencies have a mandate to publish industry data according to this improved classification system. Compared with the prior classification system—the 1987 Standard Industrial Classification (SIC) system, NAICS better incorporates new and emerging industries. Employment, establishment, and wage estimates produced by the QCEW program for 2001 to present are not comparable with SIC-based industry estimates from prior years. This limits the ability to construct a longer time series for data analysis; however, seven years of NAICS-based data (2001-2007) are now available.

Fifty-seven NAICS industries at the most detailed (six-digit) level make up the Battelle definition of the health and biomedical industry. These detailed industries are aggregated up to 11 major subsectors of the industry. Two of the detailed NAICS industries, Testing Laboratories (NAICS 541380) and Physical, Engineering, and Biological Research (NAICS 541710), are adjusted in this analysis to include only the share of these industries directly involved in biological or other life science activities. To isolate these relevant life science components, Battelle used information and data from the US Census Bureau's Economic Census.

For more information on the BLS Quarterly Census of Employment and Wages, see <http://www.bls.gov/cew/home.htm>.

⁴¹ In general, QCEW monthly employment data represent the number of covered workers who worked during, or received pay for, the pay period that included the 12th day of the month. Virtually all workers are reported in the state in which their jobs are located. Covered private-industry employment includes most corporate officials, executives, supervisory personnel, professionals, clerical workers, wage earners, piece workers, and part-time workers. It excludes proprietors, the unincorporated self-employed, unpaid family members, and certain farm and domestic workers. An establishment is an economic unit such as a farm, mine, factory, or store that produces goods or provides services. It is typically at a single physical location and engaged in one, or predominantly one, type of economic activity for which a single industrial classification may be applied. Total wages: Covered employers in most states report total compensation paid during the calendar quarter, regardless of when the services were performed. A few state laws, however, specify that wages be reported for or be based on the period during which services are performed, rather than for the period during which compensation is paid. Under most state laws or regulations, wages include bonuses, stock options, severance pay, the cash value of meals and lodging, tips and other gratuities, and—in some states—employer contributions to certain deferred compensation plans such as 401(k) plans.

⁴² Major exclusions from UI coverage, and thus from the QCEW data, include self-employed workers, some wage and salary agricultural workers, unpaid family workers, railroad workers, and some state and local government workers.

Reference Tables and Figures for Indiana and the US

Table A-1. United States Health and Biomedical Industry Employment Metrics, 2007

Industry & Subsectors	2007 Establishments	Percent Change Estab, '01-07	2007 Employment	Percent Change Empl, '01-07	2007 Location Quotient
United States					
Total Private Sector	8,680,218	12.2%	114,014,700	4.3%	N/A
Total Health & Biomedical Industry	845,508	14.5%	16,589,682	14.8%	N/A
Hospitals	7,760	9.2%	4,461,036	11.3%	N/A
Doctor/Health Practitioner Offices	446,743	13.7%	3,606,306	17.4%	N/A
Personal Care Facilities	66,495	10.8%	2,942,614	10.8%	N/A
Strategic Medical Device Supplier Industries	178,086	17.2%	2,061,729	12.0%	N/A
Ambulatory Health Care Services	29,103	34.6%	1,143,682	40.6%	N/A
Outpatient Medical Care Centers	20,184	28.9%	509,531	27.0%	N/A
Research, Testing, & Medical Laboratories	22,053	32.7%	449,162	18.7%	N/A
Health Industry Wholesale	30,383	-0.3%	420,423	12.7%	N/A
Medical Devices & Equipment	14,863	1.0%	409,453	3.5%	N/A
Drugs & Pharmaceuticals	2,621	4.0%	294,776	5.0%	N/A
Veterinary Services	27,217	9.3%	290,970	25.0%	N/A

Source: Battelle analysis of Bureau of Labor Statistics, QCEW data from the Minnesota IMPLAN Group.

Table A-2. Indiana Health and Biomedical Industry Employment Metrics, 2007

Industry & Subsectors	2007 Establishments	Percent Change Estab, '01-07	2007 Employment	Percent Change Empl, '01-07	2007 Location Quotient
Indiana					
Total Private Sector	152,937	4.6%	2,502,686	0.7%	1.00
Total Health & Biomedical Industry	15,578	10.2%	382,567	15.1%	1.05
Hospitals	141	9.3%	102,789	9.9%	1.05
Doctor/Health Practitioner Offices	7,412	4.7%	77,230	17.1%	0.98
Personal Care Facilities	1,139	3.3%	70,051	9.4%	1.08
Strategic Medical Device Supplier Industries	3,517	13.5%	42,706	17.1%	0.94
Drugs & Pharmaceuticals	44	7.3%	19,525	5.3%	3.02
Medical Devices & Equipment	287	2.5%	19,472	40.8%	2.17
Ambulatory Health Care Services	488	16.2%	17,632	38.5%	0.70
Outpatient Medical Care Centers	451	24.2%	11,407	33.6%	1.02
Health Industry Wholesale	1,159	45.6%	8,571	26.0%	0.93
Research, Testing, & Medical Laboratories	346	28.8%	6,926	5.1%	0.70
Veterinary Services	594	6.6%	6,258	18.0%	0.98

Source: Battelle analysis of Bureau of Labor Statistics, QCEW data from the Minnesota IMPLAN Group.

Figure A-1. Employment Composition of the Health and Biomedical Industry in Indiana, 2007

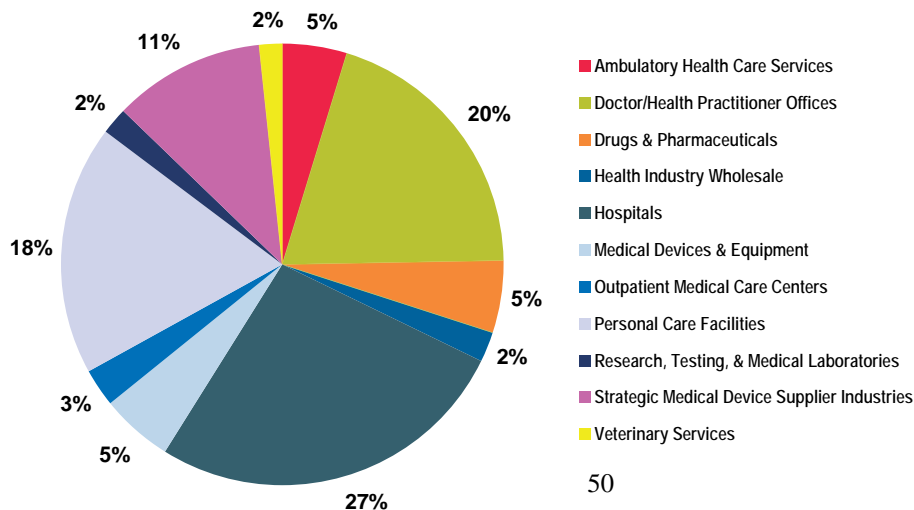


Figure A-2. Employment Composition of the Health and Biomedical Industry in the US, 2007

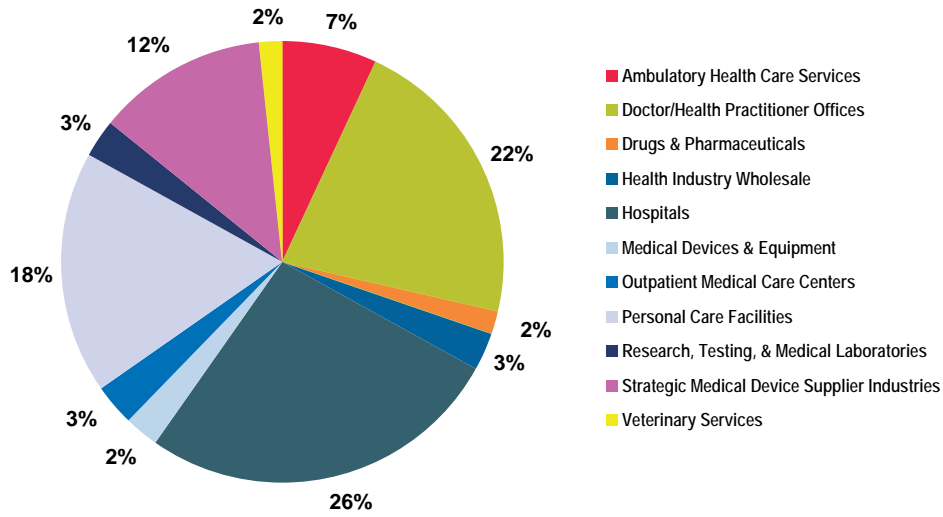
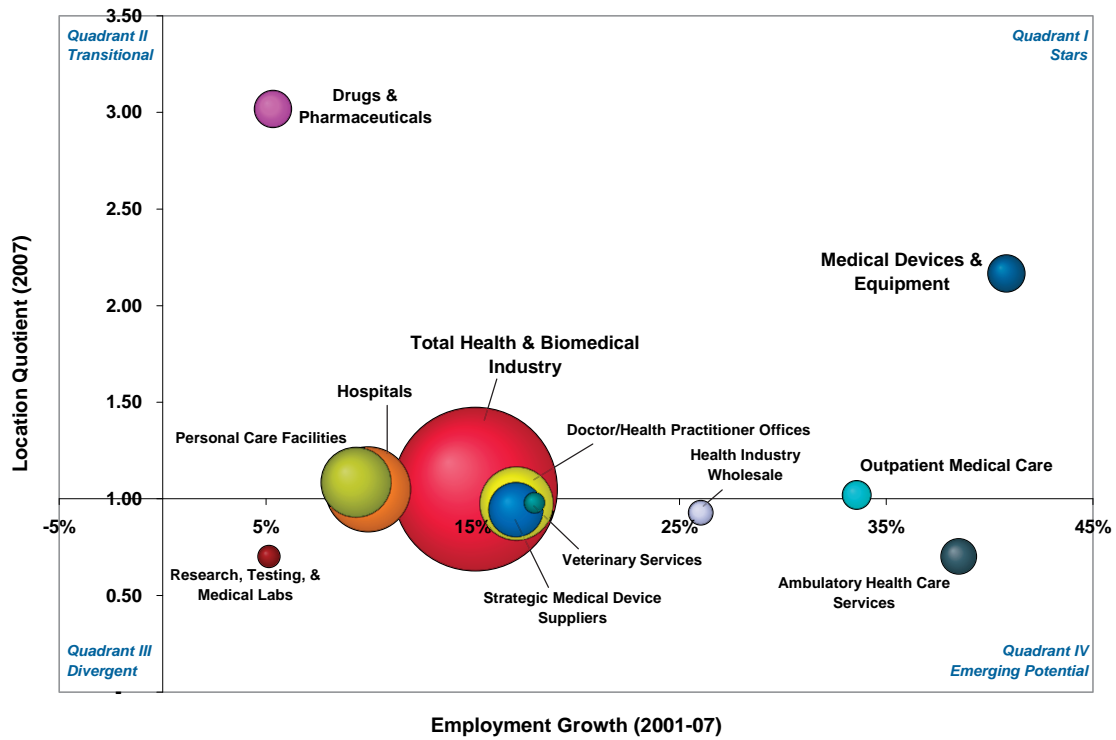


Figure A-3. Indiana Health and Biomedical Industry Subsectors, Degree of Specialization, Employment Growth, and Size, 2007



Source: Battelle analysis of Bureau of Labor Statistics, QCEW data from the Minnesota IMPLAN Group.

Table A-3. Average Annual Wages for Indiana Health and Biomedical and other Industries, 2007

Industry	Avg. Annual Wages, 2007
Drugs & Pharmaceuticals	\$ 100,899
Health Industry Wholesale	\$ 86,060
Management of Companies and Enterprises	\$ 72,674
Medical Devices & Equipment	\$ 60,965
Research, Testing, & Medical Laboratories	\$ 56,496
Doctor/Health Practitioner Offices	\$ 55,039
Finance and Insurance	\$ 52,642
Professional, Scientific, and Technical Services	\$ 51,450
Wholesale Trade	\$ 51,430
Manufacturing	\$ 51,142
Strategic Medical Device Supplier Industries	\$ 49,987
Total Health & Biomedical Industry	\$ 46,453
Information	\$ 46,313
Hospitals	\$ 41,844
Outpatient Medical Care Centers	\$ 40,678
Total Private Sector	\$ 37,606
Arts, Entertainment, and Recreation	\$ 29,237
Ambulatory Health Care Services	\$ 26,338
Veterinary Services	\$ 25,192
Personal Care Facilities	\$ 24,448
Retail Trade	\$ 22,577

Source: Battelle analysis of Bureau of Labor Statistics, QCEW data from the Minnesota IMPLAN Group.

Given the focus of this economic analysis on the health and biomedical sector, there was one major subsector of the Battelle “Biosciences” industry definition that was not represented—the agricultural biosciences industry or specifically, “agricultural feedstock and chemicals.” At the request of BioCrossroads, Battelle added this appendix table for reference.

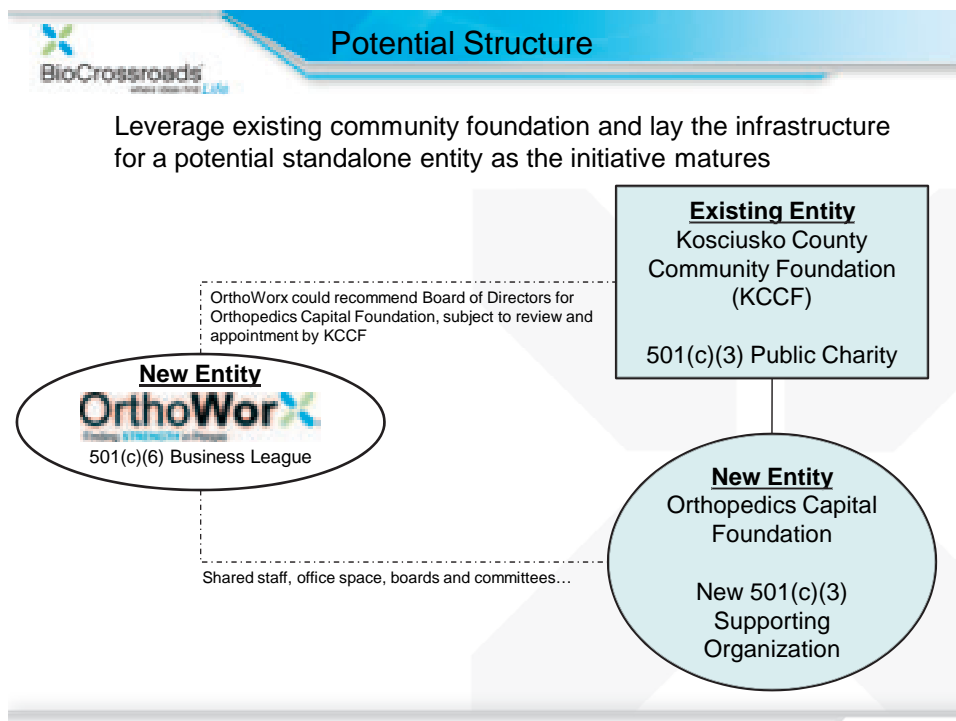
Table A-4. Agricultural Feedstock and Chemicals Sector, employment metrics, 2007.

Region	2007 Establishments	Percent Change Estab, '01-07	2007 Employment	Percent Change Empl, '01-07	2007 Location Quotient
Agricultural Feedstock & Chemicals Sector					
U.S. Total	2,281	7.2%	109,772	-9.4%	N/A
Indiana	44	26.8%	4,846	-9.1%	2.01
Kosciusko County	-	-	-	-	-

Source: Battelle analysis of Bureau of Labor Statistics, QCEW data from the Minnesota IMPLAN Group.

Appendix II: Potential OrthoWorx Structure

- OrthoWorx could be created as a 501(c)(6) business league and the Orthopedics Capital Foundation (OCF) established as a 501(c)(3), 509(a) type 1 supporting organization.
- OrthoWorx and OCF to share executive leadership and have a common professional staff.
- OCF to be a supporting organization of the Kosciusko County Community Foundation (KCCF), with KCCF maintaining own existing staff, programs, resources, mission.
- OrthoWorx would be authorized to appoint at least one member to the OCF board of directors to ensure program and funding fidelity to OrthoWorx mission. Initially, KCCF would appoint a majority of members to the OCF board.
- OrthoWorx would be the brand encompassing both the business league and charitable and educational focused initiatives funded by OCF.
- Membership in the business league would be supported by significant (for Warsaw) annual fees, and open by invitation-only to high-level industry and community leadership committed to and capable of advancing key components of the OrthoWorx mission.
- The initial connection to KCCF outlined in this structure is assumed to be legally required and certainly beneficial, but temporary, with the intent that as OrthoWorx and OCF mature and meet appropriate tests for support, OCF may migrate to become a separate and direct supporting organization of OrthoWorx.



Appendix III: IN-OrthoNet Proposal

Indiana Orthopedics Innovation Network (IN-OrthoNet)

A White Paper to BioCrossroads submitted by Indiana Research Universities

Indiana is fortunate to be the “orthopedics capital of the world” with three of the top five global orthopedic implant manufacturers, generating in excess of \$8 billion each year in revenue, located in the state. Moreover, Indiana ranks second, only to California, in the medical device industry, due in large part to the orthopedics industry. While these companies all have active research programs, current product portfolios are based on major discoveries and translation that are increasingly decades old. In order to maintain a competitive advantage, Indiana must be repositioned on the leading edge of incubating new technologies that carry the potential to transform the orthopedics industry. Therefore, the IN-OrthoNet will expand and enhance university capabilities and collaboration, better compete for federal research funding, and enable the stimulus of new discoveries and translation in promising new research areas, including regenerative medicine or tissue engineering, orthobiologics, bionanotechnology, biosensors, pharmacogenomics, proteomics and bioinformatics – to name just a few – with the ultimate potential of leading to a new wave of orthopedic start-ups, corporations and clinicians that call Indiana home.

The mission of the IN-OrthoNet will be to stimulate the translation of innovative orthopedic technology from discovery to commercialization and the clinic. The IN-OrthoNet will provide an open, common nexus of infrastructure, expertise, clinical data, seed funds and other resources available to link entrepreneurs, clinicians and basic science researchers seeking to develop and translate innovative orthopedic technology to the clinic. The mission of the IN-OrthoNet will be achieved by:

- 1) ***Implementing*** a centralized IN-OrthoNet administrative staff, directed by a preeminent leader in orthopedics, who will cast the vision, develop and manage the network.
- 2) ***Organizing*** a network of all available orthopedic resources in the state of Indiana, including researchers, clinicians, laboratories, companies, animal facilities, cell lines and tissues, implant retrievals and clinical data.
- 3) ***Connecting*** and plugging interested parties into Indiana resources. For example, a start-up company in need of resources to test the feasibility of their new technology will be able access the IN-OrthoNet to be connected with individuals and facilities with the requisite expertise and infrastructure. A clinician or academic researcher with an idea for a new innovation will be aided in partnering with entrepreneurs and companies. A researcher in need of clinical data to support a hypothesis for an NIH proposal will be able to find or generate the data from available medical records. The formation of collaborative teams spanning universities, start-up companies, corporations and clinicians will be streamlined.
- 4) ***Providing*** competitive seed funds for collaborative teams to discover and translate innovative orthopedic technology. The IN-OrthoNet administrative staff will organize review and oversight panels with experts able to evaluate and provide guidance to specific projects.
- 5) ***Supporting expanded infrastructure***, including staffing, for translational research and development supported by the IN-OrthoNet. Existing basic research facilities at Indiana research universities have neither the capacity for additional translational research projects nor are optimized for applied research requiring rapid commercialization and sensitivity to intellectual property rights. Core facilities and staff dedicated to translational research will provide start-ups or corporations lacking specific expertise, equipment and infrastructure “one-stop shopping” on a fee for service basis

without the complex administrative issues associated with academic research facilities. The translational research facilities will further provide a middle ground for cross-pollination of scientific expertise in discovery with business expertise in commercialization.

Our vision is to ensure that Indiana is a fertile environment for clinicians, researchers, entrepreneurs, start-up companies and existing corporations to synergistically collaborate in the translation of innovative orthopedic technology, leading to improved healthcare and economic growth. This environment will attract new start-ups, clinical researchers and entrepreneurs to Indiana, and lead to corporate expansions and acquisitions within Indiana. Moreover, the IN-OrthoNet will enable academic and clinical researchers to focus on discovery and basic research, and small-businesses and corporations to focus on commercialization, by standing in the gap.

Appendix IV: Dr. Rick Sasso Report

BioCrossroads

CICP Foundation: Indiana Orthopedics Sector Initiative

Rick C. Sasso MD

Professor

Chief of Spine Surgery

Clinical Orthopedic Surgery

Indiana University School of Medicine

Indiana Spine Group

Indianapolis, IN

The state of Indiana is fortunate to house a wealth of orthopedic surgical talent within its borders. Warsaw alone is home to three of the world's largest orthopedic manufacturing companies and the largest spine manufacturing facility on the globe. Indiana University School of Medicine is one of the largest medical schools in the country and Purdue University has one of the most prestigious veterinary schools in the nation. Additionally, some of the most current and progressive FDA sponsored clinical trials are being done by Hoosier orthopedic and spine surgeons. There is not another state in this country with more orthopedic focused research and manufacturing ability.

Unfortunately, there is not much collaboration between these world-class centers. The synergistic possibilities are immense, but there are many obstacles to achieving this goal. An independent initiative such as this from BioCrossroads stands the best chance of capitalizing upon these valuable Indiana assets and assuring this state remains the orthopedics capital of the world.

A three-pronged approach could provide the catalyst to support and bring together the Indiana orthopedic industrial complex. This would include #1: building a surgical training facility that can provide hands-on training in a state of the art skills laboratory with conference facilities, operating room equipment and a cadaver laboratory. #2: constructing an independent biomechanical testing facility to serve orthopedic manufacturers, research universities, orthopedic surgeons and other innovators in the orthopedic device market space. And #3: securing a pre-clinical testing facility providing access to animal models and other pre-clinical services for orthopedics, biologics and resorbable technology.

#1: Education is critical to the orthopedics industry. Surgeon training is a vital step in the release of a new device or technique. Orthopedic manufacturers require modern training facilities in order to teach the proper use of their products and the FDA many times requires surgeons complete a comprehensive training program before using new technology. The modern surgical training facility includes a cadaver laboratory with complete operating room set-up including microscopes, fluoroscopy, and image navigation technology. Video and audio connection to an in-house auditorium is essential for moderators to ask and answer questions from participants in the auditorium in real-time. Interactive technology is also necessary for live feeds from operating rooms and auditoriums around the world. This facility should be

attached to a very nice hotel for the participants and faculty members to stay and this hotel should also be able to provide catering services to the training auditorium. This facility needs to be very easy to access from a large international airport so that time-strapped surgeons waste the least amount of time traveling.

#2: An independent biomechanical testing facility will benefit and serve all orthopedic interests in the state. Manufacturers need an independent laboratory to conduct many diverse loading tests as mandated by the FDA prior to approval of their devices. There are a limited number of testing facilities in this country that can provide these types of services. Product approval is often times delayed while waiting for critical biomechanical testing. An orthopedic-focused independent biomechanics lab will help our state's orthopedic manufacturers drive their products to market faster and benefit our state economy. This facility can also serve the innovative surgeons and researchers of Indiana with early stage design, product development, and proof-of-concept validation.

#3: A pre-clinical orthopedic animal testing facility would not only provide a positive impact to the orthopedics industry in our state but also to all companies that must produce FDA mandated pre-clinical animal data for their products. There are very few facilities that can provide this type of research data, while at the same time, the FDA is increasing the amount of animal data necessary for PMA applications. As technology is advancing, we will need more animal examination of wear debris in motion-sparing devices, biologic evaluation of gene therapies, and histological study of resorbable technology.

Much good and relief of suffering from orthopedic disabilities have come from technologies and procedures devised within our state. Nurturing this innovation is important and this plan will help our orthopedic engine continue to run efficiently and effectively. The above plan is ambitious but certainly attainable. Its implementation will not only maintain Warsaw's status as the orthopedics capital of the world for years to come, but it will also achieve the goal of making Indiana the orthopedics research capital of the world.



About BioCrossroads

BioCrossroads (www.biocrossroads.com) is Indiana's initiative to grow, advance and invest in the life sciences, a public-private collaboration that supports the region's existing research and corporate strengths while encouraging new business development. BioCrossroads provides money and support to life sciences businesses, launches new life sciences enterprises (Indiana Health Information Exchange, Fairbanks Institute for Healthy Communities, BioCrossroadsLINX, and Datalys Center), expands collaboration and partnerships among Indiana's life science institutions, promotes science education and markets Indiana's life sciences industry.

Contact

BioCrossroads
300 N. Meridian St., Suite 950
Indianapolis, IN 46204
Phone: (317) 238-2450
Fax: (317) 238-2451

For general inquiries regarding this report and its contents, please contact **Matt Hall** at (317) 238-2468 or m.hall@biocrossroads.com.

For media inquiries, please contact **Lori LeRoy** at (317) 238-2456 or leroy@biocrossroads.com.



300 N. Meridian Street
Suite 950
Indianapolis, IN 46204

317.238.2450

www.biocrossroads.com