VOLUME 8, ISSUE 15 | MAY 8, 2012

Orthopedics This Week

week in review

breaking news

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Europe's elections have reset the deck. Back to square one. It's going to be a difficult week—even month. Dollar will strengthen. Silver lining—maybe more money will be available to fund healthcare in Europe. Is the Euro at risk? Are we heading to a future of the French Franc, Greek Drachma and Spanish Peseta? At least they'd be able to issue currency denominated sovereign debt. Like Japan.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Orthofix	16.23%	8.35%	Compared to 23 other orthopedic companies, OFIX has the lowest PE to Growth Rate in the industry.
2	2	Conmed	10.09	(7.67)	EPS up 16%. Operating profit margin up 30 basis points. New cash dividend for shareholders. What's not to like?
3	3	NuVasive	6.63	26.17	22% increase in sales is terrifically encouraging. Tighter profit margins speak to how tough the fight is for market share.
4	5	Johnson & Johnson	24.93	(0.99)	Could DePuy's merger with Synthes be an accomplished fact in the next 60 days? Yes.
5	7	Integra LifeSciences	13.34	5.81	FDA clears Integra's Vu IBD device for anterior lumbar fusion. Beats expectations in Q1. Up two spots.
6	4	Zimmer	24.95	(2.20)	Large, diversified international companies like ZMH will feel the brunt of Europe's volatility. At these PE levels, still cheap.
7	9	Symmetry Medical	5.29	7.36	Gross profit margins higher (25% vs. 20%). Operating income up 43%. Sales up 19% sequentially. Up two spots.
8	6	Stryker	23.68	(1.64)	After OFIX, SYK has the best PE to Growth ratio. SYK in holding pattern until CEO in place.
9	8	Smith & Nephew	21.50	1.34	SNN spins off biologics business, then increases investment in negative pressure wound therapies.
10	10	Medtronic	28.24	(0.29)	Searching for a catalyst at MDT. New technology? Time for some Memphis Rock 'n Roll – y'all.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Kensey Nash	KNSY	$38.32	$332	33.01%
2	NuVasive	NUVA	$20.25	$874	26.17%
3	Wright Medical	WMGI	$20.85	$820	10.32%
4	Orthofix	OFIX	$40.34	$754	8.35%
5	Symmetry Medical	SMA	$7.59	$278	7.36%
6	TranS1	TSON	$3.50	$95	6.38%
7	Integra LifeSciences	IART	$36.23	$979	5.81%
8	RTI Biologics Inc	RTIX	$3.70	$207	3.35%
9	Smith & Nephew	SNN	$50.04	$8,971	1.34%
10	Medtronic	MDT	$38.15	$39,699	-0.29%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	$1.48	$62	-37.82%
2	TiGenix	TIG.BR	$0.69	$63	-17.49%
3	Conmed	CNMD	$27.80	$786	-7.67%
4	Alphatec Holdings	ATEC	$2.14	$192	-6.96%
5	Exactech	EXAC	$15.55	$205	-3.66%
6	MAKO Surgical	MAKO	$39.67	$1,689	-3.48%
7	CryoLife	CRY	$5.06	$139	-2.88%
8	Tornier N.V.	TRNX	$24.31	$956	-2.88%
9	Zimmer Holdings	ZMH	$63.15	$11,123	-2.20%
10	Stryker	SYK	$53.87	$20,521	-1.64%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$38.15	$39,699	11.88
2	Zimmer Holdings	ZMH	$63.15	$11,123	12.81
3	Johnson & Johnson	JNJ	$64.74	$177,716	12.90
4	Stryker	SYK	$53.87	$20,521	14.14
5	Orthofix	OFIX	$40.34	$754	14.46

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$20.85	$820	53.46
2	NuVasive	NUVA	$20.25	$874	47.09
3	Symmetry Medical	SMA	$7.59	$278	30.36
4	Kensey Nash	KNSY	$38.32	$332	26.80
5	Exactech	EXAC	$15.55	$205	21.90

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$40.34	$754	0.83
2	Stryker	SYK	$53.87	$20,521	1.31
3	ArthroCare	ARTC	$25.47	$704	1.36
4	Zimmer Holdings	ZMH	$63.15	$11,123	1.38
5	Stryker	SYK	$53.96	$20,573	1.35

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$20.85	$820	5.67
2	NuVasive	NUVA	$20.25	$874	4.87
3	CryoLife	CRY	$5.06	$139	4.52
4	Symmetry Medical	SMA	$7.59	$278	2.53
5	Smith & Nephew	SNN	$50.04	$8,971	2.22

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Symmetry Medical	SMA	$7.59	$278	0.77
2	Alphatec Holdings	ATEC	$2.14	$192	0.97
3	Exactech	EXAC	$15.55	$205	1.00
4	Conmed	CNMD	$27.80	$786	1.08
5	CryoLife	CRY	$5.06	$139	1.17

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.69	$63	55.16
2	MAKO Surgical	MAKO	$39.67	$1,689	19.98
3	Synthes	SYST.VX	$171.02	$20,314	5.11
4	TranS1	TSON	$3.50	$95	4.98
5	Kensey Nash	KNSY	$38.32	$332	4.64

PSR: Aggregate current market capitalization divided by aggregate sales and the calculation excluded the companies for which sales figures are not available.

Survey says…

By Robin Young

Wikimedia Commons and JTNeill

Taking the temperature of surgeons and hospitals is one of Wall Street's most helpful past times. Every month, one or two new surveys hit our desk. Lately these surveys have contained some surprises. So we thought we'd share them with you.

Hospitals First

Headlines tell us that hospitals are not in great shape. The big chains (Tenet Healthcare Corp., HCA or Universal Health Services) are reporting that admissions and earnings are slightly down and bad debt expenses are higher. Sounds pretty typical for a recession. So we were a bit surprised to see the results from Wells Fargo's Hospital Volume Report on April 16.

This monthly survey of U.S. hospitals is conducted by IMS Health and Wells Fargo Securities LLC. The survey tracks data from 650 hospital representing approximately 9 million inpatient stays and 96 million outpatient visits annually and continues with 100% of inpatient and outpatient visits for all sample hospitals.

Here is the opening sentence from the report:

"Total inpatient admissions increased by 1.1% and outpatient visits decreased by 3.7%. Trends in the South were strong with inpatient admissions up 3.0% and outpatient was down 0.4%."

In terms of sectors of care, Wells Fargo's analysts wrote: "Ortho appears stronger than Cardio. Among ortho categories, growth rates for knees and hips improved in February whereas spine and shoulders got worse."

So, here are the key points from Wells Fargo's survey of hospitals in the U.S.

- Inpatient admissions increased by 1.1% and outpatient decreased 3.7% (year-over-year)
- Commercial inpatient admissions increased 3.6% and outpatient

admissions increased 1.4%
- Inpatient orthopedic and neurological surgical visits increased 1.4% and 1.6%, respectively
- Total ER visits declined 0.2% with outpatient ER visits down 5.4% and inpatient ER visits up 1.5%
- Uninsured admits grew 14.7% (!!) based on inpatient ER visits for other payers which includes uninsured.

Orthopedic Hospital Volume Trends

Hospital Setting	Payer Type	2011												2012	
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
Inpatient % change	**All Payers**	**2.4**	**(1.5)**	**5.3**	**(1.0)**	**(0.6)**	**2.1**	**(3.8)**	**0.5**	**2.7**	**(5.5)**	**(0.1)**	**0.3**	**2.8**	**1.4**
	Commercial	0.9	(1.5)	3.7	(1.9)	(1.0	0.9	(4.9)	0.7	(0.2)	(5.2)	(1.6)	0.2	2.5	(0.3)
	Medicaid	9.7	(3.6)	5.5	(3.8)	(3.0)	2.6	(4.9)	0.4	18.4	(12.5)	0.3	(5.3)	1.6	4.8
	Medicare	2.9	(2.0)	6.6	0.1	0.4	2.7	(4.5)	(2.8)	1.5	(4.9)	(0.8)	1.3	3.5	1.0
	Other	5.1	7.3	11.3	3.2	0.6	9.5	18.2	28.1	21.5	(4.2)	23.5	0.6	0.4	19.1
Outpatient % Change	All payers	(3.7)	(3.2)	(5.5)	(4.5)	6.1	0.7	(5.8)	(5.4)	(8.7)	(8.4)	(5.9)	(3.4)	(2.2)	(7.4)
	Commercial	(4.5)	(3.2)	(7.9)	(6.4)	5.3	(0.2)	(6.5)	(7.8)	(11.4)	(9.8)	(6.4)	(3.3)	(7.1)	(12.4)
	Medicaid	4.5	19.7	24.2	5.1	9.0	10.0	1.1	(8.8)	2.4	(8.2)	8.4	(4.6)	12.9	(1.1)
	Medicare	(1.6)	(3.8)	(1.8)	0.0	10.8	2.3	(2.1)	3.2	(5.3)	(5.3)	(11.0)	(2.7)	12.7	9.3
	Other	(6.5)	(19.6)	(13.4)	(4.3)	(1.2)	(3.2)	(15.3)	(1.2)	0.7	(2.2)	6.1	(6.3)	(5.0)	(3.7)

Source: Wells Fargo Equity Research and IMS Health

Except for "Other" inpatient, most orthopedic hospital volume categories are either down or flat and all were surprisingly volatile. "Other" inpatient showed the most consistent and significant growth rates of any category.

Breaking this data down into its components also uncovered some reasonably surprising trends.

Hospital Setting	Visit Type	2011												2012	
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
% Change	**Hip**	**0.1**	**(7.1)**	**7.1**	**(1.3)**	**2.1**	**1.3**	**2.5**	**0.3**	**12.2**	**(2.7)**	**5.6**	**7.0**	**9.6**	**14.4**
	Knee	(5.8)	(12.3)	(0.5)	(6.4)	(5.1)	(3.9)	(15.5)	(15.1)	(10.2)	(16.8)	(13.1)	(4.0)	(4.3)	(2.3)
	Shoulders	21.5	(1.1)	15.3	2.1	(3.6)	4.0	(3.1)	15.9	21.4	(5.3)	9.7	4.4	15.2	13.0
	Spine Fusion	3.0	5.4	2.3	5.6	7.2	8.9	(1.8)	(0.3)	4.8	(3.3)	(3.1)	5.3	8.9	4.9

Source: Wells Fargo Equity Research and IMS Health

A couple of trends stand out in this table. First is the seasonal pattern for shoulder visits. The best quarters are the first and third. The worst is the April-June (2nd) quarter. The other glaring message in the data is how different hip and knee growth trends are. Knees are weak and hips are strong. And finally spine hospital visits are clearly holding their own despite an increasingly challenging reimbursement environment.

Spine Surgeon Survey

Earlier this quarter Bank of America's (BofA) medical technology analyst Bob Hopkins issued the results of his survey of 75 spine surgeons. Here are his summary points:

- Surveyed surgeons expect spine fusions volumes at their hospitals to be flat in 2012 after a 1% (on average) increase in 2011
- 79% of the surveyed surgeons do not expect fusion volumes to be lower in 2012
- 62% of the surveyed surgeons have not seen incremental pushback from insurance companies over the last three months
- For those physicians who are planning to shift share from one manufacturer to another in the near future, rep relationships were cited as the #1 reason for the shift. Price was #2 driver and technology was #3.

The Bank of America survey talked to surgeons in 25 states, with 40% being neurosurgeons and 60% orthopedic spine surgeons. The average size of hospital represented in BofA's survey was 378 beds within a range of 200-1,000. The average number of fusions performed by responding surgeons was 171 per year within a range of 75 to 400. Lumbar fusions were 49% of the fusions performed by responding surgeons. MIS fusion represented 34% of the fusions performed by reporting surgeons. Finally, Medtronic Inc.'s products were used in 30% of the fusions performed by responding surgeons (DePuy Orthopaedic, Inc. was 14%, Synthes, Inc., Stryker Corporation and NuVasive, Inc were roughly 10% each and other companies made up the remaining 27%).

Surgeon Expectations for 2012

Realized (2011) and Expected (2012) Year-Over-Year Change in Fusion Surgeries		
	2011	**2012E**
0 to 5% more fusions	13.3%	25.3%
5 – 10% more fusions	12.0%	9.3%
Greater than 10% more fusions	6.7%	4.0%
The same number of fusions	49.3%	34.7%
0 – 5% fewer fusions	9.3%	4.0%
5 – 10% fewer fusions	9.3%	17.3%
Greater than 10% fewer fusions	0	5.3%
Weighted Average	**1.3%**	**0%**

Source: Bank of America, Bob Hopkins

Of those surgeons who report that they are expecting lower fusion volumes at their hospital in 2012, here are the most commonly mentioned reasons for a downturn:

- Insurance (38% of the respondents)
  - o Poorer insurance coverage
  - o Harder to get insurance authorization
  - o No insurance support for spine fusions
- The economy is down across the board
- Higher deductibles
- Volumes are dependent on group practitioners and the number in that group
- The number of spine surgeons in their area increased

Insurance Pushback

Interestingly enough, 61% of the surgeons surveyed said that they had NOT seen any change in insurance company payment policies; 39% did report that they were seeing more pushback from insurance companies. As to which types of fusions were triggering a negative insurance response, the most common answers mentioned were degenerative disc disease (DDD) and multi-level fusions.

Biologics

Of the surgeons surveyed 72% said that NO company had a biologic product which differentiated from Infuse. However, 28% said "yes" there are biologic products which have differentiated from InFuse. Which products were those?

Here are the most common responses:

- MSC's (mesenchymal stem cell)
- Trinity
- Stem cells with autograft
- Actifuse
- OP-7
- NuVasive's cancellous extract with stem cells
- Bioactive glass with autograft BMP (bone morphogenetic protein)
- Osteocel
- Stem cells
- Osteoprogenitor cell biologics
- DBX
- Osteocel plus
- Calcium triphosphate

Vendor Opinions and Forecasts

Of the surgeons surveyed 33% said that their hospitals are restricting the number of spine fusion product vendors allowed into the hospital and 40% said that their hospitals will be restricting vendors in 2012. As to vendor loyalty, spine surgeons remain a fairly stable group. Only 14% (1 in 7) said that they planned to switch more than 5% of their business to a new vendor in 2012 (although 17% said that they had switched recently).

Finally, which vendor did these surgeons believe would take the most share in their hospital over the next 12 months and which company would they expect to lose the most share?

Largest Expected Market Share Gainer According to Surveyed Surgeons	
Medtronic, Inc.	32%
Stryker Corporation	13%
DePuy Orthopaedics Inc.	11%
NuVasive, Inc.	8%
Synthes, Inc.	7%
Biomet, Inc.	5%
Zimmer, Inc.	4%
Alphatec Spine, Inc.	3%

Source: Bank of America, Bob Hopkins

Largest Expected Market Share Loser According to Surveyed Surgeons	
Medtronic, Inc.	23%
DePuy Orthopaedics, Inc.	12%
Synthes Inc.	8%
Stryker Corporation	5%
NuVasive, Inc.	5%
Biomet, Inc.	1%
Zimmer, Inc.	1%

Source: Bank of America, Bob Hopkins

All in all, the surveys are showing that the market for spinal implant products is proving to be more durable than the headlines about insurance company pushback might suggest. Wells Fargo's hospital survey was certainly interesting and the weakness in knee visits combined with the unexpected strength in both hip visits and spine fusions shows the value of that survey. ♦

Orthopedics This Week

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Is the Golden Age of Medicine Peaking?

By Walter Eisner

Wikimedia Commons, Andrew Huth, and RRY Publications

Sixty years ago medical imaging was an X-ray and a light box. Then Raymond Damadian, M.D., used magnetic resonance to identify healthy tissue from cancer. CT, MRI. and PET scanners revolutionized medicine by making decision-making simpler, safer and more accurate.

One hundred years ago children were dying because of unsafe water and milk. Water and milk safety as a public choice began around 1910. Meat, food, drugs and devices began later. Public health may be the single greatest medical innovation of all time.

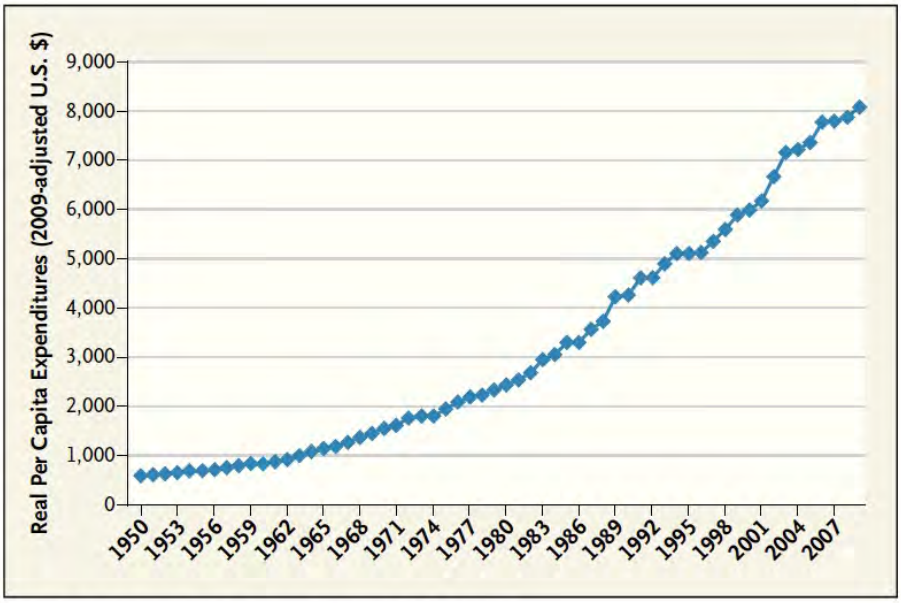
Think about all the changes that have created modern health care over the last century: insulin, vaccines and immunizations for diphtheria, whooping cough and tetanus, later polio, measles, mumps, rubella, hepatitis A and B, H flu and meningococcal meningitis.

Antibiotics and modern surgical techniques, safer and shorter acting anesthetics like fentanyl which allow patients to go home a few hours after an operation, micro and robotic surgery. Blood transfusions. Chemotherapy and radiation oncology.

Fiber optic medical instruments. Soft tissue repair. Artificial joints. Video monitors and laparoscopic instruments.

And the coffee maker in the physicians' break room.

Yes, these last decades have been a golden age of medicine.



U.S. Per Capita Health Expenditures, 1950–2007.

NEJM

Since the end of the Second World War and the boom of the Post-War Generation, health care spending, as a share of the GDP (gross domestic product), almost quadrupled from 4.6% in 1950 to more than 17% in 2009. In most peer countries, the share is 9 to 11%.

Clearly, the advances those dollars purchased are what made these past decades such a remarkable period of medical and intellectual ferment.

But at 17% of GDP and heading, most experts believe, to 20% of U.S. GDP, are the resources devoted to medical care and new technology going to start crowding out other spending?

Three Major Trends

Victor Fuchs, PhD., writing in *The New England Journal of Medicine* (*NEJM*)(n engl j med 366;11 nejm.org March 15, 2012) said there were three major trends that contributed to the shift of resources in the United States to health care.

1. Rapid advances in medical science and technology.
2. Substantial gain in health outcomes attributed to medical care.
3. Increases in health care expenditures fueled by private and public insurance payers who now pay 90% of the total bill for care.

Fuchs also cited as major trends:

- the increased role of the federal government in funding health care
- the decline in inpatient use of hospitals (fewer admissions and shorter stays) and the expansion of hospital outpatient services
- the shift in the physician workforce toward more women, more specialists, and more hospital-based physicians
- new medical technologies that now present clinicians with a menu of 6,000 drugs and 4,000 procedures to choose from.

End of the Era?

The problem with golden ages is that they eventually have to end. Could the rising cost of modern health care be putting a squeeze on funding particularly during this period of U.S., and indeed, global, debt concerns?

The rapid growth of health expenditures, writes Fuchs, has implications for the financial viability of federal and state governments and has resulted in stagnation of wages in most industries.

In 2009, the 17% health care slice of the nation's pie represented a larger share of the economy than all manufacturing, or wholesale and retail trade, or finance and insurance, or the combination of agriculture, mining, and construction.

Slowing Economic Growth

From 1950 through 2009, Fuchs found that there was an almost continuous increase in annual real per capita health expenditures, with the exception of a two-year pause in the mid-1990s, when the effect of managed care was at its peak.

The relative rate of increase was greater between 1950 and 1980 than between 1980 and 2009—4.6% versus 4.1% per year—primarily because of the introduction of Medicare and Medicaid in 1965.

Unfortunately, the slight slowing in the rate of growth of health expenditures since 1980 was accompanied by even greater slowing in the growth of the

GDP (per capita adjusted for inflation), from 2.6% per year in 1950–1980 to 1.8% per year in 1980–2009.

Thus notes Fuchs, the gap between the rate of growth of health expenditures and that of GDP increased from 2.0% to 2.3% per year between the two periods.

Supply and Demand

Fuchs says the most important explanation for the increase in real per capita health expenditures is the availability of new medical technology and the increased specialization that accompanies it.

Between 1974 and 2010 alone, the number of U.S. patents for pharmaceutical and surgical innovations increased by a factor of six.

Second in importance is the spread of public and private health insurance, which diminishes the effect of health care prices on demand.

"There is a positive-feedback loop between new technology and the spread of health insurance: new technology stimulates the demand for insurance, and the spread of insurance stimulates the demand for new technology," writes Fuchs.

Finally, a small portion of the increase, typically 0.1 or 0.2 percentage points per year, is attributable to the aging of the population.

There are roughly 79 million "Baby Boomers" who were born between the years of 1946 and 1964 with about 10,000 retiring every day. That is going to keep happening every single day for the next 19 years.

Rise of the Third-Party

Fuchs found that the sources of payment for medical care have changed significantly since 1950.

The growth of government's share, and especially the federal share, can be explained, says Fuchs, by the public's desire to cover more of the public with insurance and private insurers' difficulty in providing coverage for the elderly and the poor. Federal legislation also substantially extended public coverage for children.

Personal Health Care Expenditures in the United States from 1950 through 2009.*

Variable	Year or Period		
	1950	1980	2009
Per capita expenditures (2009 dollars)	407	2,050	6,807
Source of payment (%)			
Out-of-pocket	56	27	14
Third-party	44	73	86
Private or public (%)			
Private	73	60	53
Public	27	40	47
Federal	13	26	35
State and local	14	14	12
	1950–1980	1980–2009	1950–2009
Average annual rate of change (% in 2009 dollars)			
Out-of-pocket	3.0	1.9	2.4
Third-party	7.1	4.7	5.9
Private	4.7	3.7	4.2
Public	6.7	4.7	5.7
Federal	7.8	5.0	6.4
State and local	5.2	3.8	4.6

* The percentage of payments by the federal government was calculated on the basis of National Health Care Expenditure data. Data are from the Department of Health and Human Services and the U.S. Census Bureau.

NEJM

A decline in out-of-pocket payment and a rise in third-party payment (both private and public), an increase in government's share of payment and a decrease in the private share, and an increase in the federal government's share as compared with that of state and local governments, have contributed to that change.

Fuchs wrote that third-party payment has grown partly because of expensive interventions that expose individuals to large financial risk.

Managed Care

No history of the last 50 years of health care would be complete without noting how managed care affected hospitals and physicians. Until about 1990, most insured patients could choose their providers and physicians' decisions weren't second guessed by insurers.

The rapid growth of health care expenditures in the late 1980s, combined with sluggish growth of the GDP, fueled a demand for change and insurers contracted with providers. Prices were negotiated in advance and physician decisions became subject to insurance company review. Fuchs says the effect on health care expenditures was dramatic as growth rates fell to 2% per year by the mid-1990s.

The 3:2:1 Formula

Since 1950, health expenditures have gone primarily to hospitals, physicians, and drugs. Fuchs found the rate of growth of expenditures in each of these categories between 1950 and 2009 to be fairly close to the rate of growth of total health expenditures.

As a rule of thumb, the ratio 3:2:1 does a fairly good job of describing the relative importance (in dollar terms) of hospitals, physicians, and drugs.

Spending for hospital care and physicians received a boost between 1950 and 1980 when Medicare and Medicaid were introduced.

Spending for drugs accelerated sharply after 1980 following the introduction of a host of new products for treating heart diseases, mental illness, gastrointestinal disorders, and cancer and a large increase in private and public insurance coverage for drugs.

The Physician Genesis

The number of active physicians in the U.S. quadrupled between 1950 and 2009.

The number of physicians per 1,000 population increased from 1.41 to 2.73, an annual growth rate of 1.1%, with large increases in the percentage of female physicians, specialist physicians, and hospital-based physicians.

Female physicians, wrote Fuchs, have different preferences regarding annual hours of work, night coverage, self-employment, specialty choice, and other aspects of practice.

Notes Fuchs, more and more physicians are choosing to become specialists or subspecialists and those decisions have increased considerably the number of years an average physician spends in training. There are now 150 specialties, up from a dozen 50 years ago.

Changes in Organization and Delivery

Fuchs argues that the shift away from office-based practice, along with possible changes in payment systems, may portend a time when most medical care will be delivered by teams of physicians and other health care models such accountable care organizations (ACOs).

Instead of reimbursing individual doctors and hospitals per procedure, lump-sum payments are made to clinicians working as a formal ACO team.

Fuchs also cites the recent trend of a sharp division between physicians who treat outpatients and others, called hospitalists, who treat only inpatients. The number of hospitalists has grown from about 1,000 15 years ago to approximately 30,000 in 2011.

Another trend noted by Fuchs is the use of electronic medical records (EMRs) in physicians' offices.

Era of Big Data?

Fuchs says perhaps the most important future trend is the replacement of the current system of organization and delivery with competition among large accountable care organizations serving defined populations.

Historians aren't fortune tellers. Will the Golden Age of Medicine be replaced by the Era of Big Data as described in Eric Topol, M.D.'s book, *The Creative Destruction of Medicine*? We'll soon know. ♦

Barrack, Lombardi Square Off: MIS a Risk Factor for Failure?

By Elizabeth Hofheinz, M.P.H., M.Ed.

Robert Barrack: "It's rare for us to see a revision knee from the community that failed in 12-15 months, but it's the norm for MIS knees." Adolph Lombardi: "But Robert, if your community has a number of surgeons who are attempting MIS, you're going to see more failures."

This week's Orthopaedic Crossfire® debate is "MIS: A Risk Factor for Early TKA Failure." For the proposition was Robert L. Barrack, M.D. from Washington University Medical School in St. Louis. Against the proposition was Adolph V. Lombardi, Jr., M.D. of the Mt. Carmel New Albany Surgical Hospital in Ohio; moderating was Steven J. MacDonald, M.D., F.R.C.S.(C) of the University of Western Ontario.

Wikimedia - KaihsuTai and Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Barrack: "There is some support in the literature for short term benefit to an MIS TKA [minimally invasive surgery total knee arthroplasty]. The data is pretty soft and is for 6-12 weeks. There are a lot of problems with these studies, however. These are all done by designers and proponents of the system utilized; they're prone to selection and observer bias. These are very experienced, high volume surgeons, and may not be representative of the results that most surgeons with less experience and lower volume can expect. There is little or no literature on MIS total knees performed by community surgeons."

"We did a study looking at all revision total knees at three referral centers that do revisions from community surgeons. These are first time revisions—not infections or re-revisions. In an MIS knee…it looks cosmetically excellent. The incision is only about 10cm; the definition in the literature is generally <14cm…ours were between 10 and 12cm. And the proximal extent of the incision was within 1cm of the proximal portion of the patella. We had 236 first time revisions; about 80% had been done through a standard approach. In this time period we had done 44 revisions of MIS knees. So we compared the MIS revisions to those done through a standard approach…by gender, diagnosis, time to revision, and reason for revision."

"We found: MIS patients were younger, there were more females and large females…and the time to revision was shocking. Less than 15 months to revision for the average MIS knee compared to about seven years to revision of a component placed through a standard incision. MIS failures were much more likely to occur in the first year; more than 80% occurred within two years. They were much more likely to fail through malrotation or instability. Yet, they were much less likely to have lysis or wear as a cause of failure."

"Examples: One knee surgery was done by a surgeon who took three hours, so he bailed out to a standard incision in the other knee and did it in half the time. The right knee was painful, with tibia loosening at a year. In another case of patellar instability, the femur and tibia were malrotated…requiring revision at eight months."

"These are the 'catastrophic' failures that were revised within 1-2 years. What

are the mid- and long-term results of those that do stay in place? MIS procedures magnify the common errors of total knee replacement. In one case, a varus knee in a large female with limited motion, the patient had a standard knee on the opposite side and had more motion and better clinical results. Her postoperative course was somewhat better in the standard knee side than the MIS side."

"The downside of the MIS knees: higher complication rate, more outliers (even among the experts). There has been a published result of a prospective, randomized study of MIS versus standard among proponents of MIS knees and at 12 weeks they found no difference, although the MIS knees did have a significant number of delayed wound healing. Their conclusion was that there was no improvement over a standard approach."

"The title of this debate is NOT: 'the complication rate of MIS is invariably higher' or 'MIS is a bad, bad thing.' The question is, 'Is MIS a risk factor for early failure of TKA?' I would say, based on the high number of early revisions that we're seeing and our published results, the answer is 'yes.'"

Dr. Lombardi: "MIS: it's not a risk factor for early failure. A patient came to see me last week, and was obviously not an MIS patient…only eight months postop. There was radiolucency on the medial tibial plateau; a range of flexion of about 60 degrees. Another patient with a long incision…and again, a painful, malaligned knee. Technique trumps incision length."

"My data: From 1994-96 with a standard medial parapatellar approach in 1,291 knees. We'll compare that to a limited incision done by two of us—Keith Berend and myself—and 3,631 knees. The male/female distribution was quite similar. We did more CRs [cruciate retaining] in the MIS group than in the standard group, but less patients required manipulation in the limited incision group…and there were less reoperations in the limited incision group."

"MIS is also 'Multidisciplinary Interactive System.' It's the 10 steps you need to pull the whole operation together. Do a good orthopedic assessment, a good history and physical, align patient expectations with your expectations, and motivate your patient. Also, have a good preoperative clearance, so when

the patient hits the OR they're going to be a candidate for surgery that day. And we know that preoperative rehabilitation can decrease length of stay and anxiety. If we educate our patients better they will come through surgery quicker with less pain, less anxiety, decreased length of stay, and increased satisfaction."

"We've also understood from the MIS movement how to handle pain better…and we need to treat it on a multifactorial basis…epidurals/spinals/regional blocks/local anesthetic; we need to use anti-inflammatories preop and perioperatively, and get them started on a long-acting Oxycontin or another medication."

"You need a very responsive anesthesia team to get a good spinal if that's what you prefer—or a femoral nerve block. We don't like a femoral nerve block, however, because that means we can't get the patient up without a knee immobilizer. We have a multimodal prophylactic antimetics system consisting of Decadron, Zofran, and a Scopolamine patch."

"The operative intervention is critical. If you're going to approach this patient with a small incision, proceed with caution in these patients: muscular male, those with increased BMI [body mass index], osteopenia, patella baja, decreased ROM [range of motion], a significant flexion contracture or deformity, severe bone loss, thin skin (patient with RA [rheumatoid arthritis] or diabetes), and those patients who had an open reduction or an osteotomy of some type."

"Use an incision that you are familiar with. If you've been doing a midvastus, make it smaller. If you've been doing a medial parapatellar, maybe shrink that one down. We know there's literature to confirm that indeed these patients do better early on, probably because we don't violate as much of the suprapatellar pouch."

"And we're making sure we protect the key ligamentous structure during the whole operation. We're identifying the landmarks that we need to get good rotational control, and I think this has been helped by instrumentation that has been streamlined by all the manufacturers to help us make smaller incisions and get the products in correctly. Also, you can combine this with navigation."

"Or you can use an MRI-generated total knee where we make an actual mold of the patient's anatomy to give you a jig to put on the patient. You can do this through a smaller incision and appropriately align the parts."

"We are aggressive with pain management…and patients are out of bed within hours of the operation—full weight bearing. Our average length of stay in 1997…3.9 days for traditional; as we incorporated rapid recovery it went down to 2.8 days in 2003. As we progressed with a standard incision and the rapid recovery, it was 2.7 days; as we added smaller incisions we got down to 2.2 days."

"The reality of MIS is that it's multifactorial. My take home message is: MIS is here to stay."

Moderator MacDonald: "Robert, what would it take in terms of a prospective, randomized clinical trial to sway you…or do you think it's more complicated than that?"

Dr. Barrack: "It's not that MIS is bad—I do MIS on most of my knees. It's rare for us to see a revision knee from the community that failed in 12-15 months, but it's the norm for the MIS knees. The question for the audience is, 'What applies to their practice?'"

Dr. Lombardi: "But Robert, if your community has a number of surgeons who are attempting MIS, you're going to see more failures. In our community we still have a large number of surgeons doing longer incisions. Hence, my patients who come in have long incisions and have the same types of problems you're talking about with MIS."

Dr. Barrack: "Are you seeing failures in 12-15 months?"

Dr. Lombardi: "Both of those patients were 8 to 9 months postop."

Dr. Barrack: "We looked at all of our revisions over several years and it's relatively rare to see a revision in a year or two. And I don't think MIS is being done on that large a scale—and this was an experience at three centers, so I'm concerned that there is a high risk. You're not going to get as good fixation, exposure, and ligament balance early on without more work, so you have to be more selective."

Moderator MacDonald: "Adolph, the ideal indication in your practice would be the thin, non-osteopenic woman—just kidding."

Dr. Lombardi: "That is where you should start…thin female, maybe with a valgus knee, where the patella subluxes very easily. Once you accomplish that you move on into more difficult cases."

Moderator MacDonald: "Robert, what do you tell a patient who is pushing MIS?"

Dr. Barrack: "Three-fourths of the time I do it, but if I have a 300lb patient or someone with too much deformity I tell them that it may not be the best thing for them."

Dr. Lombardi: "I encounter that all the time."

Dr. Barrack: "I take a pen and put a dot at the top of their kneecap and below the joint line and say, 'that's the minimum.' A lot of patients are shocked and think we're doing an arthroscopic procedure."

Moderator MacDonald: "Adolph, how much benefit have you seen from the multimodal approach versus from a smaller incision?"

Dr. Lombardi: "We're getting patients out faster with a shorter incision; and you can't determine the psychological perspective of the patient. When they see a small incision, closed, subcuticular with wound glue, they're excited. So perhaps this has much to do with organizing a good team around you and doing the right thing with respect to managing pain."

Dr. Barrack: "We've seen equal, surprisingly good results through standard incisions if you use all those modalities. If you shrink your incision a little you'll probably get similar results."

Moderator MacDonald: "Thank you."

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On (and Off) the Record

By Elizabeth Hofheinz

RSA Prevents Certain Revision Surgeries…Best Orthopedic Workplace? Gallup Makes Award...BONESUPPORT Wins Top European Technology Award...Practicing Medicine Where it Really Matters….and more.

New RSA Technique Eliminates Unnecessary Revision Surgery Wayne G. Paprosky, M.D., a hip and knee surgeon at Midwest Orthopaedics at Rush, knows if you're implant has been naughty or nice, er, well, if it's gone a wanderin'…He tells *OTW,* "Through the use of radiostereometric analysis (RSA) we are having great success at monitoring hip and knee implants; using miniscule beads, we can tell whether an implant has moved to the slightest extent. Since we began in January 2012 we have used RSA in well over 200 patients and have now worked out the 'bugs.' For example, we had to adapt the delivery device, and can now shoot the beads in with special guns. We are faster, and the placement of the beads has improved such that we can now do a better job of interpreting the results. Patients are given X-rays the day after surgery, and the scans are sent to Halifax, Nova Scotia, where special computers read the beads."

"This is going to be very valuable in the next six months when Zimmer comes out with a new cementless knee. There is the likelihood that we will eventually figure out the bead placement for shoulder and ankle surgery as well. Patients think it's great that we can 'follow' them. They know that if in a year and a half they have pain, but the scan shows that their beads have *not* moved, then they won't have to have a needless surgery. In the event that they *have* shifted, then rather than wasting time with pills and tests we can get them to the OR before they lose more bone. Orthopedic surgeons should be cognizant of this option…and certainly whenever they are doing an elective surgery they should use a device that has been tested with these beads. Especially given the metal-metal debacle, there is no way I'm going forward without using RSA."

HSS Best Orthopedic Work Place Says Gallup Hospital for Special Surgery has received the 2012 Gallup Great Workplace Award, an honor bestowed on

only 27 organizations worldwide this year. The hospital received the award because its results demonstrate one of the most "productive and engaged" workforces in the world. *OTW* asked HSS President and CEO Louis A. Shapiro the following question: What is the first indication a patient has when he or she enters HSS that "things are different here?" Shapiro told *OTW*, "It's not what they see, it's what they feel! They sense that everyone is on the same page and can easily tell that people really care about the organization and how staff and patients interact. Yes, you would expect the CEO to say that, but truly, it's validated every day when patients stop me in the elevator, send me 'thank you' letters, etc."

And, says Shapiro, the good feelings are backed up by numbers. "In the first quarter of 2012 our patient satisfaction results said it all: our composite score—which is all questions combined—was in the 99th percentile. To achieve that kind of number everyone in leadership has to feel in their hearts that culture and engagement is important. Then, if you believe it, you have to demonstrate that consistently in your actions. It's all well and good that I believe it but my actions have to work their way to the front line leadership who at the end of the day create this special environment."

"The concrete things we do to create this environment include leadership rounds where the executive team sits down with employees and discusses patient safety and opportunities for improvement; there are also breakfast meetings with employees who started 90 days prior. In addition, we have a leadership academy where we invest in the frontline leadership to ensure that they understand employee engagement. The key to any of this being a success, however, is follow up. We make it a habit to follow up on the suggestions of all employees. That is part of the reason why Gallup found us to be an 'engaged' workplace. HSS is a place where employees feel responsible for the organization's success. They sense that they are part of a team, and that their contribution and voice mean something. It may sound clichéd, but we are indeed like a family."

BONESUPPORT Wins Top Technology Award BONESUPPORT, a company focused on injectable bone substitutes for orthopedic trauma, bone infections and instrument augmentation related to orthopedic surgery, has been selected as a Top 100 Winner for Red Herring's 2012 Europe Award, a prestigious list honoring the year's most promising private technology ventures from the European business region. BONESUPPORT was one of only nine winners within the healthcare categories.

Osteoarthritis (OA): Catching it Early Carla Scanzello, M.D., Ph.D., is an assistant professor of rheumatology at Rush University Medical Center. She is also the 2012 winner of the Orthopaedic Research Society/Orthopaedic Research Education Foundation Travel Award. Dr. Scanzello tells *OTW*, "The ORS/OREF award was for my work regarding early-stage knee OA. We discovered that synovial fluid (SF) from early-stage knee OA patients contains a factor that could modulate inflammatory activation of synoviocytes. Since inflammation is variable in OA, the most difficult part is understanding the complexity of what causes one person to develop inflammation versus another. We think this factor may relate to that complexity."

"To study the impact of inflammation at an early point in the disease—at the point where patients are first at risk—we are following patients who have had a partial meniscectomy because the

meniscal tear population is a nice clinical model of patients at risk for knee OA progression. We're starting to see that individuals who have synovial inflammation are not only more symptomatic at the time of surgery, but over time may develop worse knee symptoms by two years post-surgery. In addition, we are looking at the mechanism of inflammation in these patients, and focusing on immune receptors critical in the initiation phase of inflammation, called Toll-like receptors. Research has shown that a number of molecules produced during cartilage injury can trigger these receptors and lead to inflammation in the joint."

"One interesting molecule is fibronectin, which is expressed by multiple tissues in the joint…and certain forms of fibronectin may bind these receptors to promote inflammation. So we are exploring the expression patterns of different forms of this molecule which may trigger joint inflammation after an injury like a meniscal tear. We know that many of the patients with meniscal tears will progress to joint replacement…we hope that if we can understand what is causing inflammation then we may be better able to predict who will progress to full blown OA… and can we stop that progression or slow it down by intervening in the initiation phase of inflammation."

James Caillouette, M.D. Wins Founders' Award The California Orthopedic Association has bestowed an honor on Dr. James T. Caillouette, surgeon in chief at Hoag Orthopedic Institute in Irvine, California. He has received the group'sprestigious 2012 Founders' Award, an honor given once a year to an individual who has exemplified the group's high standards for leadership in the field of orthopedics. One major accomplishment credited to Dr. Caillouette by the association was his leadership in the merger of two state-of-the-art surgical centers and other entities into Hoag Orthopedic Institute, one of only a few such health care models in the nation. ♦

company

Wright Sales Decline, Beat Expectations

Wright Medical Group, Inc.'s first quarter revenue of $126.7 million and $0.17 earnings per share beat consensus on the top and bottom lines. Beating expectations and a positive guidance for the remainder of the year boosted investor confidence and sent the company's stock up by over 10% after the May 1 announcement.

Overall, reported revenue fell 6.4%. Sales declined in hips, knees and biologics by 9.6%, 5.3% and 21.3% respectively.

Extremity sales were a bright spot, climbing 5.5%, while the company is midway through reorganizing efforts to convert 80 sales reps to direct reps in its extremities sales force. The company now has 110 direct reps and 90 indirect reps and expects to have around 140 direct reps and 60 indirect reps when finished. Analysts expect to see improvements in the business as sales productivity increases.

The company launched four new foot and ankle products during the quarter and saw an 11% increase in sales for those products. Management attributed the increase due to the continued success of their Inbone products, the Pro-Toe VO Hammertoe Fixation System, the January 2012 launch of the Ortholoc 3Di Ankle Fracture System and the early success from the March 2012 launch of the Claw II Polyaxial Compression Plating System.

The biologics business decline, according to management, was primarily due to an agreement to license the company's Graftjack brand in 2011.

Post-Disruption

Wright's story is one about trying to recover after new President and CEO Robert Palmisano took over a company whose sales efforts were disrupted by an exceptionally tumultuous federal monitoring program after a deferred prosecution agreement with the Department of Justice. Palmisano announced plans to implement a cost restructuring plan in the third quarter of 2011.

Wright Medical Technology, Inc. and yahoo.com

Wright Medical Group, Inc. 1Q12	Sales ($ in millions)	% Change*
Total Reported Sales	**$126.7**	**down 6.4%**
Hips	$41.5	down 9.6%
Extremities	$36.2	5.5%
Knees	$31.1	down 5.3%
Biologics	$15.2	down 21.3%
Other	$2.7	down 11.7&

Source: Wright Medical Group, Inc.

Management reaffirmed 2012 guidance, calling for revenue of $472 million-$489 million (versus the consensus's $482 million) and EPS of $0.08-$0.18 (versus the consensus's $0.16).

In a 10-Q SEC filing on May 2, the company stated, "We believe that our U.S. ortho-recon business will continue to be unfavorably affected by distributor transitions and challenges associated with implementing enhancements to our compliance processes and we believe that our U.S. ortho-recon business will be unfavorably impacted by our U.S. sales force conversion in 2012."

Palmisano's Expectations

Palmisano, commented, "Although our fourth quarter results were stronger than anticipated, we are not satisfied with our 2011 financial performance relative to the market opportunities, and we have much work ahead of us to improve our execution, efficiency and return to a high growth company. My top priorities will be to grow our foot and ankle business above market rates, run a much more focused and efficient ortho-recon business, and increase cash generation. I believe these initiatives will in turn drive growth and shareholder value."

Palmisano continued that the company is planning to, "substantially increasing our investment in medical education and foot and ankle product development to drive market adoption of new products and technologies." Those efforts were, as we reported, severely impacted by the federal monitoring program.

"As our guidance implies, these transformational changes for our business

will require significant investment in 2012, which will negatively impact our full-year 2012 results. However, we believe these investments will generate significant future returns, including accelerating foot and ankle sales growth rates and improving inventory management and cash generation. We are enthusiastic about our plan and look forward to executing our current strategies and improving our performance."

Tamping down expectations and then beating them is a good road to recovery while the business is still declining and searching for a bottom.

—WE (May 4, 2012)

NuVasive's Impressive First Quarter

NuVasive, Inc.'s 22% rise in sales to $151.7 million in the first quarter was impressive. Investors noticed and drove the company's stock up by over $4 to around $21 the day after the quarterly results were announced.

In the U.S., sales for the company's lumbar products rose 11.7%, cervical products rose 20.2% and biologics gained 15%.

Company Chairman and CEO Alex Lukianov told analyst on April 30 that it remains his goal to grow NuVasive into the third largest spine company in the world and reach $1 billion in revenue.

Spine Volumes

Lukianov also told analysts that, while payer push-back and pricing pressure remain in spine, he is not hearing from the field that things have gotten any worse. In fact, it's his sense that the market has bottomed out.

Wells Fargo Analyst Larry Biegelsen noted that NuVasive is the first pure spine company to report earnings during the quarter and based on the results of the larger orthopedic companies with spine segments who have already reported, the spine market remains challenged due to mid-single-digit pricing pressure and payer pushback on procedure approval.

"Our hospital procedure volume data suggests that spine procedures rebounded in the first two months of 2012, with 4% combined growth (excluding the extra day in Feb) over January and February of last year," wrote Biegelsen.

NuVasive, Inc. 1Q12	Sales ($ in millions)	% Change*
Total Reported Sales	**$151.70**	**21.90%**
U.S. Lumbar	$91.20	11.70%
U.S. Cervical	$14.20	20.20%
U.S. Biologics	$25.90	15.00%
U.S. Monitoring	$9.40	-9.60%
International	$10.90	35.00%

Source: NuVasive, Inc.

Sales and Margins

The story line about NuVasive has always been about the company's market share growth strategy. Margins on revenue continue to be challenging as Lukianov noted the company invests heavily in infrastructure to be able to respond immediately to customer needs. "That's why we opened a distribution center next to FedEx in Memphis," he told analysts. He believes the ability to be more responsive than competitors allows the company to convert surgeons when their current supplier is out of inventory and increase penetration with existing customers.

"Our profitability in the teens will increase," he said.

Market Dynamics

Lukianov said he believes there is "churning" going on in the spine industry as the smaller manufacturers with around 25-35% of the spine market are taking share from the larger players. He also noted that pressure on InFuse is opening pathways for demineralized bone matrix (DBM) use.

NuVasive and RRY Publications

When asked about physicians-owned distributors (POD), Lukianov said he believed the POD business model undermined innovation and was not good for the industry. He is hoping for a legal change of their status.

"Our financial performance in the first quarter of 2012 attests to excellent execution of our market-share taking strategy, and gives us increased confidence in our ability to achieve our full year revenue and profitability guidance. As we focus on execution toward our 2012 objectives, we are also making the necessary investments into NuVasive's differentiation and share taking strategy. Our commitment to maintain NuVasive's innovative prowess, to drive superior clinical outcomes, and to nurture our Absolute Responsiveness culture are the drivers of our success to date and will carry us beyond $1 billion in revenue. Looking forward, we expect our top line to grow in conjunction with an improving profitability profile and continual improvements in free cash flow. We are laying the groundwork today to become the #3 spine company in the world," said Lukianov in summarizing the quarter.

Raj Denhoy, Jefferies & Co. analyst wrote that his key observations about the quarter were that NuVasive remains the fastest growing spine company and continues to take significant share, even in the face of numerous competitive launches—managing to post healthy double digit growth despite more competition and continued weakness in the overall spine market."

—WE (May 2, 2012)

Orthofix Beats Expectations – Again

"It's our goal to get bigger," Orthofix International N.V. President and CEO Bob Vaters said at the end of his quarterly call with Wall Street analysts on April 26.

Having just announced the sale of Breg, Inc., the company's sports medicine business; beating earnings consensus while reporting a 4% rise in sales; and returning to positive growth in the company's spine stimulation business, the CEO can be forgiven for his optimism.

"I am very pleased with the performance during the quarter, especially the company's return to investing in R&D while still maintaining double-digit earnings growth. With the signing of the agreement to sell the Sports Medicine business, we believe our strengthened balance sheet and narrowed focus on our value proposition in the Spine and Orthopedic businesses will provide a better platform to continue to create value for our shareholders," said Vater.

The increase in operating margins and sale of Breg sets the stage for even stronger operating results, wrote *OTW* Publisher Robin Young in his weekly Power Ratings column. "Orthofix, true to form, surprised investors and now the upgrades are streaming in."

For the quarter, Orthofix reported a 4% increase in revenue on a constant currency basis of $143.1 million. Spine growth improved as spine stimulation, the company's largest product line,

Orthofix International NV 1Q12	Sales ($ in millions)	% Change*
Total Sales	**$143.1**	**4.0%**
Spine Stim	$39.3	2.0%
Implants/Biologics	$35.8	5.0%
Total Spine	$75.0	3.0%
Orthopedic	$41.0	4.0%
Sports Medicine	$27.1	10.0%

Source: Orthofix International NV

Image created by RRY Publilcations LLC. Orthofix International N.V.

returned to growth for the first time in five quarters.

Spine sales of $75.0 million grew by 3%. Spinal implants and biologics sales of $35.8 million grew by 5% as biologics growth remained strong and offset weaker implant growth due to pricing pressure. Spinal stimulation sales of $39.3 million grew by 2%.

The company noted strong biologic sales as its Trinity Evolution product benefited from the leakage of sales away from Medtronic, Inc.'s InFuse in spine surgeries.

—WE (May 1, 2012)

Former Kyphon Marketing Manager Sentenced to Jail

Jennifer Rutherford, the former senior marketing manager for Kyphon, Inc. who pled guilty last July to defrauding the company out of millions of dollars, has been sentenced in a Minnesota federal court to 45 months in prison.

Rutherford admitted orchestrating a scheme between June 2004 and June 2009 whereby she created sham companies that sold non-existent merchandise to Medtronic, Inc. Medtronic acquired Kyphon in July 2007.

According to a U.S. Department of Justice statement on April 27, Rutherford was responsible for selecting vendors to supply marketing merchandise that company representatives could distribute at trade shows and industry conferences, such as key chains, baseball caps, and tee-shirts.

Wikimedia Commons and Andrew Bardwell

Rutherford, of San Jose, California, admitted creating three shell companies and then pretending to buy merchandise from those companies. Subsequently, she submitted invoices to Medtronic for payment of the goods. However, no merchandise ever existed. The total Rutherford caused Medtronic to pay to her for non-existent merchandise was at least $2.1 million.

That's a lot of tchotchkes.

It's not often, in an era of deferred prosecutions, corporate integrity agreements and federal monitors at orthopedic device companies, that we see someone actually do hard time for cheating about alleged services and products rendered.

—WE (April 30, 2012)

legal

"Bellwether Trial" for DePuy ASR Hip Lawsuits

More than 6,000 lawsuits have been filed in state and federal courts by patients who claim they were harmed by DePuy Orthopaedics Inc.'s ASR metal-on-metal hip.

Lawyers have now agreed in front of a federal judge to conduct a "bellwether trial," to help determine potential liability and damages, according to a May 1 Bloomberg report.

The lawsuits, according to court documents, share factual issues as to whether DePuy's ASR XL Acetabular Hip System, a device used in hip replacement surgery, was defectively designed and/or manufactured, and whether DePuy failed to provide adequate warnings concerning the device, which DePuy recalled along with another ASR device,3 the ASR Hip Resurfacing System, in August 2010.

6,200 Lawsuits

Lawyers for patients and the company reportedly met with the Ohio federal judge overseeing the pretrial collection of evidence in 4,200 federal lawsuits. Another 2,000 are in state courts. Both sides are negotiating a way to choose suitable plaintiffs to help resolve whether the company bears blame and how much each case could be worth, said the Bloomberg article.

"The parties are in agreement that we would like to have a bellwether trial," company attorney Robert Tucker told U.S. District Judge David Katz at a hearing in federal court.

In January, DePuy's parent, Johnson & Johnson, reported that it had already spent about $800 million on the recall and in the past two years. At the hearing, Tucker reportedly told the judge that the company has produced more than 37 million pages of documents in discovery. By stacking that paper, "you would have seven towers equal in height to the Empire State Building," Tucker said.

First Trial in Vegas

According to Bloomberg, plaintiff's attorney Ellen Relkin said the first trial is scheduled to begin in state court in Las Vegas in mid-December. Another trial is slated for January in state court in Maryland. She said the first federal trial could be next March or April.

DePuy recalled its 93,000 ASR hips worldwide, including 37,000 in the U.S., saying more than 12% of the devices failed within five years. Lawsuits in federal and state courts describe patients in pain and immobilized by joint dislocations, infections and bone fractures.

FDA Ortho Panel Hearing

The recall and subsequent spotlight on all large-diameter metal-on-metal hips, including those made by other manufacturers, resulted in British surgeons recently recommending that surgeons stop using the devices in patients. The FDA said recent studies noting an increased failure rate of the devices has "added to the agency's existing concerns." In response the agency announced on March 29, that it will convene its Orthopaedic and Rehabilitation Devices Panel on June 27-28, 2012.

The federal case is In re DePuy Orthopedics Inc., ASR Hip Implant Products Liability Litigation, 10-MD-2197, U.S. District Court, Northern District of Ohio (Toledo).

—WE (May 2, 2012)

wikipedia and Carptrash/Justice

biologics

Startup to Salvage Surgery Detritus

This is one of the most innovative and clever new company ideas we've heard about in a long time. Why didn't someone think of this sooner?

A Cleveland, Ohio, based startup has set up itself to bank tissues and stem cells collected during surgery and store them for patients for use in later bone graft procedures and stem cell therapies. Named CellBank Technologies, LLC, the company intends to acquire the stem cells and bone grafting tissues from patients during knee and hip replacement surgeries. According to Brandon Glenn, of *MedCity News* in an April 27 news release, CellBank's plan is to collect materials that would otherwise be discarded for use in potential future bone graft surgery. The company plans to also store patients' stem cells for future use.

CellBank's founder and president, Rachel Uram, said that the problem with harvesting autologous bone graft tissue is that doing so requires a second painful surgery for doctors to obtain the patient's own cells. CellBank's plan is preserve the bone, marrow and stem cells collected during knee and hip surgeries and make them available to the firm's customers for possible future use.

"Autograft, which involves harvesting your own bone-grafting tissue, is the gold standard, but it's so hard to get," Uram said.

One of the company's principles is Arnold Caplan, a biology professor at Case Western Reserve University and the father of the modern stem cell industry. Dr. Caplan, through his publications and mentoring of young stem cell companies is directly responsible for roughly $150 million in current stem cell product sales in the United States. Investors take note.

—BY (May 3, 2012)

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large joints

Sports Participation Wears Out Implants

Does participation in high-impact sports wear out a hip implant? According to a study by Matthieu Ollivier, of the Sainte-Marquerite Hospital in Marseille, France, the answer is "Yes." As reported in the April 26 press release in the periodical *Product Design and Development*, "patients who participate in high-impact activities such as

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football, skiing, tennis or martial arts, significantly increase the wear rate and reduce the 'lifespan' of hip implants in adults who have undergone total hip replacement surgery more than a decade earlier."

A great many patients want to return to their favorite sport after receiving a total hip replacement. And many surgeons urge physical activity on their patients. Yet, until Ollivier's research, not much was known about the impact

of sports participation on the lifespan of implants.

Ollivier and his colleagues compared the function, wear rates and lifespan of hip implants (or so-called 'survivorship'), measured by either the need for revision due to mechanical failure, or signs of loosening, in 70 patients who took part in high-impact sports. A second group consisted of 140 patients with lower activity levels. Measurements were taken at least 11 years after the participants had the surgery. The patients were also asked to complete sports and quality-of-life questionnaires and doctors took X-rays of the patients' hips and pelvises.

What did they learn? Even though patients practicing high-impact sports had better function and better quality of life scores than did the patients who were involved in lower-level activities, at ten years after the surgery, involvement in high-impact sport reduced the durability of the implants. At 15 years' follow-up, the survivorship of the implants was 80% in the high-impact group compared to almost 94% in the low-activity group.

The authors conclude: "These observations confirm experts' concerns about the potential risk related to high-impact sport and both patients and surgeons should be aware of these risks. Since participation in sport is now a reality for a significant number of total hip arthroplasty patients, surgeons may need to adapt their choices of bearing surfaces in implants to accommodate this growing trend."

—BY (May 3, 2012)

Extremity Replacement Gaining on Hips & Knees

Move over hips and knees—the extremities are coming. A report by Visiongain, a London-based business information firm, predicts that the global extremity devices market will be worth $2 billion by 2016,according to the report "World Market for Orthopaedic Extremity Devices 2012-2022," published in April 2012.

The orthopedics sector of medical devices market has been driven, in recent years, by the artificial joint replacement and orthobiologics segments. Now, according to Visiongain, the fastest growing segment within the artificial joint replacement market is the extremity implants market. "The replacement of extremity joints of the shoulder, ankle, elbow, wrist and digits is witnessing growth," the new report says.

The report noted, "Technological advancements in the field of extremity implants have seen innovations such as reverse shoulders and mobile bearing ankles that help repair the joint condition and improve mobility for patients. Device manufacturers are also developing new implant materials that have better safety profile. This trend in technological advancements will continue during the forecast period and will also be a key factor that will sustain growth of the extremity devices market."

Rupali Vadhera, a healthcare industry analyst, said in the April 25 press release: "A worldwide aging population is triggering a rise in the incidence of age related disorders such as arthritis and osteoporosis. The increase in these conditions is being further compounded by the escalating levels of worldwide obesity (owing to the extra pressure placed on hips, ankle and knee joints) amongst the population which has now reached epidemic proportions. In addition, an increase in demand for surgical procedures that offer improved comfort and active lifestyle will further drive growth of this market."

—BY (May 3, 2012)

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Pierced Ears Offer Clue to Knee Regeneration

An observation of a laboratory mouse with a pierced ear has led Washington University, St. Louis, Missouri, researchers to the proposition that the same genes that promote healing after cartilage damage may also protect against osteoarthritis.

Osteoarthritis, the most common form of arthritis, affects 25 million people in the United States and is linked to the breakdown of cartilage, which acts as a shock absorber to cushion the joints.

Scientists discovered cartilage-healing properties in some strains of mice when they pierced their ears to tag and identify them. They found that, in some mice, the holes in their ears quickly healed. Because so much of the ear is made from cartilage and healing occurred so rapidly in the mice ears, the researchers suspected that these mice also may be able to regenerate cartilage in their joints.

Principal investigator Linda J. Sandell, Ph.D., the Mildred B. Simon Professor of Orthopaedic Surgery, and her team bred the mice that healed rapidly with other mice that healed more slowly, and they found that the mice that could quickly heal and regenerate cartilage in the knee also were less susceptible to osteoarthritis.

Injury to a joint is a major risk factor for osteoarthritis, but not everyone develops osteoarthritis following an injury. "Some people—and these mouse studies suggest that someday we may be able to predict which people—fare much better after an injury," Sandell said. "We want to find a way to identify the genes that protect them. We've identified genes that correlate with healing and with protection from osteoarthritis. The work is in its beginning stages, but now that we've found a correlation, we want to look at even more strains of mice so that we can actually map the location of the genes that cause osteoarthritis and the genes that help to repair cartilage."

She added that, "The main problem with biological treatments is that currently, we can't detect osteoarthritis in its early stages. Better understanding of the genes that influence the disorder may help us do that."

—BY (May 3, 2012)

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RA and Obesity: Missing Link?

Mayo Clinic researchers were wondering…Obesity and rheumatoid arthritis (RA) are both on the rise. Might they be related? After studying data from 813 adults with RA and 813 controls, the Mayo team found that a history of obesity puts women at significant risk of developing rheumatoid arthritis.

Along with his colleagues, co-author Eric Matteson, M.D., chair of the Division of Rheumatology at Mayo Clinic in Rochester, found that RA cases rose by 9.2 per 100,000 women from 1985-2007. Obesity accounted for 52% of the increase. Smoking's prevalence remained constant over the years studied, ruling it out as an explanation for the rise in RA.

Wikimedia Commons and Tibor Végh

"We know that fat tissues and cells produce substances that are active in inflammation and immunity. We know too that obesity is related to many other health problems such as heart disease and diabetes, and now perhaps to autoimmunity," Dr. Matteson said in the April 25, 2012 news release.

Dr. Matteson told *OTW*, "We know that the risk of developing rheumatoid arthritis has been increasing in recent years and we're not sure exactly why that is. We know that rheumatoid arthritis risk is related to smoking and we know that the smoking has gone down in recent years but still we're seeing an increase in the number of people who are developing rheumatoid arthritis. What we found was that consistent with the increase of being overweight in the general population there is also an increase in overweight among people who have RA, and what we discovered was that being overweight is actually a risk factor or appears to be a risk factor for developing rheumatoid arthritis."

Dr. Matteson also commented to *OTW*, "What's new here is that we were able to look very specifically at a well-defined population of patients who have rheumatoid arthritis and compare them to a very well-defined, characterized comparator group of patients. In the past there has [sic] been some studies that have tried to look at this link and they have had disparate results. Some studies have suggested there is a link, other studies have said there isn't a link. But no study has done the evaluation with the same vigor that we did. So, the way that we performed this study by comparing people who have similar ages and sex and other risk factors enabled us to very carefully evaluate what the additional contribution of being overweight to the risk of developing this disease might be."

"We would very much like to pursue further research into this question. We have plans to try to explore what the biology of a potential link is between obesity and the development of autoimmune diseases like rheumatoid arthritis."

—EH (May 2, 2012)

One-Third of Arthritis Patients Anxious or Depressed

Not so shocking, perhaps… Researchers from the Centers for Disease Control and Prevention (CDC) have determined that one-third of U.S. adults with arthritis (45 years and older) report having anxiety or depression. According to findings that appear in the April 30 issue of *Arthritis Care & Research*, anxiety is nearly twice as common as depression among people with arthritis.

The study, led by Louise Murphy, Ph.D. with the Arthritis Program at the Centers for Disease Control and Prevention, selected individuals who were previous responders to the CDC's Arthritis Conditions and Health Effects Survey—a representative population of U.S. adults 45 years or older with arthritis symptoms. Researchers identified 1,793 participants with doctor-diagnosed arthritis or other rheumatic conditions.

Anxiety was more common than depression in this population at 31% and 18%, respectively. One-third of respondents reported at least one of the two conditions, and 84% of those with depression also had anxiety. However, only half of participants with anxiety or depression arthritis sought mental health treatment in the prior year.

"Given their high prevalence and the effective treatment options that are available, we suggest that all people with arthritis be screened for anxiety and depression," said Dr. Murphy in the April 30, 2012 news release. "With so many arthritis patients not seeking mental health treatment, health care providers are missing an intervention opportunity that could improve the quality of life for those with arthritis."

Dr. Murphy told *OTW*, "Orthopedists can help through the following three steps: First, screen all people with arthritis for anxiety and depression. The Hospital Anxiety and Depression scale is an efficient and scientifically sound tool for identifying mental distress; orthopedists or other health care providers can screen during clinic assessment."

Morguefile and Jane M. Sawyer

"Secondly, treat people with anxiety and depression. Clinical treatment options include counseling (such as cognitive behavioral therapy) and medications. Alternately, refer to other health care providers on team or other clinicians such as psychologists and psychiatrists."

"Lastly, recommend two convenient, low cost and evidence-based public health interventions like self-management education classes which were developed to address the psychosocial effects of arthritis. Their many scientifically proven benefits include sustained reductions in depression and emotional distress and increased confidence in their ability to manage their arthritis. Further information is available at http://www.cdc.gov/arthritis/interventions/self_manage.htm Encourage physical activity such as walking, swimming or biking each week, which not only leads to improvements in both the physical symptoms of arthritis but is a proven method for reducing emotional distress. At least 150 minutes per week is recommended. This may seem overwhelming but evidence indicates that people can experience benefits if they break it up into sessions as little as 10 minutes at a time. Please see: http://www.cdc.gov/arthritis/interventions/physical_activity.htm"

—EH (April 30, 2012)

extremities

New Anchor for Rotator Cuff Repair

Is this product cool or what?

Smith & Nephew, who now distributes a full range of orthopedic implants in more than 90 countries, has introduced an innovative new design for suture anchors for rotator cuff repair. The firm claims that, unlike solid-core anchors traditionally used in rotator cuff repair, the new HEALICOIL PK suture anchor provides more thread engagement and greater pullout strength than its competitors, even in osteoporotic bone.

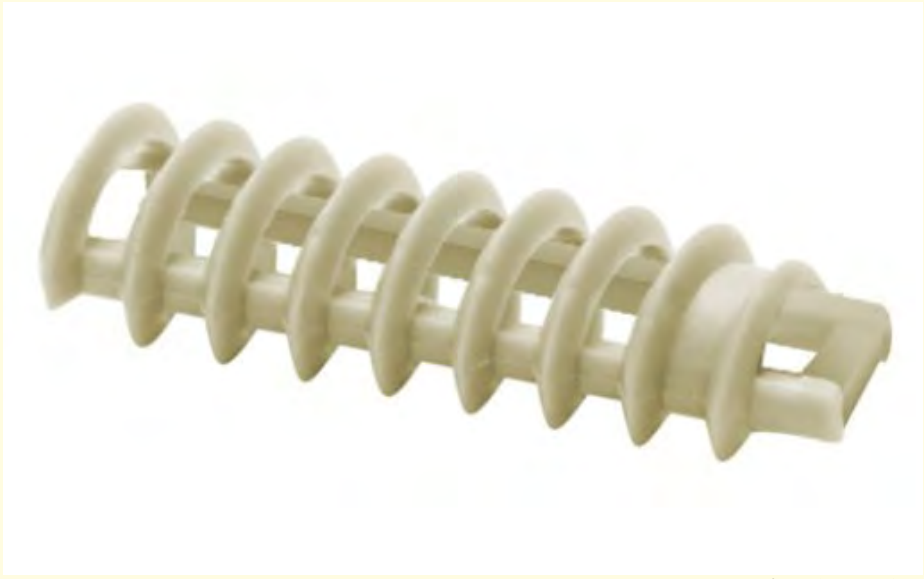
(The rotator cuff, made up of a group of four muscles whose tendons converge to help stabilize and move the shoulder, is subject to a considerable amount of wear and tear with regular daily activities. Smith & Nephew estimates that over one million rotator cuff procedures are performed on an annual basis globally.)

The new anchor's design, according to the company, means that less material is left in the shoulder than with solid-core anchors which are beneficial where space is limited and multiple anchors are required. The anchor is made from PEEK-OPTIMA polymer from Invibio.

James C. Esch, M.D. of San Diego, California, said, "HEALICOIL PK has everything I'm looking for in the next generation of suture anchors. It uses a minimal amount of material, it's triple-loaded with high-strength sutures and it's easy to insert in both hard and osteoporotic bone."

"With its distinctive open-architecture design, the HEALICOIL PK suture anchor brings a new level of innovation to rotator cuff repair," said Alain Tranchemontagne, Senior Vice President within Smith & Nephew's Advanced Surgical Devices division in the April 24 press release. In addition to rotator cuff repair, he says that the HEALICOIL PK suture anchor is also indicated for use in gluteal tendon repair.

—BY (May 3, 2012)



Courtesy of Smith & Nephew

spine

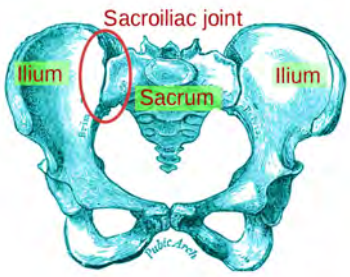
SI-BONE Hits Training Milestone

SI-BONE, Inc., a company that has already trained 700 U.S. surgeons on its iFuse Implant System, is announcing that it has now trained over 100 surgeons in eight European countries on this system. The company expects to train an additional 100 surgeons in the EU in the next 12 months.

SI-BONE Europe is holding an average of one surgeon-training lab per month with several faculty members, including German, Italian, Scandinavian and Austrian spine surgeons, leading these specialized sessions. Training includes a half-day of didactic lecture followed by hands-on cadaveric procedures.

Andrea Mercanti, Vice President, European Operations, commented in the April 23, 2012 news release, "We are pleased with the significant surgeon adoption of the iFuse in major EU markets Surgeons who are using the iFuse are seeking to improve patient outcomes through MIS SI [minimally invasive surgery/sacroiliac] joint fusion. Early retrospective data indicate patients may be experiencing significant quality of life improvements as a result of treatment with iFuse."

The iFuse is a titanium implant coated with a porous plasma spray acting as an interference surface fit, designed to decrease implant motion. By providing immediate post-operative stabilization with fusion occurring over a number of months, iFuse accomplishes the goal of open SI joint fusion through an MIS approach, without compromising structural integrity of the surrounding sacroiliac bones.



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The iFuse does not require special SI joint preparation, which can be very difficult for surgeons to perform on a multi-planar, irregular shaped joint. The iFuse requires no bone harvesting, nor does it require the use of demineralized bone matrix, or BMP (bone morphogenetic protein), which is expensive and off-label for the SI joint.

Asked about the comments they are getting during the training sessions, Jeff Polack, VP of Marketing for SI-BONE, told *OTW*, "Surgeons are saying, 'The iFuse technique appears straight forward; The SI joint patient population is an underserved patient population; I wasn't trained to think about the SI joint as a pain generator. This could be an answer to confounding patients that didn't do well with lumbar fusion; 'It makes sense to work the SI joint in with my diagnostic algorithm for chronic low back pain patients.'"

As for how they are selecting the surgeons, Pollack commented to *OTW*, "Spine surgeons, both ortho and neuro, are candidates to perform the iFuse procedure. We give particular attention to those that have performed traditional SIJ fusion techniques in the past and to those with a busy thoracolumbar fusion practice. Adjacent level disease goes down the spine as well as up and the SI joints represent the terminus of the caudal spine."

—EH (May 5, 2012)

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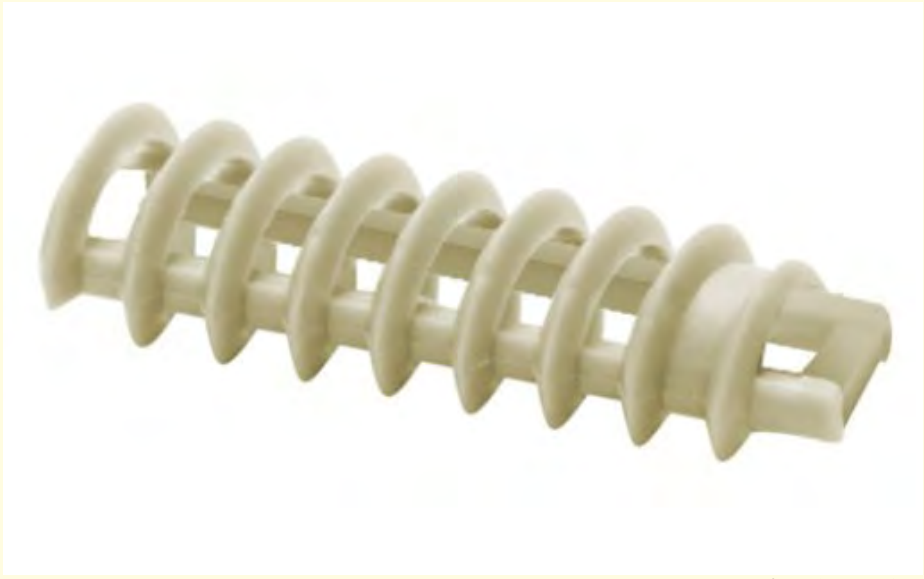

Courtesy of Smith & Nephew

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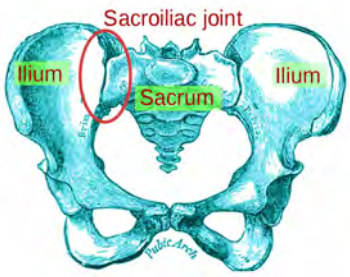

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