

Orthopedics This Week

week in review

4 The Doc Rebellion ♦ A group of physicians says that the new health care law denies their rights to own and operate their own hospital. They have rebelled and gone to court to fight for every American physician's right to due process and equal protection under the law.

8 Tornier Wants to "Go Public" ♦ Tornier, the leading supplier of shoulder implants, has formally declared its intention to "go public". Leaping into the public markets these days is not unlike deciding to swim in shark infested waters. The waters may look appealing, but its not for the faint of heart.

13 Dr. C-E-O: Practice Management ♦ Drs. Michael Freehill and Tom Grogan detail important aspects of running a practice, including staff issues, governance, and the wide array of time- and money-saving technologies now available to physicians.

17 The Big Flip ♦ The anterior approach to total hip replacement finally gets its day in the sun. So why did it take 20-plus years for the front-facing surgery to catch on? And how are physicians, patients and hospitals jumping on the procedure's bandwagon? One thing's for sure, things are definitely looking up.



picture of success

30 Dr. Michael Schafer ♦ Dr. Michael Schafer, Chairman of the Department of Orthopaedic Surgery at the Northwestern University, first learned of orthopedics when he contracted polio as a child. He has since trained nearly 300 residents, and greatly affected the field.



breaking news

- 21 Medafor Shareholders Crush CryoLife**
- Physician **Medicare** Cuts Imposed
- Polymer Fibers to **Rebuild Tissue?**
- Sumter **Whistleblower** Battle
- World Cup** and STOP Campaign
- Durom Hip** Cases Consolidated
- Hip Exercises and **Patellofemoral Pain**

For all news that is Ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Smith & Nephew joined the chorus this week singing the pricing blues. Orthopedic manufacturer operating margins, which remain generally strong, must be under pressure and the question, really, is where can managements find savings—R&D? Marketing and Distribution? Cost of goods?

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Johnson & Johnson	27.03%	(4.02%)	JNJ has traded in such a tight range. No doubt due to that 3.60% dividend. Number one safe harbor during these choppy markets.
2	2	Zimmer	27.69	(5.69)	Zimmer's strong profit margin has always given it a comparatively low P/E. That plus low expectations make ZMH #2
3	7	Orthofix	13.51	(1.69)	That time of quarter again when dreams of cash flow start filling investors heads. Low valuation with surprisingly good results.
4	3	Kensey Nash	38.72	(5.37)	As we point out last week, this company is a little cash machine. Cash on hand rivals annual sales.
5	6	Symmetry	10.70	(6.08)	SMA keeps defying gravity. Strong stock despite less than stellar earnings expectations this quarter.
6	8	Exactech	12.72	(6.53)	EXAC will surprise this quarter. No way they grow sales 11% and report down earnings—which is Wall Street's consensus.
7	4	Medtronic	32.01	(6.92)	MDT just cannot get respect in this market. The numbers tell the story. Lowest P/E, lowest future P/E.
8	5	Stryker	25.88	(7.00)	Standpoint Research (who?) upgraded SYK. Unfortunately it didn't move investors.
9	10	Integra LifeSciences	14.86	(4.69)	Consensus of 14 analysts is that IART will report almost 20% EPS growth. That's actually pretty impressive.
10	9	Alphatec	(0.28)	(7.37)	From here on out, analysts say, ATEC is profitable on \$200 million in sales and a global footprint.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg
1 CryoLife	CRY	\$6.19	\$177	8.8%
2 ArthroCare	ARTC	\$30.43	\$820	3.2%
3 Mako Surgical	MAKO	\$13.19	\$445	-1.2%
4 Smith & Nephew	SNN	\$46.75	\$8,310	-4.1%
5 CONMED	CNMD	\$20.46	\$597	-6.4%
6 Wright Medical	WMGI	\$17.14	\$665	-6.7%
7 Symmetry Medical	SMA	\$10.45	\$376	-7.1%
8 Synthes	SYST.VX	\$105.85	\$12,562	-7.5%
9 Kensey Nash	KNSY	\$21.48	\$209	-8.9%
10 Johnson & Johnson	JNJ	\$58.46	\$161,240	-9.1%

Worst Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg
1 Osteotech	OSTE	\$3.22	\$58	-25.5%
2 Orthovita	VITA	\$2.60	\$200	-24.6%
3 TiGenix	TIG.BR	\$2.28	\$70	-23.6%
4 RTI Biologics Inc	RTIX	\$3.25	\$178	-19.4%
5 Capstone Therapeutics	CAPS	\$0.70	\$29	-18.6%
6 Alphatec Holdings	ATEC	\$4.82	\$421	-18.4%
7 Orthofix	OFIX	\$29.77	\$524	-12.9%
8 Exactech	EXAC	\$17.70	\$228	-12.4%
9 NuVasive	NUVA	\$38.00	\$1,490	-12.1%
10 Medtronic	MDT	\$38.13	\$41,980	-11.9%

Lowest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E
1 Kensey Nash	KNSY	\$21.48	\$209	11.66
2 Medtronic	MDT	\$38.13	\$41,980	11.76
3 Johnson & Johnson	JNJ	\$58.46	161,240	12.53
4 <i>Average</i>			<i>\$10,949</i>	<i>12.75</i>
5 Zimmer Holdings	ZMH	\$54.01	\$10,950	13.02

Highest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E
1 Smith & Nephew	SNN	\$46.75	\$8,310	66.01
2 RTI Biologics Inc	RTIX	\$3.25	\$178	54.04
3 NuVasive	NUVA	\$38.00	\$1,490	34.36
4 Symmetry Medical	SMA	\$10.45	\$376	20.85
5 CONMED	CNMD	\$20.46	\$597	18.79

Lowest P/E to Growth Ratio (Earnings Estimates)

Company	Symbol	Price	Mkt Cap	PEG
1 CryoLife	CRY	\$6.19	\$177	0.60
2 Orthofix	OFIX	\$29.77	\$524	0.67
3 NuVasive	NUVA	\$38.00	\$1,490	0.84
4 Alphatec Holdings	ATEC	\$4.82	\$421	0.88
5 Exactech	EXAC	\$17.70	\$228	0.98

Highest P/E to Growth Ratio (Earnings Estimates)

Company	Symbol	Price	Mkt Cap	PEG
1 CONMED	CNMD	\$20.46	\$597	8.06
2 Symmetry Medical	SMA	\$10.45	\$376	1.98
3 Johnson & Johnson	JNJ	\$58.46	\$161,240	1.80
4 <i>Average</i>			<i>\$10,949</i>	<i>1.59</i>
5 RTI Biologics Inc	RTIX	\$3.25	\$178	1.56

Lowest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR
1 Osteotech	OSTE	\$3.22	\$58	0.60
2 CONMED	CNMD	\$20.46	\$597	0.82
3 Orthofix	OFIX	\$29.77	\$524	0.93
4 Symmetry Medical	SMA	\$10.45	\$376	1.04
5 RTI Biologics Inc	RTIX	\$3.25	\$178	1.09

Highest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR
1 TiGenix	TIG.BR	\$2.28	\$70	68.25
2 Mako Surgical	MAKO	\$13.19	\$445	11.52
3 Synthes	SYST.VX	\$105.85	\$12,562	3.70
4 NuVasive	NUVA	\$38.00	\$1,490	3.67
5 Alphatec Holdings	ATEC	\$4.82	\$421	2.92

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The Doc Rebellion

By Walter Eisner

Can the government single out physicians as the sole class of citizen NOT allowed to own a hospital?

That's the question a group of physicians is asking a Texas court to answer.

The Due Process (5th) and Equal Protection Clause (14th) Amendments to the U.S. Constitution require that all citizens be treated the same. That means the mechanic should be treated the same as the physician.

Physician Special Treatment

Over the years however, Congress has treated physicians differently from other citizens for a variety of reasons that purportedly further a public purpose.

If a mechanic figures out how to make a better part for a car, he or she can get a patent, begin manufacturing, distribute and use the product and bill customers whatever the market will bear. The government also does not tell the mechanic that he or she cannot own an auto-body shop if they refer cars to the shop.

But that's exactly what the government did in the recently passed health care bill. The government told physicians they cannot own a hospital if they refer Medicare patients there.

As the largest payer of health care in the U.S., the federal government has a legitimate public purpose in



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getting the biggest bang for its buck in negotiating prices with providers. Through the Medicare/Medicaid program, the government has passed various laws, including Federal Anti Kick-back statutes, which impose requirements on physicians not imposed on the mechanic.

It has been a long time since physicians have gone to court to demand their due process and equal protection rights.

That all changed on June 7, when a small group of physicians at the Texas Spine and Joint Hospital rebelled and asked a court to stop the government from enforcing Section 6001 of the Patient Protection and Affordable Care Act.



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They join a long history of American rebellions going back to the Shayes and Whiskey Rebellions. Unfortunately history was not kind to those rebels.

Physician Hospital Law

Section 6001, or the “Physician Hospital Law,” (PHL) deters the opening of any new physician-owned hospital that cannot obtain Medicare certification by December 31, 2010 and disallows the expansion of existing Medicare-certified physician-owned facilities. In short, the **law limits the existence of but one type of Medicare servicing hospital—the facility that happens to be owned by physicians.**

In their Motion for a Preliminary Injunction, the physicians claim the purpose of the PHL was to, **“permit non-physician-owned hospitals to succeed, and to weaken and ultimately close physician-owned hospitals. Congress was driven by forming cozy legislative coalitions and picking winners in competitive markets.... Driven by these irrational and anticompetitive reasons, Congress has impermissibly prevented the increase of service to Medicare patients at only one type of hospital—those owned by physicians.”**

They claim the law is, “illegitimate and irrational, and thus violates the Due Process clause of the U.S. Constitution. The law’s restriction on patient care and patient choice on the basis of the occupation of a hospital’s owner is also a blatant affront to Equal Protection.”



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Massachusetts 1986

The last instance we could find of a group of physicians challenging a law on “Due Process” grounds was in 1986 when Massachusetts physicians argued that a ban on “balance billing” deprived doctors of the “liberty” to practice their profession.

A Massachusetts statute made a physician promise not to “balance bill” a condition for obtaining a license.

An appeals court said that a state can require high standards of qualification...but any qualification must have a rational connection with the applicant’s fitness or capacity.

The physicians argued that the “balance bill” condition imposed by the state on medical licenses was not

rationally connected with this “fitness or capacity.” medicine.

However, the court said the promise not to “balance bill” simply amounted to a rule. And, there is nothing irrational about a state saying a doctor, entering the profession, must promise to follow the rules. The physicians lost.

Government Vendor

The government will likely argue that a physician seeking Medicare/Medicaid payments is simply a vendor, and there is nothing irrational about government, as a third-party payer, establishing rules of reimbursement.

This case will certainly be appealed by the losing side and could eventually reach the U.S. Supreme Court. At

that point, a decision could be issued that recognizes a physician's right to have control over their own means of production. This fight, on behalf of every physician citizen in America, could become a landmark decision as important as Dred Scott, Brown, and Miranda.

The Tyler Rebels

Charley Gordon, M.D., and Mike Russell, M.D., were not looking for a fight. Drs. Russell, Gordon and their partners were just trying to expand their hospital in Tyler, Texas.

They opened their doors in 2002, after converting an abandoned Montgomery Ward store into a hospital. In 2008, they spent \$2.1 million to purchase land to double their 20-bed hospital.

The physicians received zoning approval from their city council, which has cost \$426,252 to date. In 2009, they terminated commercial leases for structures located on the newly acquired property. These leases had yielded a total of \$533,236 a year in rents. The group paid \$23,061 in property taxes in 2010 for the additional property, and incurs debt service on the land purchase of \$61,784 annually.

Dr. Russell, the incoming President of the Physician-Owned Hospital Association, conferred with the Association and determined that his hospital was the perfect candidate for challenging the new law. His hospital was 100% physician-owned and the



BEFORE

AFTER

group had just gone through a very public process to get approval for expansion plans.

Unfair and Harmful to Physicians

Russell told OTW that he and his partners were forced to bring legal action, "based on the unfair treatment of physicians with respect to ownership of hospitals. The [PHL] is unfair and harmful to physicians and their patients on a number of fronts. Particularly, physicians are forbidden to have any ownership interest in a hospital to which they refer Medicare beneficiaries.

"Imagine telling pilots that they can't own interest in an airline company. This regressive law in effect takes us back to a time when people of a certain class were denied rights just because of their background."

Not only do the physicians believe the law is unconstitutional, they believe it's not good for patients. "Numerous studies have demonstrated that physician-owned facilities offer improved outcomes at decreased cost. We are proud to consistently rank in the top 5% of all Texas hospitals for outcomes in orthopedics," added Russell.

Backroom Politics

Why was this provision even included in the new law?

"Simple backroom politics," said Russell. "The powerful tax-exempt American Hospital Association lobby agreed to support the health care bill, provided that the feds would help stifle their only real competition."

Russell says he and his partners have clearly been harmed by this law. "But the real injustice has been to our patients,

and we feel that we owe it to them to bring it to the attention of the courts.”

Gordon said that when the physicians opened their hospital, he and his partners were concerned with the direction of the two large hospitals in their community.

He says that in the ensuing years he has seen what competition can do. “Both competing general care hospitals have drastically improved their own efficiencies, quality, and physical plants as a result of our being in the marketplace. As a result, all patients in the Tyler area and the East Texas Region have seen improved quality, more comfortable accommodations, and significantly improved customer service and satisfaction.”

Gordon believes a successful outcome of this suit could allow more competition in the marketplace by, “not allowing the government to single out physicians as the single class of citizen NOT allowed to invest in health care.”

American Hospital Association Quid Pro Quo

The physicians blame the American Hospital Association for using the health care reform debate in Congress to achieve a goal they could not achieve

in the marketplace—put the physicians out of the hospital business.

There are about 5,815 hospitals in America. Only 265 of them, or 4.5%, are owned by physicians.

According to their Motion, “Highly-placed proponents of health care reform in Washington announced that cuts in Medicare rates would be required for the health care books to balance long term. Faced with the certainty of Medicare reimbursement reductions, complaining hospitals promised vigorous opposition to health care reform.

“To appease the non-physician-owned hospital majority, bill handlers were asked, in a deal cut in early July 2009, to eliminate the competition from physician-owned hospitals. The large-hospital lobby agreed to forgo \$155 billion in Medicare payments over ten years to help finance health care reform in exchange for government placing severe restrictions on any new physician-owned facilities.

“This promise...enabled the bruised non-physician-owned hospitals to boost revenues and trim outlay by conserving funds they ordinarily spent improving care, training staff, and meeting competition from better-run physician-owned facilities.”



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The physicians believe that this rebellion can be successful.

“Nearly a century ago,” states their Motion, “Justice Oliver Wendell Holmes drew a line in the sand...when he wrote, ‘[A] strong public desire to improve the public condition is not enough to warrant achieving the desire by a shorter cut than the constitutional way of paying for the change.’”

Pray for the rebels. ♦

Tornier Wants to “Go Public”

By Robin Young

Tornier, the French company whose name is synonymous with well-engineered shoulder implants, announced on June 8th that it intended to sell roughly \$205 million in common stock to the global investing “public.” The company has filed registration statements in the U.S. and, if the launch is successful (and it should be), Tornier’s common stock will start trading on the NASDAQ global market under the symbol TRNX.

Over the first 6 months of this year, 57 companies have braved the stock markets to “go public.” Of those, 23% or 40% are trading higher than their offering price and 34% or 60% are lower. The decision to file an IPO and the process to complete registration is a slow moving process. Considering the volatility of the public markets, both in the U.S. and in Europe, this can prove to be nerve-wracking for managers and underwriters alike. Of the last three orthopedic IPOs, two are underwater and one is 40% above its initial offering price.

The following table summarizes the last three orthopedic IPOs.

Table 1

Company	Date of IPO	Sales in IPO Year	2010E Sales (\$ in millions)	Percent Change	IPO Stock Price	Current Stock Price	Percent Change
MAKO Surgical	Feb-08	\$3 million	\$45 million	1400%	\$10/share	\$14/share	40%
TranS1	Oct-07	\$16 million	\$26 million	63%	\$15/share	\$2.82/share	-81%
Alphatec Spine	Jun-06	\$74 million	\$207 million	179%	\$9/share	\$5.18/share	-42%

Source: Robin Young Consulting and company reports

All three companies grew their business dramatically post IPO. In absolute dollar terms, Alphatec has grown its business the most—adding fully \$130 million to revenues in the four years since IPO. As measured by percent change, MAKO jumped 1,400%. Despite strong top line growth from both Alphatec and TranS1, moving the stock price into positive return territory is terrifically difficult.

Going public is not for the faint of heart.

Tornier’s Case for an IPO

Tornier’s IPO is clearly a bet on the emerging extremities market and the global market for orthopedics. At the time that the current owners (Warburg Pincus, Vertical Group and Split Rock partners) acquired the company from Alain Tornier in 2006, the investment rationale for the firm was to leverage Tornier’s reputation for extremity implant innovation, in particular its shoulder franchise, into a broader line of upper and lower extremity products. Over the ensuing four years, CEO Kohrs and his team:

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- created a single, extremity specialist sales channel in the United States
- added new products to the line of shoulder joint implants and foot and ankle products
- entered the sports medicine and orthobiologics markets
- added to Tornier's small line of hip and knee products

Management also raised R&D spending from \$3.8 million on an annualized basis in 2006 to \$18 million last year, a 374% rate of increase. To put that in perspective, in 2006 R&D was 4% of sales. In 2009 R&D was 9% of sales.

In its registration filings, Tornier's management is making the case that all of these moves have increased the company's addressable market from \$2 billion in 2006 to approximately \$7 billion in 2009.

The Tornier Product Offering – Today and Tomorrow

Through acquisition and a sizeable increase in licensing and R&D, Tornier's product line has grown to into four major product categories:

- Upper extremity joint reconstruction and trauma repair products including joint replacement and bone fixation devices for the shoulder, hand, wrist and elbow. 59% of total sales
- Lower extremity joint reconstruction and trauma repair products including joint replacement and bone fixation devices for the foot and ankle. 10% of total sales
- Sports medicine and orthobiologics products including products to mechanically repair tissue-to-tissue or tissue-to-bone injuries, in the case of sports medicine, or to support or induce remodeling and regeneration of tendons, ligaments, bone and cartilage, in the case of orthobiologics. 6% of total sales
- Large joint (hip and knee) repair and reconstruction products including hip and knee joint replacement implants and ancillary products. 25% of total sales

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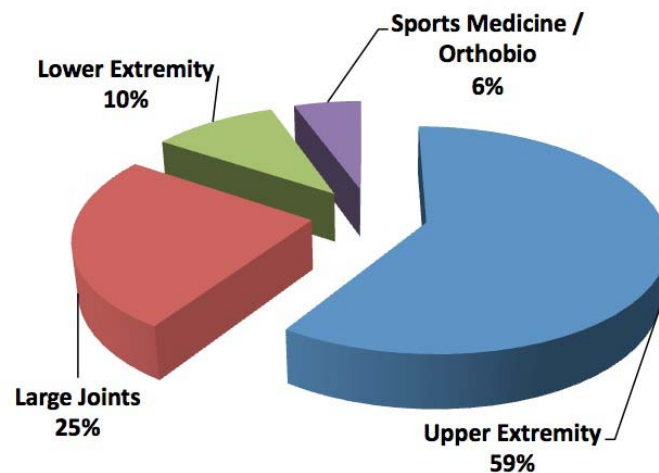


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Tornier First Quarter 2010 Sales (\$ in millions)



Source: Robin Young Consulting and company reports

Overall, Tornier's reported sales for the first quarter of 2010 increased 22%. Of the four product categories, the fastest growing line is Tornier's sports medicine/orthobiologics line which rose 201% from an admittedly low base (\$3.4 million this quarter vs. \$1.1 million for the same period a year earlier).

Strategically, Tornier's goal is to provide surgeons with the most complete line of upper and lower extremity products and then augment these lines with a large, dedicated extremity-focused sales organization. In many ways, the company's strategic orientation is embodied in its corporate tag line—"Specialists serving specialists."

Tornier's other major strategic objective is, simply put, to be profitable. Since 2006, R&D and sales and marketing expenses have risen sharply. Of course, the payoff has been rapidly expanding product lines and a growing distribution force both inside the U.S. and internationally. In its registration, the company referred to this spending as an "investment." Presumably, post IPO the company hopes to harvest the fruit of this investment and, for the first time since 2005, turn a profit.

The Extremity Market

One of the reasons we love IPOs is that the good old SEC requires companies to give their best estimates of market sizes and future growth rates.

Here is Tornier's best estimate of its major markets as described in its S-1 filings. Enjoy.

Table 2

Major Orthopedic Market	2009 Market Size (\$ in billions) as Determined by Tornier's Management	2009-2013 Estimated Compound Annual Growth Rate (CAGR)
Spine	\$7.20	NA
Knee Joints	6.8	5%
Hip Joints	5.7	5%
Trauma	5.2	12%
Orthobiologics	3.9	11%
Sports Medicine	3.3	10%
Extremity Joints	0.9	11%
TOTAL	\$33.00	10%

Source: Robin Young Consulting and company reports

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Interestingly, the extremity market is, in Tornier's judgment, the smallest of the major orthopedic markets. Specifically, "extremities" refers to implants and instruments used to replace shoulder, elbow, hand, and foot and ankle joints. Tornier is making the case that the smallest of the major markets has been under-served and underdeveloped by the major orthopaedic companies.

Tornier, which holds the #2 market share (as measured in revenues) markets the following product lines in extremities:

Table 3

Product	Description	Year(s) of Introduction	Region Currently Marketed
Aequalis Shoulder Joint	Shoulder joint replacement implant to treat pain or disability due to arthritis, severe trauma and other conditions. The Aequalis system includes versions for traditional resurfacing, reverse, fracture and reverse fracture joint replacement.	1991-2009	United States and International
Affiniti Shoulder Joint	Shoulder joint replacement implant to treat pain or disability due to arthritis, severe trauma and other conditions. The Affiniti system is based on a "soft tissue balancing" surgical philosophy.	2007	United States and International
Ascend Shoulder Joint	Shoulder joint replacement implant to treat pain or disability due to arthritis, severe trauma and other conditions. The Ascend system is a bone-sparing design.	2009	United States
Aequalis Trauma Systems	Specialty shoulder plates and nails for reconstruction of 2-part, 3-part and some 4-part proximal humeral fractures.	2007-2009	United States and International
CoverLoc Wrist Plate	Metallic trauma plate used to stabilize distal radius fractures as they heal. The CoverLoc technology allows the screws to pull bone fragments to the plate and lock them for stability, while also covering the screw heads to minimize soft tissue irritation.	2006	United States and International
Latitude Elbow	Elbow joint replacement implant to treat pain or disability due to arthritis, severe trauma and other conditions. The Latitude system provides for anatomic reconstruction of the elbow joint.	2000	United States and International
Pyrocarbon Radial Head	Radial head (of the elbow joint) replacement implant to treat pain or disability due to arthritis, severe trauma, and other conditions. The system consists of a titanium expandable stem, a titanium angled neck and a pyrocarbon articular head.	2002	International
RHS Radial Head System	Radial head (of the elbow joint) replacement implant to treat pain or disability due to arthritis, severe trauma and other conditions. The anatomic bipolar system consists of multiple stem diameters and head sizes to match a wide range of patients.	2006	United States and International
Pyrocarbon Hand and Wrist	A range of interposition spacers or complete joint replacements manufactured from pyrocarbon for arthritic bones to relieve pain and restore function of the hand and wrist joints.	1994-2009	International (some thumb implants in the United States)
Intrafocal Pin Plate	Internal pin/plate fixation system for minimally invasive stabilization of distal radius fractures.	2005	United States and International
Salto Talaris Ankle Joint	Total ankle joint replacement implant to treat pain or disability from severe arthritis. The Salto Talaris is a precision bearing (2-part) implant.	2007	United States
Salto Ankle Joint	Total ankle joint replacement implant to treat pain or disability from severe arthritis. The Salto is a mobile bearing (3-part) implant.	1997	International
Nexfix Fixation System	Specialty plates, compression screws, and pins with instrumentation designed to facilitate bone and joint fusion procedures of the foot.	2007	United States and International
Futura Foot Implants	The Futura product line includes forefoot joint replacement implants to treat pain or disability from severe arthritis or other conditions, and flatfoot correction implants.	1996-2004	United States and International
Stayfuse Fusion System	A two-part locking implant to fuse joints of the toes.	2001	United States and International
Wave Calcaneal Plate	Metallic trauma plate used in calcaneal fractures (heel bone) with a small incision.	2009	United States
Ankle Fusion Plate	Specialty CoverLoc plates to stabilize the ankle joint for fusion procedures. Available in both lateral and anterior versions based on surgeon preference.	2010	United States

Product	Description	Year(s) of Introduction	Region Currently Marketed
Resorbable Fixation System	Bioresorbable pins and screws used in trauma and bone fusion to stabilize the bone fragments and resorb over time.	2007	United States and Selected International Countries
Osteocure	Cylindrical and wedge shaped implants with a resorbable, porous scaffold to support bony in-growth and to fill defects left by surgery, trauma or disease in the foot.	2005	United States

Source: Robin Young Consulting and company reports

All in all, Tornier and its owners have created a very full plate to offer surgeons and, now, investors. Will the market understand and appreciate what CEO Kohrs and his team are offering? With an "A" list of underwriters, prospects look good.



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Dr. C-E-O: Practice Management

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

Dr. A: “It’s just a minor fracture. I’ve looked at everything; now you can see the nurse who will walk you through what we’re going to do.”

Dr. B: “OK, so we have some good news here. You have a simple fracture, meaning that the skin is still intact. What I would like to do is called a reduction, whereby we realign the bone...”

It’s no mystery which surgeon will receive accolades from the patient—not to mention calls from his or her friends and family. With regard to practice management, doing patient care right is a powerful way to ensure that your group succeeds—and survives in this competitive environment. But, say our experts, there are other important tools that you can, well, put into practice.

Dr. Michael Freehill, the CEO and President of Sports and Orthopaedic Specialists, a practice with four locations in Minnesota, has participated actively in the creation of a well-organized practice. He says, “There are several building blocks of a well-run practice, the first of which is often misguided. Many practices overemphasize marketing when it’s unclear if it actually pays off. What does result in more patients is word



of mouth. *The bottom line is that if you are taking good care of patients then the marketing will largely take care of itself.*"

Not that you shouldn't be assertive in letting others know what your practice has to offer, says Dr. Freehill. "Your competitors are advertising, so you should do so as well. But many health systems are cutting back on the marketing dollars. In such an environment it helps to be creative; the Internet is one of the most cost effective ways to do this. It is inexpensive to develop a website that can provide a significant amount of information on the practice, as well as interactive videos. Additionally, it is often effective to deliver presentations to groups such as the Chamber of Commerce or groups of physicians."

And don't forget the staff care, advises Dr. Freehill. "Who you have on staff and how connected to the practice they feel is critical. Start with hiring an exceptional practice manager who knows people well and who understands that he or she must delegate in accordance with the specific needs of the practice. With regard to hiring, newspaper ads typically do not

try to let them have a say in how the practice is run on a daily basis. We have an idea box that allows people to anonymously put forth ideas as to how we can improve patient care or enhance efficiency. The key is to follow up on these suggestions."

Whatever the staff is involved with, you want them to be enthusiastic... even if it is in the somewhat dry areas of coding and billing. Dr. Freehill: "Keeping coding on track is critical to the sustainability of the practice. Coding is getting increasingly complex and is costly because of having to upgrade coding software or purchase new software to remain in compliance with regulations. More and more hoops to jump through means that you must have more people to handle the extensive activities involved in coding."

"On the billing side, the primary issue is one of timeliness. The longer you hold onto a bill the longer you are giving the payor a free loan. You should have all of your i's dotted and t's crossed so that when you submit the bill the first time it is 'clean.' Also, you must be proactive in anticipating obstacles that might occur. For example, if a procedure is out of the ordinary we

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have a system that works. We had a server breakdown last year and the backup didn't have enough capacity. That meant no electronic scheduling or billing. During this expensive outage we reverted to pen and paper activities...and learned a few important lessons."

"You should have all of your i's dotted and t's crossed so that when you submit the bill the first time it is 'clean.'"

work as you get a flood of applications from unqualified individuals. In this instance as well, word of mouth is best. Another significant issue is how to maintain enthusiasm within the group in terms of engaging support staff and ensuring that they feel like part of the practice. To the extent possible,

send the insurer a letter comparing what we did to the more common procedure. That has significantly helped us obtain payments."

But what if those letters were stored on a problematic server? "Information technology is also vital, and you must

Leaving his own role until last, Dr. Freehill says, "Governance is of course vital to the practice's future. When I took over as CEO five years ago I met with each person about his or her concerns and needs. While most people were dedicated to their jobs, some individuals were not engaged

“We were doing 19,000 images annually; when I did the math it turned out that we saved \$9,000 per year by converting to the CR system.”

with the practice and I had to let them go because they were affecting the rest of the staff's morale. I have found that seeing the world from the staff's perspective results in great rewards because they know you are trying to understand what they have to grapple with.”

Hopefully, the new technology available to practices will make things easier for all involved. Dr. Thomas Grogan, an orthopedist in Santa Monica, California, has studied a number of system management programs that can increase the efficiency of practice management. He states, “One of the tools available is the electronic medical record (EMR); there are also electronic health records (EHR), a digitalization of the paper chart that can be put on the Internet.

EMR goes beyond EHR in that it gives outcome quality data that can be sent to doctors electronically. This allows physicians to compare their practice to other practices, something that is of great interest to the government.”

But with the costs involved, not all are signing on. Dr. Grogan: “The average EMR system costs \$40-\$50,000; as a result of this, and the fact that it doesn't add to the bottom line, only 15% of doctors actually have these in place. There is data suggesting that out of every dollar saved by the use of EMR, 91 cents of that is saved by the holder of the risk (the government or insurance company). For the practice, the big savings with EMR is in a reduction of errors. To incentivize doctors to adopt EMR, the government has put forth a policy whereby they would pay doctors a supplement via Medicare so that the average doctor gets an extra \$40,000 if they use EMR...and if the data they submit demonstrates ‘meaningful use’, i.e., quality outcome data.”

Rather than adopt this system, however, Dr. Grogan has adopted a “wait and see” attitude. “I am waiting for the dust to settle, meaning that I will purchase an EMR when the powers that be say *this is the* EMR to have. I don't want

to purchase a system and then be in a position where the regulations change. The key is to become digitalized in a cost efficient way.”

One way to shave costs, says Dr. Grogan, is by using a PACS (picture archiving communication system). “With a PACS you take Xray images using a cassette and a computed radiography (CR) machine that reads the image. That data is stored in a computer and interpreted via a software program into an image that can be put on a computer screen. As it is now the Xray machine generates the Xray, the image is placed on a film and that film has to be developed (meaning that you pay developers). In a process that takes only 40 seconds, the CR reader reads the image on the cassette, puts it in a digital format and takes the image and sends it to a computer. The software then converts it to an image that can be put on a computer screen.”

“To take an Xray in my office costs \$7 and includes the cost of buying and developing the film (\$1.51 per image), maintaining the processor, storage, etc. A digital system, on the other hand, has no ongoing costs. We were doing 19,000 images annually; when I did the math it turned out that we saved \$9,000 per year by converting to the CR system.”

Furthering the acronym soup, we have the CEDS—cross enterprise document sharing systems. “Remember in the old



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“I am now testing a system powered by zocdoc.com whereby any doctor—or patient—can go onto my site, hit the scheduling icon, and see what availability I have that day. This system should really help doctors maximize productivity.”

days when Apples and PCs couldn't 'talk' to one another? That is what CEDS is all about. At present, if I want to share an image with another doctor, I have to give the patient a disc with his or her data—and the software to view it. That is highly inefficient. CEDS creates common points so that medical professionals can share images. Let's use digital photos as an example...you can put them on any computer because the system to read them is universal. We don't have that in medicine when it comes to medical records or Xrays. When Apple and Microsoft started to connect the user had to buy a bridge program—that is where we are now in medicine with CEDS.”

And then there is the old fashioned telephone, which could be on the wane in some offices. “As it is now, if a pediatrician or other doctor needs me

to see his patient, someone from his office must call my office to check my availability. I am now testing a system powered by zocdoc.com whereby any doctor—or patient—can go onto my site, hit the scheduling icon, and see what availability I have that day. This system should really help doctors maximize productivity.”

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The Big Flip

By Jacqueline Rupp

Across the U.S., hospital press releases and marketing blitzes are being fired off touting the benefits of anterior hip replacement surgery. As orthopedic operating rooms become fitted with operating tables designed for the procedure, patients are catching the bug and requesting the procedure.

The Origin of the Flip

Of course anterior positioning is not a new concept. Hip replacements from the front have been happening since the early 1980s and, some would argue, decades before that.

Joel Matta, M.D., Medical Director of the Hip and Pelvis Institute at the Saint John's Health Center in Santa Monica, is often credited with bringing the procedure to the States but he prefers to assign credit to French surgeon Emile Letournel, M.D., who in fact demonstrated the procedure to Dr. Matta and then proceeded to teach it to him as well.

Its popularity was not exactly an overnight sensation. While it may be gaining support and practitioners now, it had its skeptics in those early years. Matta, a fracture specialist, was not exactly a hip reconstruction insider and that, perhaps as much as anything, kept adoption rates



Alice's Adventures in Wonderland/Wikimedia Commons

low for many years. Today however anterior may actually be one of the hottest catch phrases in hospitals and more than a few rank and file hip reconstruction-ists are singing its praises to a receptive audience of baby boomer patients looking for an alternative to their grandmother's hip replacement. The timing also seems right because of new advances in the equipment used. More on that later.

Marketing Angle

It's hard to make hip replacements sound sexy. But add the words "new," "revolutionary" or "break-through" and you may be on the road to something

with differentiation. The anterior approach has become a marketing vehicle for individual practices and, increasingly, patients are seeing such ad tag lines as "Less Pain, No Cane" and "Bringing the Future Here."

There are even blogs specifically dedicated to the anterior approach and websites created by physicians and hospitals to take patients through the entire process. Of course these sites often come well stocked with patient's testimonials which invariably include many stories of patients getting back to actively enjoying life shortly after surgery.

Some enterprising docs have gone so far as to secure such website domain names as AnteriorHip.com if for no other reason than to capitalize on the search engine interest of potential patients. It's clear this is a new development for the tried and true joint surgery. And for patients, this is one of the few times in the procedure's history where there's something to get excited about.



Anterior Approach Ad/
Abington Memorial Hospital

What's All the Hype About?

But what exactly is the fuss all about, the anterior approach does just mean the hip replacement is performed with incisions in the front, rather than side or back of the body. The claim, of course, is that such a small change in location could shorten patient recovery times.

Of course, surgeons have been working with approaches (i.e., the two-incision approach) which promise to reduce the level of muscle and soft tissue trauma. One apparent advantage of the anterior approach is that the primary incision can be made in the front of the thigh, just below the hip. Therefore, to reach the diseased hip joint, the surgeon can more easily move between two primary muscles and reduce the level of muscle trauma and splitting.

In the hands of the experienced anterior practitioner and with proper patient selection, advocates of the anterior approach maintain that patient recovery times can be reduced significantly. But what raises this procedure to a level that might be considered “hot” is that several companies are now supplying advanced instrumentation and equipment that help surgeons perform more routinely successful anterior approaches to hip replacement. “We’ve been performing anterior approach hip replacements for almost four years and started out with using a conventional table. The results were pretty well received,” says Andrew Star, M.D., Chief of Orthopaedic Surgery, Abington Memorial Hospital, just outside of Philadelphia.

Star says the anterior approach has issues that are not unlike those

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encountered with traditional hip replacement surgery. “It’s not a panacea and it’s not a procedure that doesn’t involve recovery time.” But what is markedly different is that the length and severity of recovery is less. “We consistently see patients getting better much faster and having less anxiety before and after the procedure. There are also fewer restrictions afterwards.

“We can send someone home saying ‘use common sense’ rather than a list of restrictions. You don’t have to worry about how you bend, so all those everyday tasks: getting into the car, going to the bathroom, going to sleep, are all so much easier and that makes recovery significantly easier on the patient and the caregiver.” **In fact, Star says that in his practice he has anterior hip replacement patients asking to go home within 24 hours after surgery.**

Anterior-specific Operating Tables

There are a number of tables designed specifically to address the needs of the anterior approach and also take into account the many varied patient body types that surgeons encounter. These tables include Mizuho’s PROfx and Trumpf’s ArchTable. Abington Hospital has recently invested in Mizuho’s Hana table and Star says it is allowing their surgical team to vastly expand the scope of patients that are able to have the anterior approach for their hip replacement surgeries.

“When we first started, we performed 10 to 20% of our hip replacements using the anterior approach. The table has allowed us to increase that number to about 80% of our patients today. The majority of our hip replacements are now performed using the anterior approach.

“We still can’t do the tremendously muscular patients or those with severe bone deformities or patients who are extremely obese. But while the patients with extreme body types will still require traditional hip surgery, the line dividing patients for whom the anterior approach may be indicated and those for whom it is not



ANTERIOR APPROACH SURGICAL TABLE

Hana Table/Abington Memorial Hospital

has moved so far over. We are now able to offer it to more people than ever because of having this type of operating table.”

Operating tables like the Hana aren’t just about positioning. They also have other capabilities. Because, in the case of the Hana table, the material employed is x-ray friendly carbon fiber, the surgeon is able to snap off quick, real time X-rays—essential when performing less-invasive types

of procedures. “This helps us to really see where we are putting the cup and with positioning and sizing,” explains Star. “We used to take an X-ray at the end of the surgery, but with this table, we have the ability to make micro-changes as we go and, as a result, we tend to do a better job.”

The Anatomy of Innovation

So given the advantages of the anterior approach, why did it take literally decades for it to become quite nearly a main stream approach within the broader hip replacement community? There are certainly many opinions but one explanation that we heard seems to make sense.

In order for any new procedure to make its way into the mainstream of a practice is needs to clear three basic hurdles: first, it needs to be attractive enough to surgeons that they want to perform it; second, the learning curve for the new procedure must be short and relatively flat and third; finally, there must be

equipment and instrumentation that helps surgeons to achieve consistency and reliability of outcomes.

Joint replacement surgery, of course, is the poster child of a routinely successful surgery with millions of patients walking satisfactorily on their new hip. Dozens of peer review papers have documented the cost effectiveness and highly successful patient outcomes of traditional hip replacement surgery. So “if it

ain't broke, don't fix it" is probably the single biggest hurdle to the anterior approach. If traditional hip replacements work fine and patients are satisfied, why change?

Compounding the problem is that the surgery itself is technically more difficult than traditional hip replacement approaches. "Surgeons are people too," says Star, "and there is an advantage to repetition and perfecting a technique.

"The anterior approach has a harder learning curve; you have to do a lot of these procedures to really become comfortable with the surgery.

"This was enough of a change that people had to relearn their technique

and since the current results for traditional hip replacement were good, I think there was a feeling of 'why change?'"

The answer, not surprisingly, appears to be coming from the patient. Less post op pain and faster recovery times are beginning to find their way to the patient. The Genie may well be out of the bottle. Several surgeons have used the anterior approach as an opportunity to create marketing campaigns based on the ideal of a "new" procedure that delivers the hope of speedier recoveries.

A few years ago the two-incision approach was purportedly the latest and greatest development in the hip replacement community, but

complications rates turned out to be much higher for this technique than standard surgery. Right now, marketing and anecdotal numbers are all we have to judge the anterior approach's benefits. Until a peer review study is published that focuses on concrete numbers and long-term outcomes of several hundred patients the jury will have to remain out as to whether this alternative is indeed the successor to traditional surgery. ♦



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Medafor Shareholders Crush CryoLife

At a crowded Northland Inn hotel meeting room in Brooklyn Park, Minnesota, last week, Medafor, Inc.'s shareholders rejected CryoLife's attempt to take over their company by an overwhelming margin. According to the *Minneapolis Star and Tribune*, 95% of Medafor's shareholders voted against CryoLife's attempt to take over their company. Such a lopsided vote represented an unambiguous defeat for CryoLife and its CEO Steven G. Anderson.

Anderson, who launched the hostile takeover attempt of Medafor in 2009 and chose several public venues to prosecute his case, spent approximately \$6 million in the effort. Leading up to the shareholder vote, Anderson sent a letter to all Medafor shareholders urging them to vote against Medafor management and to revoke their proxies. The letter from CEO Anderson alleged that Medafor's management was destroying the value of the company.

After looking at their company's financial performance in 2009, Medafor's shareholders came to a starkly different conclusion. For the year ended 2009, Medafor reported that sales had risen 40% to \$13.8 million and for the first quarter this year, sales were up 29%. The following chart illustrates the growth of the use of Medafor's hemostat in general surgery in the U.S. Operating profits increased by \$1.7 million.

Especially embarrassing for CryoLife's 72-year-old CEO was the public



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nature of this defeat. Over the course of the past 12 months, CEO Anderson repeatedly discussed the attempted takeover with Wall Street analysts, sent multiple public letters to Medafor's shareholders and then allowed his COO D. Ashley Lee to conduct interviews with the Minneapolis press. In all of these public announcements, Anderson and Lee attacked Medafor and to analysts had confidently predicted a successful outcome.

The total cost of this attempt will reach, analysts estimate, approximately \$0.21 per share and may well prove to be deeply uncomfortable for CryoLife's shareholders, many of whom are also employees of CryoLife.

In a related but no less important development, Medafor has decided to end its distribution relationship with CryoLife. Over the past 24 months Medafor has supplied CryoLife with its flagship product—a patented

absorbable hemostasis powder which promotes rapid clotting. According to CryoLife CEO Anderson, losing the rights to distribute Medafor's innovative hemostat will cost the company as much as \$6 million in lost annual revenues.

It is probably worth noting that in 2009 CryoLife reported a precipitous decline in reported after-tax earnings from \$32.9 million (2008) to \$8.6 million (2009). CryoLife's COO stated that losing the Medafor product would materially adversely affect CryoLife.

In retrospect, one has to ask the question: What were the guys at CryoLife thinking? Not only is roughly \$6 million flushed away but now they will lose one of the strongest product lines.

—RY (June 16, 2010) ♦

The End of Regen Biologics?

Over the last three months, the final chapter in the long strange story of Regen Biologics may have been written. Two SEC filings pretty much tell the story. On May 25, 2010, Regen tried to hold its annual shareholder meeting but couldn't. Not enough shareholders showed up to constitute a quorum.

Two weeks earlier CEO Gerald Bisbee filed this statement with the SEC:

"The company has discontinued active marketing in the U.S., terminated or temporarily furloughed most of its U.S. employees, and discontinued regular financial and SEC reporting. The company has maintained subsistence level operations in order to survive through the ongoing re-evaluation process by the FDA. During this period, the company has determined that it is in the best interests of the

company and its shareholders to place substantial vendor and other obligations on hold in order to survive this period of uncertainty."

To briefly recap the Regen saga: The company, which was founded in 1987 as a healthcare data company, acquired a biomaterial technology called RBio in 2002. RBio had invented a collagen-based tissue-engineered implant for knee repair which became known as Menaflex. The FDA had required RBio to undertake a PMA study in order to measure Menaflex's safety and efficacy. The company launched the study and implanted the collagen scaffold in 288 patients at 14 centers with 23 surgeons. RBio finished study enrollment the same year that Regen acquired it in 2002.

In 2005, Regen decided to modify the Menaflex filing from a PMA to a 510(k). That decision did not speed up approval. After about three years of stormy relations with the FDA, the agency cleared Menaflex for U.S. sales in December 2008. Then last

year the agency had second thoughts. The process of clearing Menaflex, it believed, had been unusually (for the FDA) flawed. So, in an unprecedented move, the FDA decided to re-convene a panel to review, again, the data underlying the use of Menaflex in patients with torn meniscus cartilage.

That panel meeting was held March 23, 2010. The panel basically maintained that Menaflex was safe and that there was more data supporting Menaflex than for any other surgical mesh that has been cleared to date.

At the conclusion of the meeting, the commissioner said that FDA would render a decision within 60 days. It has now been 80 days and still no decision.

Regen's money is gone. Its employees are gone. Its stock no longer trades on any market. Has the FDA process effectively and finally put Regen Biologics out of business?

—RY (June 17, 2010) ♦



RRY Publications

legal & regulatory

Sumter Whistleblower Battle

A qui tam (whistleblower) lawsuit filed under seal by a board certified orthopedic surgeon, Michael Drakeford, in October 2005, has cost the Tuomey Healthcare System in Sumter, South Carolina, nearly \$45 million in fines, and possibly, another \$227 million if a second trial finds the hospital guilty of violating the federal False Claim Act.

The federal government took over as lead plaintiff in the case after investigating Drakeford's claims and charged the hospital with violating the Stark law and False Claims Act.

U.S. District Judge Matthew Perry ordered the hospital system to pay the fine after a jury found that the hospital broke the law by entering into agreements with part-time doctors working in the hospital's outpatient surgery center. The government accused the hospital of hiring doctors with the intention that they would refer patients from their practices to the center.

According to a June 5 article on *state.com*, the judge ordered a retrial on a separate claim because he erred in not allowing a deposition from the hospital's COO, which the government claims would back its contention that the hospital knew its contracts with local doctors could be illegal and a violation of the False Claims Act.

Against the advice of their attorneys, the Tuomey Board fired back on June 14 on the hospital's web site.

Tuomey Board Responds

It's fitting that Sumter is the place where the first shots of the Civil War were fired. The Board called the case "an epic battle against the federal government, which was started by the allegations of one local doctor... That doctor only raised those concerns after negotiations broke down because Tuomey refused to pay him more money than what was allowed in our fair market value opinions."

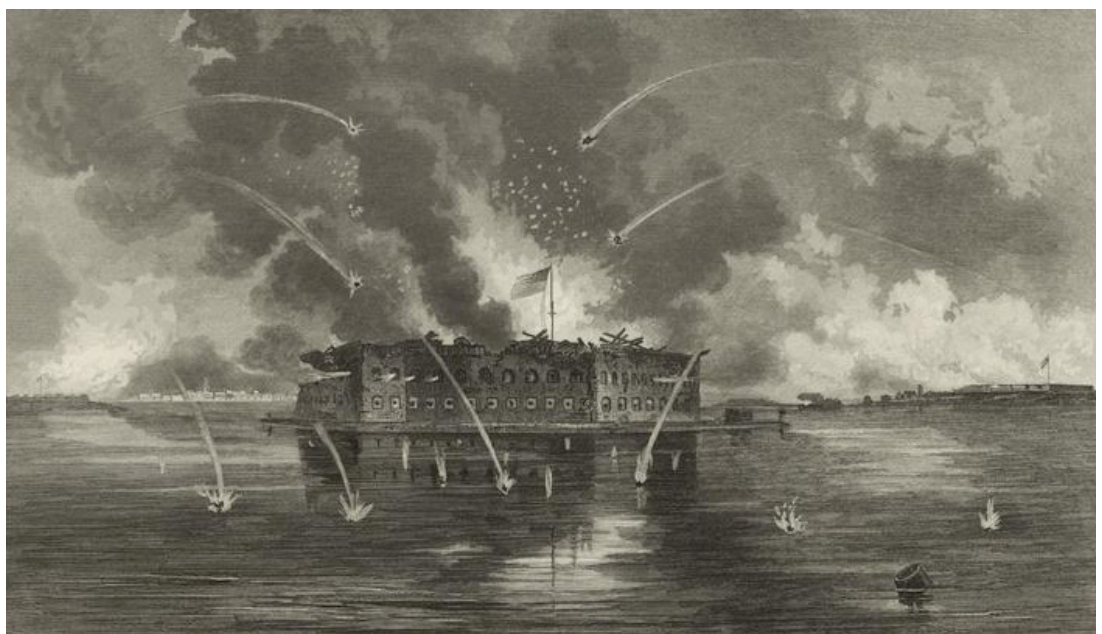
According to another *state.com* article, the hospital's attorney reportedly derided Drakeford at the trial, saying that far from having pure motives; Drakeford was in competition with the hospital. "He wanted to hurt Tuomey," said the lawyer, who at times shot Drakeford long, scornful glances. "The other doctors—they wanted to be

with Tuomey. Of course, that made Dr. Drakeford mad!"

The Board's web post continued, "The Board implement a strategy to work more closely with the physicians on its medical staff in an effort to improve the quality of care provided in Sumter and to create a more stable environment for physicians who work in the community. Tuomey's Board felt that it needed to create these arrangements in order to keep these physicians in the community as the business side of practicing medicine weakened making it more difficult to practice medicine in our community."

The government claims that there is ample evidence to prove that hospital leaders were warned that their strategy would be a violation of federal law. The new trial will let a new jury make that decision.

—WE (June 15, 2010) ♦



Bombardment of Fort Sumter, 1861/Wikimedia Commons

Durom Hip Cases Consolidated

There are 45 separate lawsuits currently pending in seven different federal courts across the U.S. that involve patients suing Zimmer over the company's Duram Cup hip implant. All those lawsuits will now be consolidated for pretrial litigation in a U.S. District Court in New Jersey.

That's according to a ruling on June 9 by the U.S. Judicial Panel on Multidistrict Litigation. The lawsuits will all be transferred to Judge Susan D. Wigenton's courtroom in New Jersey.

The Panel decided that the cases should be consolidated as part of a multidistrict litigation, or MDL, since they involve sufficiently common questions of fact. Since most of the cases were already pending in New Jersey federal court, the Panel determined that was the most reasonable location for centralization.

According to an *AboutLawsuits.com* posting on June 11, Zimmer opposed centralization of the suits because the cases involve individualized fact issues and might derail the company's attempts to reach settlements.

"Centralization should pose no realistic obstacle to Zimmer's settlement efforts," wrote Judge John G. Heyburn, Chairman of the Panel on Multidistrict Litigation, in the order. "Should the parties to one or more actions believe that early resolution through mediation or other means is possible, they are free to approach the transferee judge to adjust the pretrial schedule accordingly."

Each claim will still remain an individual lawsuit that would be returned back to the jurisdiction where it was originally filed for trial if it does not settle or otherwise resolve during pretrial litigation.

The Durom hip was introduced in the U.S. in 2006. Zimmer issued a temporary voluntary recall of the product in July 2008 after concerns were raised by some surgeons over the high number of failures due to loosening of components of the device. The company attributed the problems to inadequate surgeon training and revised warnings and instructions to surgeons.

Between 2006 and 2008, approximately 12,000 individuals reportedly had the Durom hip implanted. Plaintiffs claim that about 14% of those individuals have required hip revision surgery. Zimmer acknowledged that some surgeons experienced failure rates as high as 5.7%.

No date was given for pretrial hearings in Judge Wigenton's courtroom.

—WE (June 15, 2010) ♦



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TiGenix: Positive Five-Year Data

The results are in... maybe we shouldn't be creating tiny fractures. In 2002, TiGenix initiated a multi-center prospective randomized controlled trial to assess ChondroCelect's efficacy as a first-line treatment for symptomatic cartilage defects of the knee, as compared to another treatment—microfracture. ChondroCelect treatment was found to have significantly superior structural cartilage repair at one year follow-up and better clinical outcome at three years as compared to microfracture.

The new data confirm that the therapeutic effect and the clinical benefit of ChondroCelect are maintained up to at least five years after the cartilage repair intervention. As noted by TiGenix, early treatment with ChondroCelect resulted in a superior clinical benefit over microfracture and a lower failure rate. Conversely, patients who had experienced symptoms for five years or more prior to treatment did not derive substantial long-term benefit from either treatment.

"The results from this controlled clinical study confirm what a growing number of experts in the field had come to understand: it is necessary to treat patients with cartilage lesions as soon as possible in order to derive the greatest clinical benefit." said Prof. Dr. Daniël



Tigenix/CondroCelect Vial

Saris in the news release. Dr. Saris, who is with the University Medical Center Utrecht in The Netherlands, is one of the lead investigators. He added, "Several years after the damage and with progressive wear and tear, the knee joint and the underlying bone may be too damaged for treatments to be effective. The environment in the joint is disturbed and cell transplantation becomes less successful."

Gil Beyen, TiGenix's CEO, told *OTW*, "The 5-year data are an important confirmation of the results that had been seen at 36 months. ChondroCelect was the first and still is the only cell-based product that is centrally approved in Europe (as a first in class in the new Advanced Therapies Medicinal Products category). This approval, in October 2009, was based on the

clear demonstration of structural superiority (better quality of tissue) at 12 months, and of clinical benefit (combination of pain, function activity and quality of life) at 36 months over microfracture."

He also commented to *OTW*, "The 60-months results demonstrate the durability of the clinical effect and confirm the clinical benefit. In the 36-months data we had already seen the benefit of treating early (through the analysis of the subgroup of patients who had less than three years since the onset of their symptoms). This has also been confirmed in the 60-months data for patients with less than 3 years and less than 5 years since the onset of their symptoms."

—EH (June 15, 2010) ♦

Hip Exercises and Patellofemoral Pain

Put your right hip in, put your right hip out... (or maybe just do some squats). Researchers from Indiana University-Purdue University in Indianapolis have found that a twice weekly hip strengthening regimen performed for six weeks was effective at reducing (and in some cases eliminating) patellofemoral pain (PFP) in female runners.

The study, by Tracy Dierks, Assistant Professor in the school's Department of Physical Therapy, was based on the theory that stronger hips would correct running form errors that contribute to PFP, even though study participants were given no instruction in gait training.

Regarding the background on this research, Dr. Dierks told *OTW*, "This study has been the continuation of my work on running and patellofemoral pain syndrome (PFPS) over the past decade. PFPS has historically been the most prevalent injury that runners sustain."

"As we began to study this syndrome in runners, we eventually found evidence that the problem isn't necessarily coming directly from the knee. While the knee is where the pain is felt, the problems might be originating from the hip or the foot. A growing body of evidence was showing that weak hip muscles

were commonly found in runners with PFPS. As I investigated this further, I found that the weak hip muscles seemed to be leading to poor running mechanics and that these poor mechanics got worse at the end of a run when runners were tired. This really led me to develop an intervention aimed at improving



U.S. Army/Wikimedia Commons

hip muscle strength in an effort to improve running mechanics and alleviate pain when running."

The pilot study involved five runners and a control group of four runners. The exercises, performed twice a week for around 30 to 45 minutes, involved single-leg squats and exercises with a resistance band. This study is part of an ongoing study involving hip exercises and PFP pain, with 11 runners successfully using the intervention.

As for what orthopedists should know about this work, Dr. Dierks told *OTW*, "I think one of the main points would be to consider the hips and core as a possible cause when

dealing with a runner with PFPS. But also realize that the multifactorial nature of PFPS doesn't mean the hips are always the problem. The joint coupling or coordination that occurs within the entire lower extremity can often make it difficult to isolate where the problem is originating, so the foot and the knee itself need to be considered as well."

—EH (June 14, 2010) ♦

reimbursement

Physician Medicare Cuts Imposed

Physician Medicare payment cuts have gone into effect.

Medicare announced on Friday, June 18, that it will begin processing physician claims with the 21% cut required by law.

The cuts went into effect on June 1, but Medicare had instructed contractors to hold off on processing claims until the 18th because the agency expected Congress to reverse the cuts.

The Senate voted on the 18th to rescind the cuts, but the House will not vote on the fix until the following week.

Gail Daubert, a partner at the law firm of Reed-Smith and panelist on an Orthopedics This Week panel at the 7th Annual Innovative Techniques in Spine Surgery conference in Los Cabos, told attendees that the agency will reprocess the claims at the new rate agreed upon by the House and Senate.



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She said Senators Baucus and Grassley had agreed on a short-term deal that would increase payments by 2.2% until November 2010.

The Medicare cuts are required under a 1990s budget-cutting law that Congress has routinely waived.

The legislation, which costs about \$6.5 billion, is paid for with a series of health care and pension changes and received bipartisan support.

Harry Reid, Senate Majority Leader, told CongressDaily “ Also, “[t]he \$6.5 billion ‘doc fix’ price tag is fully offset with two revenue-raising provisions. One would ban hospitals from charging Medicare for outpatient and inpatient services rendered within 72 hours of a hospital admission, estimated to save \$4.2 billion. The other would raise \$2.8 billion by allowing companies to spread out their pension fund obligations over a longer period”

—WE (June 18, 2010) ♦

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Multi-Touch Electronics and Musculoskeletal Stress

Oh, no! Are “they” going to take our iGadgets away?! We don’t want to get ahead of ourselves. But, researchers from Arizona State University (ASU) and Harvard University are embarking on a project to determine the effects of long-term musculoskeletal stresses brought on by multi-touch devices.

The researchers, led by Kanav Kahol, Ph.D., of ASU, indicate that many multi-touch systems have no consideration of eliminating gestures that are known to lead to musculoskeletal disorders (MSDs), or eliminating gestures that are symptomatic of a patient population.

Project participants will be fitted with electromyography (EMG) equipment to measure muscle forces, and cyber gloves to measure kinematic features that are produced while they interact with multi-touch systems. The researchers will then evaluate the impact of those stresses.

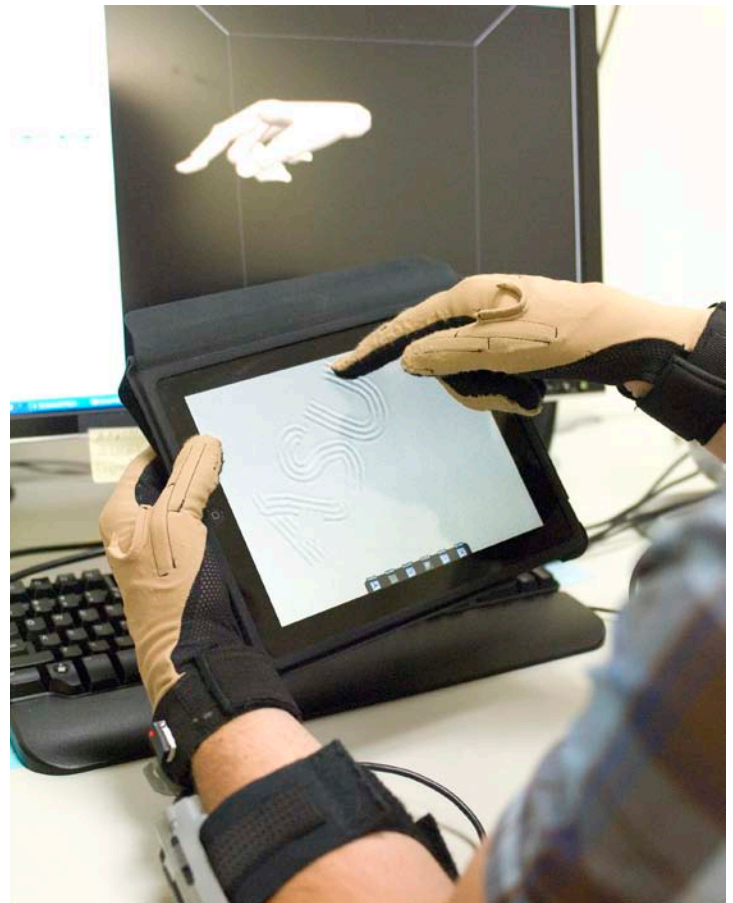
The second part of the project will develop biomechanical models where the user will be able to “enter the motion of a gesture, and the system will produce the forces being exerted through that motion, like a specific movement of the hand,” Dr. Kahol explained in the news release. “We would then take this data back to the Microsofts, the Apples and other manufacturers so they could use it when they are designing new devices.”

“The designers, the computer scientists, the programmers, they know little about biomechanical systems, they just want a system that they can employ in

a usable manner and tells them if a gesture causes stress or not,” Dr. Kahol added. “So our major challenge is going to be developing the software, the tool kit and the underlying models that will drive the tool kits.”

Elaborating on the obstacles, Dr. Kahol told *OTW*, “The challenges are many. One, we need advanced multidimensional simulations of the hand musculoskeletal systems. Secondly, we are hoping to get designers of multi-touch interactions to use these toolkits as preventative measures. The overall deliverable of the research will be a software toolkit that will allow multi-touch designers to input a gesture movement and evaluate its induced stress in a variety of situations and under different variables. In addition, the software will allow input of formal definitions of HCI tasks and produce a possible set of suitable gestures for the task from the given choices. This toolkit will provide designers with a valuable aid in designing safe multi-touch systems, while limiting design effort.”

He also commented to *OTW*, “Orthopedists need to know that multi-touch interaction may be



ASU photo by Scott Stuk

producing undocumented and unprecedented amount of stress and changes to the musculoskeletal system. While on the face of it these devices appear usable, long-term usage patterns are not known. As such the orthopedic community needs to be aware and report any cases to the larger community.”

—EH (June 17, 2010) ♦

World Cup and STOP Campaign

There are goals on the soccer field, and then there are goals in the orthopedic field...with the opening of the 2010 FIFA World Cup in South Africa, the American Orthopaedic Society of Sports Medicine (AOSSM) is taking the opportunity to remind folks around the world that these top level athletes would not be playing today if an overuse or traumatic injury had put the brakes on their careers. The AOSSM's STOP Sports Injuries Campaign reminds all soccer players to protect themselves from preventable injuries.

According to AOSSM, there are more than 3.5 million children annually (ages 14 and younger) who are treated for sports injuries that run the risk of long-term consequences. More than half of these injuries are preventable.

"As we enjoy the excitement of World Cup play, it is important to remember

that athletes like Cristiano Ronaldo, Wayne Rooney, and Landon Donovan play on a professional level that cannot be expected of our kids," said Dr. James Andrews, President of the AOSSM, in the news release. "It is important for everyone who plays a role in a young athlete's life—parents, coaches and healthcare providers—to put the athlete's health and safety first and honestly communicate about issues of pain, injury, and the need for proper recovery."

According to AOSSM, soccer players should be alert regarding the risk of overuse and trauma injuries, particularly to the lower extremities. Common overuse and trauma soccer injuries include sprains and strains and can occur to any extremity of the body. To prevent overuse and trauma injuries to the knees and feet, soccer players need proper equipment, techniques and athletic conditioning.

Tips for preventing soccer injuries include making sure that equipment,

including cleats and shin guards fit properly, and paying attention to poor field conditions that can increase the rate of injury. Players should drink plenty of fluids before playing soccer and continue to stay hydrated throughout the practice or game. If an injury occurs, they should stop playing immediately to prevent further injury and return to play only after clearance by a medical professional.

As for treating children, Dr. Robert Burger, an orthopedic surgeon with Kaiser Permanente in Granite Bay, California, told *OTW*, "It is important to differentiate kids from adults. Kids are developing bone and muscle structure daily, and injuries that are not allowed to heal may prevent proper long-term development. This, in turn, may lead to permanent growth and future structural damage which could potentially limit or worse possibly end future participation in that as well as other sports."

—EH (June 15, 2010) ♦



Derek Jensen/Wikimedia Commons

THE PICTURE OF SUCCESS

Dr. Michael Schafer

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

It is hard to imagine today, but in the middle of the last century the polio epidemic became the most notorious disease in the United States. It struck down children, mostly, and swept through entire communities with a vengeance that overwhelmed local healthcare providers. Children with polio and their families faced a life of potential paralysis. The best available treatment at the time was isolation and days or weeks encased in the “iron lung.”

Salk’s vaccine, which came out of the lab in 1953, eradicated polio. But, the campaign to treat polio victims played a critical role in creating the institutions and practice of modern orthopedic medicine. What is perhaps less well known, is that some of today’s leaders in the orthopedic community developed their passion for orthopedics and patient care after falling victim to polio themselves.

Dr. Michael Schafer, member of the Board of Directors of AAOS (American Academy of Orthopaedic Surgeons), Associate Editor for both *Spine* and the *Journal of Bone and Joint Surgery*, Chairman and Professor of the Department of Orthopaedic Surgery at the Northwestern University Feinberg School of Medicine, is just such a child of the polio era.

“I was born in Peoria, Illinois, to devoted parents who had never had the chance to attend college. When I was 10 years old I contracted polio and spent three months in the hospital—some of that time was in isolation and some of it was in an iron lung. In many respects that was the defining experience of my life in that it spurred my interest in helping others via medicine. I must credit not only the doctors, but my parents for getting me through that frightening experience. This was prior to tube feedings, so my mom used to sit at my bedside and feed me milkshakes. As for the doctors, of all those who treated me, it was the orthopedic surgeons who were the most empathic.”

Dr. Schafer: “We moved to Aurora, Illinois, at the end of my freshman year in high school, where I attended a military academy with hard-driving teachers and coaches who valued teamwork. I briefly flirted with the idea of going to the Air Force Academy—sort of a ‘boys dreaming about fire engines’ thing. But during the application process I learned that I was color blind.”

While color blindness may have kept him out of the cockpit, it didn’t stop him from heading for the OR. Michael Schafer began a premed track



Dr. Michael Schafer

at the University of Iowa in 1960. “I remained at Iowa for medical school and finished up in 1967. During those years I was blessed to work with Dr. Ignacio Ponseti, who was superb with patients in that he gave them lots of time and had tremendous empathy. I also interacted with Dr. Adrian Flatt, a hand surgeon who imbued me with his love of continuing education. While at Iowa I met Dr. Reginald Cooper, who would go on to become the Chair at Iowa, and would later become a mentor to me.”

What Dr. Schafer was learning was that medicine is a collaborative effort. At the Feinberg School of Medicine at Northwestern University in Chicago a young Dr. Schafer crossed paths with Dr. Clinton Compere. “Dr. Compere, a ‘giant’ in orthopedics, was starting to do total joint replacement and was the first surgeon in the Chicago area to do cemented total hips. He changed my rotation schedule and I was essentially his apprentice for 10 months. I would be getting ready for a case and leave to

get Clint for the OR and I would catch him with an anatomy book in his hand. Dr. Bill Kane, a spine surgeon who was Chair at Northwestern, along with Reg Cooper, really ‘cemented’ in my own mind the idea of pursuing an academic career. With Bill’s help I received a March of Dimes fellowship from the National Polio Foundation, something which allowed me to spend 12 months training in Australia. It was a terrific time to be there because the Australians were developing some very innovative technology and procedures that weren’t being done in the U.S.”

It had been 20 years since Michael Schafer was in the iron lung wondering if he’d walk again. Now a trained healer, he decided it was time to elevate his service—this time to Uncle Sam. “I returned from Australia in 1973 and knew it was time to keep my commitment to the Army; they had deferred me through residency and given me time off to go to Australia. I was assigned to Fort Jackson in Columbia, South Carolina, where my practice base consisted of the large active military population, as well as their dependents. Although I wasn’t able to do spine surgery during this time, serving as I did was the least I could do; there were a number of my classmates who had to serve abroad, and some who were killed in action.”

The Vietnam War officially ended in 1975 and by then Dr. Schafer, a Vietnam vet, had decided that it was time to come back home. “After completing my military duties, I came to Northwestern in 1974 as a junior faculty member. My family and I were glad to finally be putting down roots, as we had spent years traveling around. Two years later the Chair of orthopedics resigned and the

new Chair appointed me as residency program director. Because I was close in age to the residents I had to learn how to separate friendship from work (especially challenging when it came time to do performance evaluations).”

Just four years after returning to Northwestern, his Chair called the young Dr. Schafer into his office. “In 1978 the Chair at Northwestern retired, and he called me in and said, ‘I’ve talked to the Dean and you are now the interim chair.’ I was only 36 years old; fortunately he had established an efficient administrative structure that I largely kept intact. During the two years that I was interim chair the search team looked and looked; I felt frustrated because it seemed that a lot of people didn’t understand the program. Meantime I received an offer to return to Iowa City and interview for an academic position. A week before I was due to interview, the Dean at Northwestern suspended the search and offered me the job. I did go to Iowa for the interview, and I went through the entire process and got to see how to recruit faculty members. But I was pleased to have the chance to ‘run the show’ at Northwestern, and was honored to accept their offer.”

While numerous administrative duties awaited his attention, Dr. Schafer could see that his first task was to smooth some ruffled feathers. “There were several internal people who had been interested in the Chairmanship; fortunately, we were able to get past this and develop close friendships. I was hired with two mandates: 1) Because there had been so many Chairs, the program was on probation...it was my job to get us off that list; 2) I was asked to

build a full time faculty. As for the first task, we consolidated the residency program such that the residents don’t have to rotate outside of the city of Chicago. We have more than proven ourselves and in the last accreditation cycle were given five years, which is the maximum. In building a full time faculty, it was important to find individuals with expertise in different areas. The faculty had to understand the concept of no ‘I’ in team.”

It may be that Dr. Schafer’s dedication is affecting the life of someone in Los Angeles, Kenya, or South America. How? Through his residents. “I think that my most valuable contribution to the field has been the residents I have trained. If you take nine residents a year over a 32-year career then I have trained almost 300 individuals. They have each gone on to affect the lives of countless patients around the world. My passion is lifelong learning, something I try to impart to those I train.”

An especially meaningful highlight of Dr. Schafer’s career was being selected for the 2008 William W. Tipton, Jr., M.D., Leadership Award, an honor bestowed by the American Academy of Orthopaedic Surgeons. “Bill Tipton and I interned together years ago. He died at an early age of liver cancer and I was there at the end. He is recognized by his peers throughout the country as a real leader. One of the things I have learned about leadership is that while to one’s subordinates it looks easy, it can be really trying. Also, when you make decisions sometimes others think that you have not thought things out thoroughly. The most important, and perhaps least understood, thing is that you must be a consensus builder...you must have a talent for bringing people together

who have disparate approaches and opinions.”

“I have been an orthopedic consultant for the Chicago Cubs for 30 years and was the team orthopedic surgeon for the Chicago Bears for 10 years. These associations provided me with a unique insight into Americana.”

Married since 1966, Dr. Schafer says that he has a “super” wife who “puts up with my shenanigans.” “We have five children, all grown and sporting post graduate degrees. Add to that mix our 16 grandchildren, most of whom keep my wife Eileen very busy. While my main hobby is family, I do enjoy reading historical fiction and exercising. My kids gave me a Kindle for Christmas, so I’m playing with that and reading *Matterhorn* from the Vietnam War era.”

Dr. Michael Schafer...a passion for orthopedics that started in an iron lung and now envelops hundreds of residents, countless patients and, through his inspiring leadership, the entire orthopedic community. ♦

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