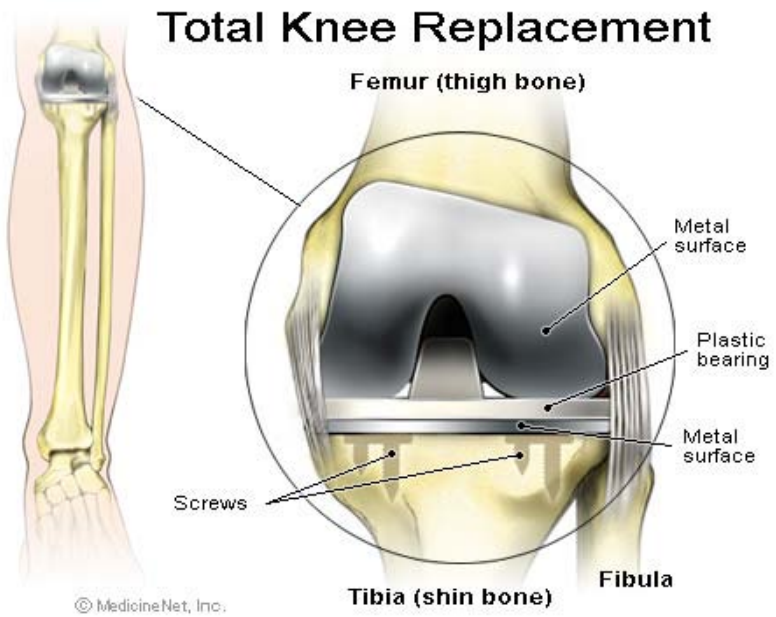
VOLUME 5, ISSUE 20 | JUNE 30, 2009

# Orthopedics This Week

## week in review





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Orthopedics This Week

VOLUME 5, ISSUE 20 | JUNE 30, 2009

# Orthopedic Power Rankings

## Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

**This Week:** One of Peter Drucker's most famous quotes is: "Efficiency is doing things right; effectiveness is doing the right things". Businesses, of course, need to do both but most are better at the former than the latter. Zimmer, unfortunately, may be failing at both. We replace Zimmer with Wright Medical this week.

| Rank | Last Week | Company | TTM Op Margin | 30-Day Price Change | Comment |
|---|---|---|---|---|---|
| 1 | 1 | Integra LifeSciences | 12.35% | 3.35% | Happy 20th birthday to Integra's 2,800 employees in 100 countries. Consensus growth rates keep IART #1 for another week. |
| 2 | 2 | Symmetry | 11.05 | 23.34 | Insider buying, new chairman and rising employee morale. Largest independent ortho OEM seems to be on the ascent. |
| 3 | 5 | Stryker | 23.18 | 5.34 | There's no way SYK won't beat expectations over the next 12 months, especially if hospital equipment purchases rebound in 2010. |
| 4 | 4 | ArthroCare | 16.87 | 11.46 | 413 days since last financial statement. Stock is at $285 million market cap. We don't need no stinkin' financials? |
| 5 | 7 | Orthofix | 8.14 | 2.19 | Key to OFIX is rising margins and, eventually, balance sheet recapitalization. We're optimistic. Up 2 spots. |
| 6 | 3 | Exactech | 13.42 | (1.25) | Current quarter is expected to be **f** at, but 3Q sales, say analysts, will grow 13%. |
| 7 | NR | Wright Medical | 6.35 | 3.93 | Back on the Power Rankings after an extended absence. Insider buying and increasing analyst attention are solid leading indicators. |
| 8 | 6 | CONMED | 9.80 | 0.39 | Why is it that the dullest companies have the most insider buying? SMA and CNMD (apologies to WMGI). |
| 9 | 10 | Johnson & Johnson | 25.36 | 2.42 | Most JNJ analysts expect lower 2Q sales and earnings. DePuy, however, should benefit from ZMH's woes and be **f** at to up. |
| 10 | 9 | Medtronic | 31.68 | 4.23 | Can a stock buyback overcome surgeon payment and off-label headlines? We doubt it. |

# Robin Young's Orthopedic Universe

## Top Performers Last 30 Days

| | Company | Symbol | Price | Mkt Cap | 30-Day Chg |
|---|---|---|---|---|---|
| 1 | Orthovita | VITA | $5.54 | $422 | 64.9% |
| 2 | Alphatec Holdings | ATEC | $3.30 | $157 | 48.0% |
| 3 | I Flow Corp | IFLO | $6.86 | $168 | 28.5% |
| 4 | RTI Biologics Inc | RTIX | $4.98 | $270 | 27.7% |
| 5 | Symmetry Medical | SMA | $9.46 | $339 | 23.3% |
| 6 | NuVasive | NUVA | $44.05 | $1,610 | 21.7% |
| 7 | TiGenix | TIG.BR | *$7.12* | *$173* | 18.5% |
| 8 | Mako Surgical | MAKO | $9.54 | $239 | 16.8% |
| 9 | CryoLife | CRY | $5.67 | $160 | 15.2% |
| 10 | Osteotech | OSTE | $4.51 | $81 | 11.9% |

## Worst Performers Last 30 Days

| | Company | Symbol | Price | Mkt Cap | 30-Day Chg |
|---|---|---|---|---|---|
| 1 | TranS1 | TSON | $6.00 | $123 | -27.0% |
| 2 | Capstone Therapeutics | CAPS | $0.66 | $27 | -15.1% |
| 3 | Synthes | SYST.VX | $96.56 | $11,463 | -8.0% |
| 4 | Zimmer Holdings | ZMH | $43.10 | $9,270 | -4.8% |
| 5 | Regen Biologics | RGBO.OB | $2.40 | $23 | -4.0% |
| 6 | Exactech | EXAC | $15.00 | $191 | -1.3% |
| 7 | *CONMED* | CNMD | *$15.45* | *$449* | *0.4%* |
| 8 | Smith & Nephew | SNN | $37.05 | $6,540 | 1.6% |
| 9 | Orthofix | OFIX | $25.65 | $439 | 2.2% |
| 10 | Average | | | *$9,429* | 2.3% |

## Lowest Price / Earnings Ratio (TTM)

| | Company | Symbol | Price | Mkt Cap | P/E |
|---|---|---|---|---|---|
| 1 | ArthroCare | ARTC | $10.70 | $285 | 6.29 |
| 2 | Symmetry Medical | SMA | $9.46 | $339 | 8.20 |
| 3 | Zimmer Holdings | ZMH | $43.10 | $9,270 | 10.58 |
| 4 | CONMED | CNMD | $15.45 | $449 | 11.57 |
| 5 | Medtronic | MDT | $34.97 | $38,900 | 11.92 |

## Highest Price / Earnings Ratio (TTM)

| | Company | Symbol | Price | Mkt Cap | P/E |
|---|---|---|---|---|---|
| 1 | Osteotech | OSTE | $4.51 | $81 | 145.77 |
| 2 | I Flow Corp | IFLO | $6.86 | $168 | 71.26 |
| 3 | Smith & Nephew | SNN | $37.05 | $6,540 | 66.24 |
| 4 | NuVasive | NUVA | $44.05 | $1,610 | 50.66 |
| 5 | RTI Biologics Inc | RTIX | $4.98 | $270 | 42.75 |

## Lowest P/E to Growth Ratio (Earnings Estimates)

| | Company | Symbol | Price | Mkt Cap | PEG |
|---|---|---|---|---|---|
| 1 | ArthroCare | ARTC | $10.70 | $285 | 0.25 |
| 2 | Symmetry Medical | SMA | $9.46 | $339 | 0.77 |
| 3 | Integra LifeSciences | IART | $26.61 | $756 | 0.79 |
| 4 | Exactech | EXAC | $15.00 | $191 | 0.82 |
| 5 | CryoLife | CRY | $5.67 | $160 | 0.89 |

## Highest P/E to Growth Ratio (Earnings Estimates)

| | Company | Symbol | Price | Mkt Cap | PEG |
|---|---|---|---|---|---|
| 1 | NuVasive | NUVA | $44.05 | $1,610 | 9.80 |
| 2 | RTI Biologics Inc | RTIX | $4.98 | $270 | 2.27 |
| 3 | Johnson & Johnson | JNJ | $56.60 | $155,960 | 1.60 |
| *4* | *Average* | | | $9,429 | *1.49* |
| 5 | CONMED | CNMD | *$15.45* | *$449* | 1.38 |

## Lowest Price to Sales Ratio (TTM)

| | Company | Symbol | Price | Mkt Cap | PSR |
|---|---|---|---|---|---|
| 1 | CONMED | CNMD | $15.45 | $449 | 0.63 |
| 2 | Symmetry Medical | SMA | $9.46 | $339 | 0.75 |
| 3 | Osteotech | OSTE | $4.51 | $81 | 0.78 |
| 4 | Orthofix | OFIX | $25.65 | $439 | 0.82 |
| 5 | ArthroCare | ARTC | $10.70 | $285 | 0.85 |

## Highest Price to Sales Ratio (TTM)

| | Company | Symbol | Price | Mkt Cap | PSR |
|---|---|---|---|---|---|
| 1 | TiGenix | TIG.BR | $7.12 | $173 | 392.97 |
| 2 | Mako Surgical | MAKO | $9.54 | $239 | 36.29 |
| 3 | Regen Biologics | RGBO.OB | $2.40 | $23 | 17.66 |
| 4 | NuVasive | NUVA | $44.05 | $1,610 | 5.62 |
| 5 | Orthovita | VITA | $5.54 | $422 | 4.79 |

# Total Knee Arthroplasty—Worth $57,000?

**By Scott Ellison, PearlDiver Large Joints Analyst**

We all know the end goal of a total knee arthroplasty (TKA)—pain relief and improved quality of life. But with the total price tag of the surgery and subsequent costs exceeding $57,000, are patients really getting their money's worth? Research led by Elena Losina, Ph.D., and colleagues at Brigham and Women's Hospital and the Boston University of Public Health shows that, yes, the end result of a TKA is actually worth every penny, but the deciding variable in determining cost-effectiveness may have more to do with location than the actual patient.

Physicians use total knee arthroplasty to replace diseased or damaged surfaces of the knee joint using implants designed to retain motion of the knee. The most common cause of such damage is degenerative arthritis—chief y osteoarthritis. As of 2007, according to PearlDiver research estimates, over 6.5 million patients suffer from osteoarthritis of the knee—of whom 4.1 million are over the age of 65. In addition, over 560,000 TKA procedures were performed in the United States in 2007.

Each one of the patients who received a total knee arthroplasty expected to have an improved quality of life. According to the report titled "Cost-effectiveness of Total Knee Arthroplasty in the United States" published in the June 22 issue of *Archives of Internal Medicine*, researchers used a computer simulation model populated with Medicare claims data and cost and outcomes data to study projected lifetime costs and quality-adjusted life expectancy. From this model, the results indicated:

- Patients who received a TKA lived over one year longer in good health than those patients who did not receive a knee replacement.
- Lifetime costs for TKA patients increased $20,800 over those patients who did not receive a TKA from $37,100 to $57,900.
- The cost per year of increased quality of life was $18,300.
- Cost and effectiveness was directly related to the volume of knee arthroplasties performed by the facility.

The results lead Losina and colleagues to the conclusion that TKA is cost effective in the Medicare patient population across all risk groups. The one caveat mentioned with this conclusion is that the higher the procedure volume of the hospital, the better the expected results will be.

Further details available through PearlDiver research shed some light on these conclusions. Counter to expectations, the total charges for a TKA in 2007 on average showed no statistical difference between patients diagnosed with comorbidities such as diabetes or hypertension prior to the procedure and those who were not. Despite the increased chance of complications resulting from comorbidities during and after the procedure—the average total charges are seemingly not affected.

In addition, TKA procedures within the Medicare population are indeed impacted by the volume of procedures done by provider, and this impact is evident even on a macro-level. As shown in Table 1, the procedure volume ranking by state clearly ref ects the relationship of volume and success. Nationwide, the highest incidence rate for revision of knee replacement in the Medicare population is 2.3% in the state of Hawaii. The second highest rate is in Delaware, which is slightly below 2.0%. Neither of these states is ranked in the top five by volume for TKA. Of the top states by volume for TKA, only one is even in the top 15 by rank of revision volumes. This story also holds true for knee implant failure.

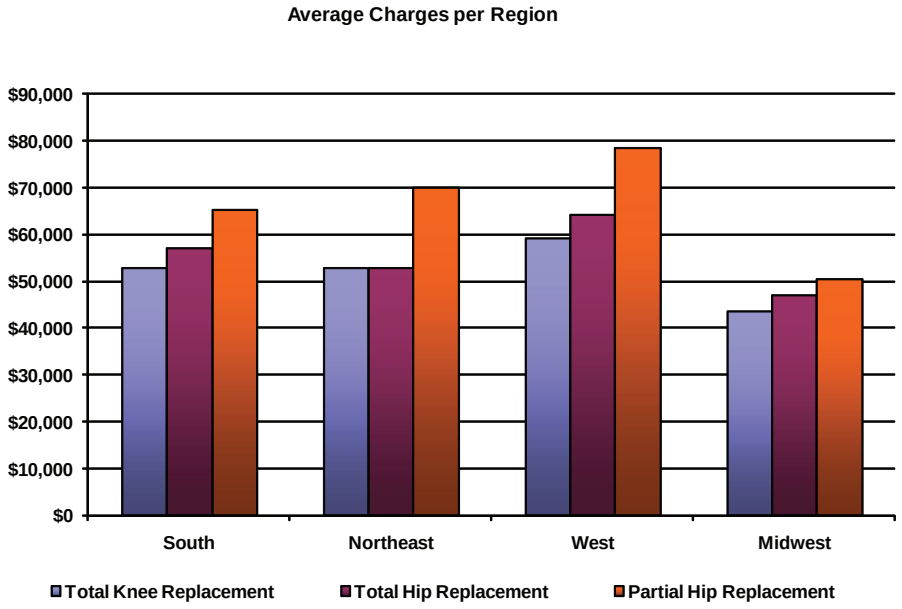
Table 1: State TKA Rank by Volume

| State | National Rank by Volume of Knee Replacements | National Rank by Volume of Knee Revisions | National Rank by Volume of Implant Failure |
|---|---|---|---|
| Texas | 1 | 25 | 20 |
| Florida | 2 | 13 | 9 |
| California | 3 | 19 | 33 |
| Ohio | 4 | 28 | 15 |
| Pennsylvania | 5 | 21 | 30 |
| Hawaii | 49 | 1 | 6 |
| Delaware | 43 | 2 | 11 |
| West Virginia | 36 | 3 | 1 |
| Maryland | 17 | 4 | 8 |
| Idaho | 38 | 5 | 2 |
| West Virginia | 36 | 3 | 1 |
| Idaho | 38 | 5 | 2 |
| Wyoming | 51 | 44 | 3 |
| Mississippi | 34 | 12 | 4 |
| Virginia | 14 | 17 | 5 |

*Source: PearlDiver Medpar Statistics, 2008 - Includes District of Columbia, Puerto Rico, and Virgin Islands*

This week, PearlDiver is releasing the results of a study that studies the variability of charges by region of the country.The most expensive region in the United States for a total knee replacement procedure is the West. According to PearlDiver data, the average insurance charge for a total knee replacement is $59,000 as compared to, for example, $44,000 in the Midwest.

This regional variability was also documented by PearlDiver for total hip replacements and partial hip replacements.




The variability of regional charges is becoming a significant public policy debating point since such variability appears to be disconnected from patient outcomes. In other words, more spending does NOT correlate with better patient outcomes. Indeed, evidence has emerged that the link between spending and patient outcomes is not only tenuous, at best, but may be random. In a seminal article in the *New Yorker* magazine "The Cost Conundrum" by Dr. Atal Gawande, which appeared this past May, Dr. Gawande visited McAllen, Texas, where he documented that higher rates of spending on diagnostic tests and procedures resulted in comparatively ***worse patient outcomes!***

For copies of the soon to be published PearlDiver White Paper on this subject please email a request for a copy to meg@pearldiverinc.com.

The study further notes that policy decisions on TKA should be made based on locality. PearlDiver research data couldn't agree more. So when deciding whether or not TKA is worth the hefty price tag, the real variable for cost-effectiveness is not who you are, but where you are.

For more articles by this author, please select the following link: http://www.pearldiverinc.com/pdi/large.jsp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Arnold I. Caplan is a pioneer in the fields of Regenerative Medicine and adult stem cell biology. He founded Osiris Therapeutics, Inc. in Cleveland in 1992 and thus, set in motion a series of events that resulted in numerous cell-based therapies coming to the market place. He has served on Scientific Advisory Boards, Boards of Directors and has consulted with business entities ranging from startups to multi-billion dollar multi-national corporations. Academically he has published over 350 scientific papers, received several prestigious awards and has trained over 125 science and medical professionals.

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*Arnold I. Caplan, Ph.D,*
*Case Western Reserve University*

*Stephen Badylak, DVM, PhD, MD,*
*University of Pittsburgh Medical Center*

*Scott P. Bruder, MD, PhD,*
*Becton, Dickinson & Company*

*Christopher M. Coburn,*
*Cleveland Clinic Foundation*

*Chris Ehrlich, BA, MBA,*
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*Case Western Reserve University*

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*Thunderbird School of*
*Global Management*

*Robert Hariri, MD, PhD,*
*Celgene Cellular Therapeutics*

*Peter Johnson, MD, Scintellix, LLC*

*William Lehmann, JD, Athersys, Inc*

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*Gail Naughton, PhD, S*
*an Diego State University*

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*Twente University, The Netherlands*

# Oh, the Stress! Post-Fellowship Transition

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

Finished medical school? Now you're a doctor. Done with residency? Now you're really a doctor. Earned your fellowship certificate? Yikes. It's the end of the line. Really. And now all of the highs and lows are yours and yours alone.

Dr. James Lubowitz, founder of the Taos Orthopaedic Institute in New Mexico, and fellowship director at that institution, has observed many newly minted surgeons go through the anxiety of taking on full responsibility for the welfare of patients. He explains, "The main issue is that someone is going from a situation where they are being supervised to a situation where they have complete autonomy. Such responsibility is enormous, especially when you're talking about an invasive interventional procedure that patients are relying on to improve their lives."

And while it may seem like the young are being hurled from the nest, in fact, says Dr. Lubowitz, there is time to adjust. "Throughout the process of becoming an orthopedist there are increasing amounts of autonomy conferred upon trainees, such that there is a gradual exposure to more and more responsibility. On the other hand, the stress is still very high, probably because no amount of gradual exposure and increased autonomy can prepare surgeons for the total responsibility that awaits them. In the end, there is no gray area. All throughout training 100% of the responsibility ultimately falls to the attending; there is always a teacher to answer questions and/or assist you. When the fellowship ends, however, the trainees go from having someone there to no one at all."

## The Reality of Responsibility

When reality sinks in, the fellows move in a little closer to soak up as much knowledge as possible. "Toward the end of the year in particular I may say, 'Do you want to watch me do it one more time? Because as of August 1st you're never going to have anyone to watch you ever again.' I don't get many 'no' responses. It's funny because for their entire training orthopedists clamor for more and more hands on experience like 16 year olds yearning to get their drivers licenses and to get their hands on the wheel. Then all of a sudden they realize, 'Hey, this is real. I'm going to be completely on my own.'"

This is not to say, however, that Dr. Lubowitz won't answer their phone calls. "Sometimes for months, and even years my former fellows contact me for advice. We have established a mentoring relationship, and they sometimes look to me for emotional support and a sympathetic ear. The problems they're facing can be related to problems we all face, so I just commiserate with them and validate their experiences."

But in the heat of fellowship, don't wait until someone starts missing rounds or says the patients are

annoying. Dr. Lubowitz: "It is important to monitor fellows for high levels of anxiety, something made easier because we have guidance from the Accreditation Council for Graduate Medical Education. This includes quarterly evaluations in which we 'screen' for any signs of burnout or extreme fatigue. Program directors should be proactive and raise those or other issues with fellows. In our program we discuss the stress of transitioning out of fellowship from the initial interview until they walk out the door."

A significant part of handling anxiety is feeling like you have some control over a situation. To this end, says Dr. Lubowitz, fellows can ease their transition by retaining their dedication to learning. "We teach fellows to develop the tools to continue their medical education. This includes courses, literature, and new techniques…all things which help them be prepared, and thus less anxious."

In addition to continued education, confidence *and* humility are important to this transition. Dr. Lubowitz explains, "Fellows who transition with fewer difficulties are those who have confidence in their surgical skills and have a realistic ability to provide an accurate self assessment. Some orthopedists have limitations, especially when they are in training. If a surgeon can say, 'This is good, but I can be better' then that shows a certain appropriate level of humility. It is human nature for even the most confident surgeon to express the occasional self doubt and humility. Part of this gets to maturity. I don't know of any other apprenticeships



where you start on your own so late in life. Sometimes in surgical training there is a real discrepancy between age and level of maturity in terms of what you know about being a professional in the real world."

WWMMD? (What would my mentor do?) That, says Dr. Benjamin Domb, a specialist in sports medicine and hip injuries at Hinsdale Orthopaedic and Loyola University in Chicago, is what **f** ows through one's mind during this period of transition. Dr. Domb, who completed a sports medicine fellowship followed by a fellowship in hip arthroscopy and joint preservation, entered practice two years ago. "You start to imagine every situation you encounter as how it might play out if you were alone and would be the one making the final decision…and of course you think, 'What would Dr. XYZ do?'"

Dr. Domb: "Most fellows feel like calling their mentors often in the first couple of months. This is especially true of those stressful moments when you'll be doing a given procedure for the first time in practice and you're up the night before thinking through the steps of the case…and you know that there will be no one there to lead you through them. These are all-consuming moments when you're thinking of the variety of things that could go wrong. Especially for cases that are unusual, it is invaluable to be able to call one's mentor and talk things over."

And then, you can always talk to yourself. "Mental rehearsal is an essential part of surgical preparation," suggests Dr. Domb. "Much of the stress we experience is because we are doing things for the first time all alone. It is helpful to visualize each step of the surgery in great detail. Review each juncture where something could go wrong and decide—ahead of time—how you would deal with it. That way these things are 'off the table' as issues to be concerned about."

Proving that nothing can replace experience, Dr. Domb says, "When you're starting out you haven't seen the followups and outcomes of the procedures you're doing. Your mentors have *told* you that xyz procedure works and you've *read* that the procedure works, but you haven't seen it for yourself. Getting further along in your practice, however, will gradually engender confidence and reduce stress. Some of my anxiety

of my anxiety emanated from the fact that a significant area of my work, hip arthroscopy, is rather new and doesn't have a long history of literature on the outcomes. After I achieved positive outcomes, however, my stress was allayed."

Some of Dr. Domb's wisdom comes from having trained at the esteemed Kerlan-Jobe Orthopaedic Clinic. "My program was dedicated to teaching us to prepare for our own cases, including the thought processes that would stick with us through the 'heat' of the moment in the OR. Such preparation instilled us with a sense of confidence that we were doing the right thing. Because we spent a lot of time reviewing the literature and evidence for cases, we came out of the fellowship not only knowing how to do surgery but with evidence indicating that we were doing it the right way."

## Advice for Newly-Minted Surgeons

Addressing the sometimes forgotten non-orthopedic areas of a fellow's life, Dr. Domb states, "In many cases fellows have just moved to the area, often with a family in tow. There is a new job, new people, and a new locale. To reduce any of this peripheral stress, I would strongly recommend giving yourself some time and moving a little bit prior to starting your new job."

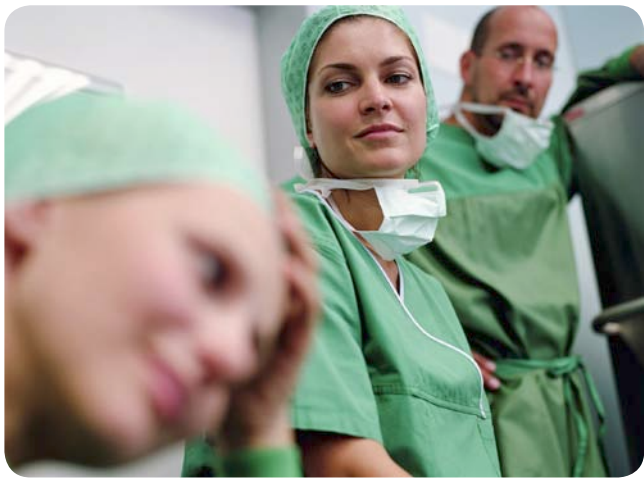
The business side of the medical world can also raise the blood pressure. Dr. Brian Wolf, the Director of the Sports Medicine Fellowship at the University of Iowa, says, "Those fellows headed for private practice often get a rude awakening when they step into the wider world and find out how



important a business background is in today's world of medicine. Unfortunately, this type of information is not part of one's training. Coding, along with other things that make a private practice viable, must be learned. There are such courses sponsored by the American Academy of Orthopaedic Surgeons, as well as the subspecialty societies, that can help make the transition out of fellowship less stressful."

Drawing a line in the sand with regard to training makes for a quick change of hats. Dr. Wolf: "As many fellows do, I went straight from fellowship to an academic setting where I was teaching fellows and residents. In a situation like this, the important thing is not to take on things that you don't feel ready to handle. You must be open to asking for advice, whether from a partner, previous mentor or colleague; people get into trouble when they are afraid to say, 'I need help.' You should also be extremely comfortable with xyz procedure, so that usually means you've done it several times. Just keep practicing the skills and get yourself to the point where you are comfortable walking someone through a case. And be patient with yourself. It is obviously a huge endeavor to take on this new role at the same time you are opening your own practice."

And if there's someone at home who can be patient with you, that's helpful too. Dr. Wolf explains, "In so many cases fellows have moved to a new town to start a practice. If your spouse and/or kids are having difficulty settling into the area then not only will they be unhappy, but so will you. You will find it hard to fully concentrate at work if your loved ones are in the doldrums. Try to get them connected with friends and colleagues' spouse. If that means you have a slower start to your practice then that's just fine. It's better than the alternative."



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# A Health Care Fourth of July

**By Walter Eisner**

Healthcare reform efforts appeared to take it on the chin a day after President Obama took his bully pulpit to the docs of the American Medical Association (AMA) meeting in Chicago on June 15.


*Photo: MSNBC*

On that day, the Congressional Budget Office (CBO) "scored" the Democrat's healthcare proposal to the tune of about $1.6 trillion, which was significantly higher than the numbers outlined by the president in his speech. That sobering bit of news caused senators to call off their planned pre-Fourth of July bipartisan announcement of a proposal that included the much maligned "public" coverage option. Senator Max Baucus, the chief Democrat on healthcare reform, said his Finance Committee would not have a healthcare reform bill to look at until after their Fourth of July recess.

Republicans who have rediscovered their fiscal conservatism and "Blue Dog" Democrats balked at the price tag, and Baucus went back to the drawing board to keep his hopes of a bipartisan reform package intact.

Thanks to the CBO, this will be another Health Care Fourth of July. Just one year ago the AMA ran television ads criticizing the "greed" of private insurance companies and threatening to cut off services to seniors if scheduled cuts of Medicare payments to physicians weren't reversed.

## Ticking Time Bomb

The president told a skeptical AMA crowd that his healthcare reform package needed to reduce the growth of healthcare spending and create a

public insurance option to keep the insurance companies honest and provide coverage for the uninsured. The AMA opposes such a public option because it fears the docs' Medicare and private rates would get cut. The opposing language is always couched in terms of patient access, but in this healthcare reform environment, everyone is looking out for themselves.

"Healthcare spending is a ticking time bomb," said the president. He asserted that if nothing changes, the country will spend one out of five dollars it earns on health care within the decade and one of three dollars in 30 years. Within a generation the entire federal budget could be allocated to health care.

Americans spent about $2.4 trillion on health care in 2008. That is approximately equal to the respective GDPs of France, Germany or England. The U.S. spending on health care is more than half of China's GDP and is equal to two-thirds of India's entire output.

While we spend about 17% of our GDP on health care, Germany and Canada spend 10.7% and 9.7%, respectively, on caring for the health of their citizens.

All that and our health outcomes, as measured by some, aren't any better than those who spend less.

## Geographic Disparities

Obama cited Dr. Atul Gawande's June 1 article in the *New Yorker,* which showed how McAllen, Texas, was

spending twice as much as El Paso, Texas, on health care, not because people in McAllen are sicker and not because they are getting better care. "They are simply using more treatments—treatments they don't really need; treatments that in some cases, actually do people harm by raising the risk of infection or medical error," said Obama.

He also cited a Dartmouth study which showed that one is no less likely to die from a heart attack and other ailments in a higher spending area than in a lower spending area.

Where are those areas of higher healthcare spending?

Dartmouth researcher Elliott Fisher told *Money Magazine* on June 16 that Miami, Manhattan, and Los Angeles are expensive. Large Eastern urban settings seem to have particularly high spending, especially those that have a lot of medical schools, like Philadelphia. But they're not all urban areas. Eastern Long Island has one of the highest costs of healthcare in the country.

Fisher said one driver of the differences in healthcare spending is the local capacity. How many hospital beds—and how many beds in major medical center hospitals—does an area have? How many physicians?

"Physicians must always stay busy to keep their practice profitable. Likewise, in hospitals a bed you have is a bed you fill. And in order for hospitals to offset the cost of caring for the uninsured, they must offer more highly profitable treatments to those who can pay. They're competing with one another to build the fanciest atriums, and they look like five-star hotels. They're bidding up orthopedics and cardiology salaries because those are revenue centers. That's what's driving up the costs of American health care," observed Fisher.

And the areas with lower spending?

Minneapolis, San Francisco and Rochester, New York. Said Fisher, "You can find pairs of communities within the same state—such as Miami and Orlando—where the spending is radically different. It's very idiosyncratic."

Fisher believes that spending for Medicare would fall by about 20% if everybody practiced medicine the way the lowest-spending fifth of the nation does.

## Porter: A Value-Based System

Although most U.S. healthcare reform efforts have focused on coverage, the far bigger long-term driver of success will come from restructuring the delivery system. That is where most of the value is created and most of the costs are incurred, writes Michael Porter, Ph.D., in an article titled *A Strategy for Health Care Reform - Toward a Value-Based System,* in the *New England Journal of Medicine* on June 3. (10.1056/NEJMp0904131)

Porter observes that the current delivery system is not organized around value for patients. He says our system rewards those who shift costs, bargain away or capture someone else's revenues, and bill for more services, not those who deliver the most value. The focus is on minimizing the cost of each intervention and limiting services rather than on maximizing value

over the entire care cycle. Moreover, without comprehensive outcome measurement, it is hard to know what improves value and what does not.

In order to achieve a value-based delivery system, writes Porter, we need to make the measurement and dissemination of health outcomes mandatory for every provider and every medical condition. He believes that results data will not only drive providers and health plans to improve outcomes and efficiency, but it also will help patients and health plans choose the best provider teams for their medical circumstances.

Outcomes must be measured over the full cycle of care for a medical condition, not separately for each intervention, says Porter. To do this, we need to measure true health outcomes rather than relying solely on process measures, such as compliance with practice guidelines, which are incomplete and slow to change.



## The CBO Roadmap

Which brings us back to the June 16 letter from CBO Director Doug Elmendorf.

Elmendorf laid out a detailed roadmap practically showing senators how the CBO can give them what they are looking for.

Wrote Elmendorf, "Many experts believe that a substantial share of spending on health care contributes little if anything to the overall health of the nation. Therefore, changes in government policy have the potential to yield large reductions in both national health expenditures and federal health care spending without harming health."

In other words, we can cut healthcare spending without harming patient health.

Elmendorf told senators that large reductions in spending will not actually be achieved without fundamental changes in the financing and delivery of health care. "Policymakers can spur those changes by transforming payment policies in federal health care programs and by significantly limiting the current tax subsidy for health insurance. This would directly lower federal spending on health care and indirectly lower private spending."

He declared that **if the growth rate of federal healthcare spending were trimmed by 1% per year during the next 20 years, the savings would roughly match the cost of an expansion of insurance coverage by the end of the decade and would exceed that cost in the next decade.**

Echoing Porter, the Elmendorf letter recommends a variety of changes that are likely to make the delivery of healthcare services more efficient. At the top of the list is a move away


from a fee-for-services system toward paying providers through fixed payments per patient, bonuses based on performance, or penalties for substandard care.

## MedPAC Authority

On the cost containment side, Elmendorf's letter suggests some things that could work. For instance, he recommends taking the power over physician payment rates out of the hands of Congress and putting it into that of a third party to keep the pressure up over time. One such suggestion was made by the president in a letter to senators a couple of weeks ago when he suggested that MedPAC (Medicare Payment Advisory Commission) be given authority to make payment decisions.

## Orthopedics Winners and Losers

A disruption of current payment and reimbursement mechanisms would create winners and losers

in health care in general and orthopedics in particular. How might reform impact orthopedics?

One of our favorite analysts, Mike Matson of Wachovia Capital, gave this question his best shot in an investor note on June 10.

Said Matson, "Our general view on reform is that it is a modest negative for the orthopedics subsector and its actual impact on fundamentals may end up being much less significant than many investors fear." Matson believes that pricing power (and margins) in the orthopedics industry is largely a result of a principal-agent problem in which surgeons (agents) are typically less concerned about implant costs than the hospital (principal). "Since we are not aware of any reform proposals that would address this principal-agent problem, we expect pressure but not a collapse in orthopedic implant prices," stated Matson.



If there is an increase in coverage for the uninsured, Matson believes that it would have two effects.

First, it would increase the pool of patients and possibly orthopedic procedure volumes and, second, it could lead to a negative mix shift in orthopedic implants since a greater portion of patients would be covered under government health plans with lower reimbursement than private insurance plans.

"We have conducted an analysis of these impacts and the volume effect dominates the mix shift effect, resulting in a net positive. If all 36 million uninsured adults were to become covered, we estimate it would expand the U.S. recon market by around 5% and reduce U.S. recon margins by 20 bps and expand the U.S. spine market by around 10% and reduce U.S. spine margins by 40 bps," wrote Matson.

With that assumption, Matson believes that Medicare inpatient reimbursement may be cut and/or the rate of growth in the market basket may be slowed from its recent 3% type growth, leading to pricing pressure on orthopedic implants. He estimates that the recon market could absorb an average 3.4% price decline and the spine market could absorb an average 7.6% price decline before the benefit from expanded coverage is offset and gross profits begin to decline.

## Data, Data, Data

All this analysis of various ways to slow the growth of healthcare spending and predictions of the impact on orthopedics will hinge on the gathering of data that demonstrates whether or not a procedure, device or service actually improved someone's health.

That's where the $1.1 billion Comparative Effectiveness Research funding in the stimulus bill comes in. This is already law and will set up a framework to provide evidence of what works and what doesn't. Advocates say this will not be used to make payment decisions. They say providing a physician with such evidence is enough to change the behavior of doctors, patients and payers.

## The Final Scrum

How will this all play out after the Fourth of July?

We look to *The New York Times* columnist David Brooks.

Brooks offered us a tour of the four-stage Kabuki theater libretto President Obama has written:

> *"The first step in this strategy is table-setting. You will spend the first several months of your administration talking grandly about the need for reform. You will invite all interested parties to the table, and you will serve a great heaping plate of pabulum. You will talk about things that no sentient person could possibly disagree with—about the need for better information technology and for more preventive care…*

*In stage two, you pass everything over to Congress. You'll need these windbags at the end, so you might as well get them busy at the beginning. This will produce a whirl of White Papers, a flurry of committee activity, a set of legislative rivalries as every chairman in the stable seeks to be the lead horse in the romp to legislative glory…*

*This brings us to the current stage: The Long Tease. Every player in this game has a favorite idea, and you are open to all of them. The liberals want a public plan, and you're for it. The budget guys are for slashing Medicare reimbursements, and you're for that. The doctors want relief from lawsuits, and you're open to it. The Republicans want you to cap the tax exemption on employee health benefits. You campaigned against that, but you're still privately for it…*

*This brings you to the final stage, the scrum. This is the set of all-night meetings at the end of the congressional summer session when all the different pieces actually get put together.*

*You want the scrum to be quick so that the bill is passed before some of the interest groups realize that they've been decapitated. You want the scrum to be frantic so you can tell your allies that their reservations might destroy the whole effort (this is how you are going to get the liberals to water down the public plan and the moderates to loosen their fiscal rectitude).*

*The scrum will be an ugly, all-out scramble for dough. You can probably get expanded coverage out of it. You can hammer the hospitals and get much of the $1.2 trillion to pay for the expansion. But you won't be able to honestly address the toughest issues and still hold your coalition. You won't get the kind of structural change that will bring down costs long-term. In the scrum, Congress will embrace the easy stuff and bury the hard stuff.*

*Which is why you have MedPAC that you want to turn into a health care Federal Reserve Board—an aloof technocratic body of experts that will make tough decisions beyond the reach of politics. You can take every thorny issue, throw it to MedPAC and consider it solved.*

*Conservatives will claim you're giving enormous power to an unelected bunch of wonks. They'll say that health care is too complicated to be run by experts from Washington. But you'll say that you are rising above politics. You'll have your (partial) health care victory. Not bad for a skinny guy with big ears."*

Members of Congress will now head back home to participate in Fourth of July parades, corn feeds and community celebrations. The airwaves will be filled with messages trying to convince voters to voice their views with their elected officials. It will be another Health Care Fourth of July.

# Military Medicine: Marching Ideas and Actions

**By Daniel Knowlton**

Soldiers in the military push their bodies to the limit as part of their every day jobs. The injuries these soldiers sustain in battle also push medicine to its limits as doctors search for new devices and procedures to quickly and effectively treat soldiers in the field. But the path from an idea to an approved, usable device can often feel long and tedious. Even the most carefully conceived medical invention can stop short of growing into fruition. So how can military soldiers and their physicians get the new devices they need to treat the strains of a new kind of warfare? It takes a solid team effort.

The Georgia Tech Center for Advanced Bioengineering for Soldier Survivability aims to speed up the long process of turning an idea into a reality by bringing doctors, engineers, and industry together. The director of this center, Dr. Barbara Boyan, who we recently featured in *OTW*'s "Picture of Success" series, says, "Our goal is to convert these ideas into actual, tangible products so that they are engineered to go into humans within three years. I thought if we could take the full capacity [of Georgia Tech] and really focus it on just a few technologies that we could in fact convert them into usable products. And it looks like that is what is happening. Everything we do is with the idea, 'What do we have to do to make it work?'"

Dr. Boyan started asking the government that very question about a year and a half ago. The initial pool of money to fund the center came from Congress in 2007. Now the center, based in Georgia Tech's engineering school, is partly funded through the Orthopedic Trauma Research Program, partly funded through the Armed Forces Institute of Regenerative Medicine, and partly funded directly through the Department of Defense.

## A Team Effort

Everything about the center, from its diverse sources of funding to the physical layout of its offices, is geared towards collaboration. "The newest building was just finished a year ago, and it has all been built since I came in 2002," says Dr. Boyan. "It's gorgeous, and the setup of all the interdisciplinary buildings is really amazing. I don't even have to leave the campus. I just walk across the courtyard, and there is an incubator facility with all the companies. That's one reason why our work is possible here. It's the

perfect environment in which to manage everyone…it's just magical."

Making devices that work, however, requires more than magic; these doctors and engineers need smart science and the motivation to get the work done. "What really drives us," says Dr. Boyan, "is the fact that, often in medical school, great ideas happen, and everybody agrees that we can study something and understand it better, but the actual converting of it into a technology that will be used by a surgeon requires engineering. I think the process usually does take a lot longer than three years, and this is the nature of the beast. I'm not saying our devices will be commercial in three years, but the technology we're developing will be ready in three years, we hope, to be tested in humans."

Dr. Boyan thrived in her own medical training, but she admits that there are difficulties with trying to create new medical devices in a purely academic setting:

> "In general, in academics, what happens is that a laboratory makes an invention. They study it and try to understand it, and if they are a laboratory that is motivated towards commercialization, they may file an invention disclosure describing what they think is the invention.
>
> Then the university tries to figure out whether or not the invention has a path to commercialization that is worth pursuing. Many times these inventions become lost in the technology licensing office while the university tries to put some value on it. It's usually so early-stage that they don't always even know what companies might be interested in picking it up. Another problem is that the invention may be a wonderful idea, but it may not be formatted in a way that the physician can actually use it."

Companies may not have a university's concentrated pool of laboratory inventors, but they do operate in a commercial world that can move faster than an academic community. "Companies can license from other companies, and they can buy other companies that may take an invention much further down the development path instead of putting all that time and energy into early-stage development. Universities can really only get to this early-stage. And that's the missing piece where a company needs to become a partner in the process. But you also need a surgeon as a partner. And what we have done is brought the surgeon together with the engineer together with the company to move the technology forward."

## New Stem Cell Technologies

So what exactly are these technologies that Dr. Boyan and her researchers are working so hard to develop? The details may still be top secret, but one major area of development now is a device to more efficiently use adult stem cells. Dr. Boyan started with the question: "You could study stem cells, but we want them to be useful, so how do you make them useful in a reasonably short period of time?"

Adult stem cells show great promise in orthopedic treatments to help the body re-grow damaged bone and cartilage, speeding up recovery time by using the patient's own cells. But researchers are still trying to figure out how to best use stem cells efficiently. "Stem cells tend not to remain at the site for very long," says Dr. Boyan. "Nobody really knows what the best amount of time is for them to be there, but it would make sense to me that we want more of them there and for a longer period of time. With the way that stem cells are now being used, they don't stay in the damaged area for very long in part because they aren't alive when we put them there, and they are also quickly removed from the scene, especially if they aren't the patient's own stem cells (allograft stem cells)."

The center is, however, developing stem cell technologies that would use the soldier's own fat-derived stem cells, because, as Dr. Boyan points out, "even the thinnest of young men out there on the battle field has subcutaneous fat."

After settling on the source of their stem cells, Dr. Boyan and her researchers went to work on turning

those cells into efficient healers. "We came up with the idea that the series of technologies that we could develop relatively quickly would be ways of placing stem cells exactly where we want them and then keeping them at that site long enough to reasonably do their job. We have developed technologies for concentrating subclasses of stem cells, and then for delivering them percutaneously so we can treat focal legions that way. We had to come up with a novel shaped syringe that will allow this kind of particle to be delivered smoothly without clumping. And we had to be able to identify a f owable carrier that wouldn't negatively impact the ability of the stem cells to do their job.

"From an orthopedic point of view, we are also taking these same ideas and using them on scaffolding to place the stem cells precisely where we want them. The concept we have is that once healing starts there is potential in these very large orthopedic defects for nonunion to occur, but if we can place stem cells at that site to jumpstart the healing process, we could prevent nonunion from happening."

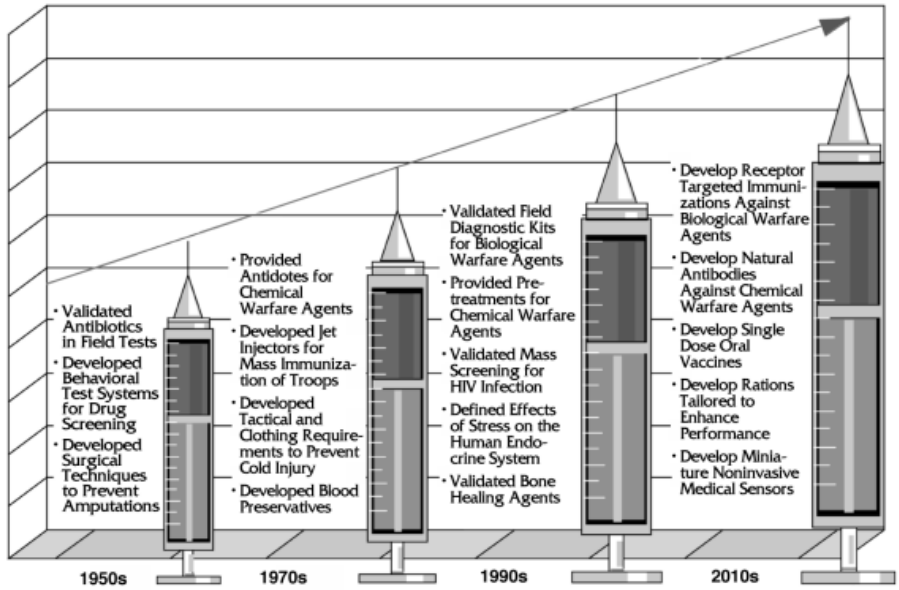
In the midst of developing this technology, collaboration again is the key. "Without having the surgeon input, we might have made the syringe a less desirable shape, or given it less effective handling properties," says Dr. Boyan. "Or we might not have made a syringe at all!"

## Gains and Strains of Collaboration

Although it may sound like these collaborations happen smoothly and easily, there can be definite challenges to getting surgeons, engineers, and companies to work together. "The surgeons have time constraints because of the need to see patients when the patients need to be seen," says Dr. Boyan. "And that can impact the way a study is done. You can have everything set up to go, and then there is an emergency, and the human comes first. There has to be a really good partnership between the surgeon and the scientist, and even for a clinician scientist, if they are in fact taking care of people, they need to treat their patients first.

"There needs to be a team, and the pure scientist part of the team needs to understand what some of the constraints of the surgeons are. But the surgeons also need to understand the constraints of the scientist. There's always funding issues, and most scientists are every bit as busy as most surgeons. Sometimes even more busy. So there has to be mutual respect."

In her own experience, Dr. Boyan has a great respect for collaborative efforts with industry: "I think it's the best. I have really nice relationships with the companies that I work with. I ask them to be part of the team as well, and I really like it when their scientists are active members. It just makes everything go more smoothly."




*Courtesy of Federation of American Scientists*

## Plans for the Future

The team effort at Georgia Tech also allows for a long pipeline of projects in addition to stem cell technologies. The next top secret devices involve using nanotechnology to develop wound dressings and guided nerve regeneration. "We're also developing some ways of linking bone fragments together to preserve them, to have the greatest opportunity for the patient to heal with their own body parts. And we're developing hemostasis products," adds Dr. Boyan.

The center also has a growing head and neck program at the request of the military. "At the start of the conf ict, most of the injuries were to

the extremities, but as the conf ict has gone on, a greater percentage of injuries are happening to the head and neck, particularly to the face," explains Dr. Boyan. "More than 25% of the injuries are actually to the head and neck, so how great would it be if we could adapt some of our orthopedic technologies to treat these cases as well?"

All these new potential technologies certainly give the Georgia Tech Center for Advanced Bioengineering for Soldier Survivability a "magical" feel, as Dr. Boyan puts it. But this is not a secret James Bond gadget lab–these new devices will hopefully, in three years, help treat real soldiers in the field. They put their lives in danger to keep others safe, and it only seems fair to push the limits of medical technology in order to keep the soldiers safe as well. And then, thanks to the quick, collaborative efforts of these surgeons, engineers and companies, the general public could also see stem cell injections and nanotechnology band aids sooner than one might think.

company news

## Invibio Supplier to MDEA Winner

The PEEK-OPTIMA pros—Invibio Biomaterial Solutions—have been recognized as a supplier to award-winning Minnesota-based Vertebral Technologies Inc. (VTI), which has been honored with the 2009 Gold Medical Design Excellence Award (MDEA) for its innovative minimally invasive InterFuse Interbody fusion system.

Meant only for medical device manufacturers, their suppliers and partners, the Gold MDEA recognizes companies for their contributions to advances in medical product design. A panel of impartial, multidisciplinary third-party jurors with expertise in a variety of related fields took the following into account when reviewing the entries: design and engineering achievement, patient and surgeon benefits, and cost-effectiveness.

The award-winning InterFuse device is manufactured from unfilled PEEK-OPTIMA polymer. According to VTI, InterFuse is designed to advance minimally invasive surgical (MIS) techniques and approaches that enable surgeon/patient benefits including:

1. Single, posterior incision (a familiar, less invasive posterior implant approach)
2. Large, ALIF-sized footprint customized to the patient anatomy
3. Less invasive approach designed to reduce tissue dissection and nerve root retraction while preserving facet joints.

Commenting to *OTW* was Dr. Jeffrey C. Felt, Chairman and CEO, Vertebral Technologies, Inc., who noted, "The Invibio team worked closely with


VTI and our manufacturing partners throughout the process and was instrumental in providing us with the biomaterial expertise and technical knowledge that enabled us to realize our revolutionary InterFuse device design vision. Invibio delivered an efficient and effective biomaterials solution mapped precisely to the unique and demanding design, performance and processing specifications of our application. They helped us evaluate their biomaterials portfolio to identify the right material specifications, worked closely with our processor to optimize the injection molding process, and at all times provided valuable technical expertise that enabled VTI to fully realize the inherent potential of a truly innovative design."

"Since our company's inception, we've had a mutually beneficial relationship with Invibio and have leveraged their insight, broad biomaterials portfolio, and hands-on technical support for our innovative and cost effective devices. We value the truly collaborative approach to product design and development that Invibio brings to the table, and look forward to continuing to work together," he said in the news release.

"Invibio is delighted that the innovative InterFuse device is receiving the recognition it deserves, and honored that our role has been recognized. VTI's InterFuse device is designed to deliver real and measurable patient benefits including reduced recovery times, shorter hospital stays, and good potential for reduced provider cost and better patient outcomes," commented David Hawks, Business Development Manager for Invibio, in the news release.

The PEEK-OPTIMA family of polymers is now in its 10th year. Invibio indicates that PEEK-OPTIMA provides a unique combination of material properties, including strength, stiffness, radiolucency, creep and fatigue resistance. In fact, more than two million devices featuring PEEK-OPTIMA polymer have been implanted in patients over the past decade.

*—EH (June 25, 2009)*

## Fire Sale at IST

Want to buy some spinal intellectual property?

Call Warren E. Agin.

Mr. Agin is the trustee appointed by the Office of the U.S. Trustee in Boston to liquidate Innovative Spinal

company


Technologies' patent portfolio. The portfolio includes surgical implants and tools designed to correct spinal problems using minimally invasive surgical techniques. Its FDA approved products include the Paramount MIS Pedicle Screw System for percutaneous single and multi-level procedures; the Paramount IBF Implant System, designed for a minimally invasive transforaminal approach; and the Cordant ACP Anterior Cervical Plate System. IST's innovative Axient system is a pedicle screw system designed to allow preservation of motion while providing the structural strength of a traditional fusion system.

The trustee plans to use proceeds from the sale to pay creditors.

IST filed a Chapter 7 bankruptcy petition on May 15 after reported rumors that Biomet was identified as a possible purchaser did not materialize.

The petition listed assets that included nine cadavers in its surgical center. A cautionary note was attached informing whoever it concerned that turning off electricity to the building could result in some unpleasant consequences. The cadavers have reportedly been properly removed from the premises in accordance with instructions provided by the deceased or their families.

The company, founded in 2002 with a portfolio of intellectual property from surgeons at Texas Back Institute in Plano, Texas, eventually moved to Mansfield, Massachusetts. The demise of the company had a very public ending as disagreements between some board members and former CEO Scott Shorer played out in the press. The lessons for the spine industry of IST are still being written.

*—WE (June 23, 2009)*

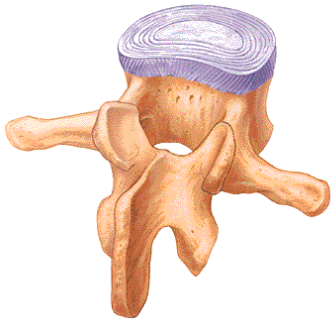
## *Anulex Raises More Cash*

In his first public announcement since taking over as President and CEO of Anulex Technologies, Rich Lunsford got to deliver good news.

Lunsford said on June 15 that the company closed on approximately $10.2 million in its fourth round of private equity financing. Just three months before Lunsford's appointment, the company had raised another $7 million.

With all that money in the bank, Lunsford says the company will have the ability to complete the enrollment and follow-up phases of its Xclose post market clinical study to show the safety and effectiveness of the device to repair the anulus. It will also provide additional investment for the company's U.S. commercialization efforts and further support the company's innovative research and development strategy.

The Xclose is a device that uses small braided polyester bands to make an X-shaped stitch over openings in the soft tissue around the spine. The company says the device will keep a disc from reherniating while speeding the recovery process.



They're also using some of the new money to beef up their executive team by hiring two new vice presidents.

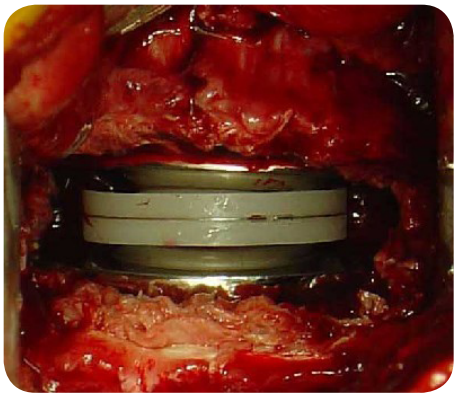
David M. Noel came over from Lifecore Biomedical in February to become Anulex's Vice President of Finance and Chief Financial Officer. Matt Meyer was appointed Vice President of Sales and Marketing, in March 2009. Meyer was previously Vice President of Marketing for KFx Medical and for ten years before that, and held a variety of senior marketing and sales positions with Medtronic Spinal and Biologics.

*—WE (June 22, 2009)*

## legal & regulatory

### Charité Preemption Victory

A U.S. District Court in Nevada threw out a Charité lawsuit last month citing the Riegel decision.



*Charité Artificial Disc*

Judge Robert Jones granted a summary motion made by DePuy Spine and JDA Surgical Associates to dismiss a suit brought by Roger Miller.

Miller had surgery on November 2, 2005 for a bulging disc. His surgeon William Smith, M.D., removed Miller's disc and implanted a Charité artificial disc sold by DePuy Spine.

Miller claimed he still had pain and had additional fusion surgery. His Charité disc remains implanted.

Miller sued on November 1, 2007, in Nevada alleging that the Charité was defective and sought to impose liability on DePuy under the state of Nevada's product liability, negligence and breach of implied and express warranties laws.

Before the case went to trial, DePuy said, not so fast...remember Riegel and federal preemption?

DePuy said that Miller was barred from suing under the state laws because the Charité disc had received Pre-Market Approval (PMA) from the FDA. The Riegel case affirmed the general rule that no state may establish any requirement which is different from any requirement in the Food, Drug, and Cosmetic Act. The granting of the PMA created federal requirements and state tort law standards are preempted.

Judge Jones agreed and wrote on May 1 that Miller would have had to prove that the disc implanted in him was manufactured out of conformity with the specifications approved by the FDA. Miller did not offer evidence to support that requirement.

This is the first case we are aware of where a Charité case has been dismissed. DePuy Spine lawyers are no doubt busy in other jurisdictions trying to get additional Charité lawsuits thrown out before Congress amends the Food, Drug, and Cosmetics Act to specifically remove the preemption clause. Such legislation has been introduced in Congress, but has not passed.

Roger Miller. Where have we heard that name before?

Naw, couldn't be the King of the Road.

*—WE (June 24, 2009)*

### Army Investigating Kuklo

The Army is now investigating spine surgeon Timothy Kuklo, M.D.

During an interview reported by *The New York Times*, Walter Reed Medical Center's commander, Col. Norvell V. Coots made the announcement on June 22 that the Army is now investigating the payments made by Medtronic to Kuklo.

Kuklo was accused by the Army of falsifying and manufacturing data from studies using Medtronic's InFuse bone growth product. The studies included soldiers with shattered shins.

The Army is investigating whether Kuklo violated military regulations by accepting a full-time teaching job at Washington University School of Medicine in St. Louis in August 2006.

*Times* reporter Duff Wilson writes that Army records show that Kuklo was a still a full-time, active-duty employee assigned to Walter Reed at the time he signed the Medtronic contract and accepted the Washington University teaching job. Military records show that he was granted "terminal leave" from the Army on December 31, 2006, and formally retired on March 31, 2007.

## legal & regulatory

Coots told the newspaper that the Army had found no records to show Kuklo sought or received permission to consult for Medtronic or take a new full-time job while still employed by the Army, as regulations require.

The Army investigation started about two weeks ago and a final report is expected within a month. Coots said he planned to make the report public. "We are trying to be as open and transparent as possible."

Kuklo is also a lawyer and has repeatedly declined to comment to the press.

A review of a Washington University Web site shows that Kuklo published over 100 peer-reviewed articles from 1997 to 2007.

Kuklo is a specialist in cervical spine and spinal deformity. His clinical interests include cervical spine, pediatric and adult spinal deformity, spinal tumors and spine trauma. His research interests include spine biomechanics, bone graft substitutes (including fracture healing and spine fusion surgery), particularly recombinant human bone morphogenic proteins, spinal deformity, management of spine trauma, and radiographic process measures and digitization.

A graduate of the United State Military Academy at West Point, Kuklo earned his medical degree from the University of Connecticut followed by a law degree from Georgetown University Law Center in Washington, D.C. He completed a transitional internship and a residency in orthopedic surgery at Walter Reed Army Medical Center in Washington, D.C., followed by a fellowship in pediatric and adult spine surgery at Washington University School of Medicine. He then returned to Walter Reed as a staff member in orthopedic/spine surgery and as residency director of orthopedic surgery, where he attained the rank of Col. U.S. Army Medical Corps (now retired).

He is currently an Associate Professor of Orthopaedic Surgery and Neurologic Surgery on leave from the University.

There is one question we don't see being addressed. While Senator Grassley pursues the financial relationship between Kuklo and Medtronic and the Army investigates whether he broke Army rules in taking payments, who is asking questions about the charges of falsifying medical data and forging colleague's signatures to that data?

*—WE (June 23, 2009)*

## biologics

### BioMimetic: PMA in Progress

What's it like to do a 90,000 page book report? Ask BioMimetic Therapeutics. The company has announced that it has submitted the pre-clinical pharmacology/toxicology and quality/manufacturing modules of its Premarket Approval (PMA) application for marketing Augment Bone Graft in the U.S., two of the three parts (modules), required for a complete PMA application to the FDA. The company is on track to file the third module, containing the clinical data, in the fourth quarter of this year. The modular application process means that applicants can attempt to resolve any concerns noted by FDA earlier than would occur with a traditional PMA application, and may ultimately shorten the review and approval timeline.

"The submission of the first two PMA modules is a significant accomplishment for BioMimetic," commented Dr. Samuel Lynch, President and CEO of BioMimetic Therapeutics, in the news release. "These submissions allow FDA to

biologics


begin their review of these modules well in advance of receiving the final clinical data later this year. We believe this modular strategy will facilitate the most efficient and timely review and ultimate FDA approval of Augment Bone Graft for orthopedic applications."

In addition, BioMimetic is announcing that it has achieved a new ISO 9001:2008 certification and ISO 13485:2003 recertification. "BioMimetic achieved certification to the new 2008 version of ISO 9001, as opposed to the prior 2000 version, six months ahead of schedule," indicated John McKay, VP of Quality and Environmental, Health and Safety for BioMimetic Therapeutics, in the news release. "The Company is one of the first in the United States to achieve the new ISO 9001:2008 certification."

Providing details on the PMA process was Leo Snel, Senior VP, Research and Development/ Protein Chemistry, who told *OTW*, "The submission of the first two modules of the PMA—the pre-clinical and the manufacturing/ quality modules—was a strong cross-functional team effort with team members working, sometimes around the clock, for four to five months. It required thousands of man hours to complete the 9,000 page submission to FDA. We expect to file the clinical module in the fourth quarter of this year. The modular submission allows FDA to begin their review of these modules well in advance of receiving the final clinical package. We believe the modular approach allows the Company to potentially resolve any concerns noted by FDA earlier than would occur with a traditional PMA application, and may ultimately shorten the review and approval timeline."

Regarding the clinical data that will be filed later this year, Snel told *OTW*, "With more than 400 patients treated, we believe this will be the most comprehensive, prospective clinical study ever completed in the foot and ankle. Further, over the course of the study, we will collect close to 90,000 pages of data. We expect that the results of the study will be reported to orthopedic surgeons at the 2010 AAOS meeting and will ultimately be published in a peer reviewed journal."

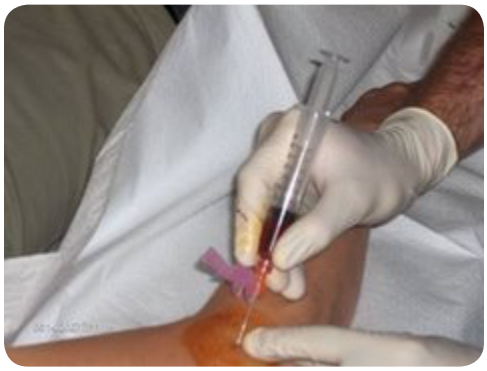
*—EH (June 18, 2009)*

## Ortho Option: Platelet-Rich Plasma

The ultimate in self-help...it seems that using a patient's own blood—platelet-rich plasma (PRP) therapy—can put the body's own growth factors to work to accelerate healing, reduce recovery time, and let individuals return to their normal activities more quickly.

The process involves putting the patient's blood in a high-speed centrifuge, which separates red blood cells from the platelets that release proteins and other particles that help the body heal itself. As indicated in the news release, the result is a concentration of platelets that is 3 to 10 times what is found in normal blood. The platelet-rich plasma is injected into the injured areas, but the healing aspects of the platelets take effect without the clotting responses that platelets usually cause. PRP therapy is currently being used in a small number of orthopedic practices and hospitals around the country with notable success.

"PRP therapy is an important biomedical advancement in the



*Tennis Elbow Injection*

## biologics

treatment of orthopaedic injuries," said Dr. Vishal Mehta in the news release. One of the few Chicago-area doctors offering PRP therapy to patients, Mehta added, "It is likely to have a major impact for treating amateur athletes —'weekend warriors'—given its relatively low cost and promising recovery for injuries for which surgery is not an option."

According to the news release, those undergoing PRP treatment can have decreased recovery time. For L.A. Dodgers' pitcher Takashi Saito, undergoing this treatment for the injury to his pitching elbow last season enabled him to avoid an estimated 12-month recovery time (which would have meant an early end to his season). Instead, he was able to pitch again before the season ended during the pennant race in September. Other professional athletes, including Hines Ward and Troy Polamalu of the Pittsburgh Steelers, have undergone the PRP treatment. Researchers say that it could potentially be helpful in treating arthritis and osteoarthritis as well.

"Because it is a new treatment, research is still underway to measure its success across a broad spectrum of injuries and situations," added Dr. Mehta. "Each case needs to be evaluated on an individual basis, and many patients are finding success with PRP."

Dr. Mehta told *OTW*, "I became interested in the use of PRP while doing research during residency at the University of Chicago. There, I was studying the use of specific growth factors (bone morphogenetic protein (BMP) 12, 13 and 14) on improving tendon healing. The problem is that it is difficult to determine which one of thousands of growth factors to apply to a tendon to improve healing. Therefore, it makes a lot of sense to try to amplify the body's natural process by using PRP. You are essentially harvesting and concentrating the growth factors that naturally help the body to heal and then applying them to damaged tissue. It just makes a lot of sense."

Regarding the future of PRP, Dr. Mehta told *OTW*, "I think this will catch on quickly. I think its biggest application is in areas of tendon/ligament injury where we currently don't have any good solutions such as tennis elbow (lateral epicondylitis), patellar tendinitis, achilles tendonitis, partial thickness rotator cuff tears and ligament sprains. Because this is the patient's own tissue, the risks are somewhat limited. There is always the theoretical risk that you encourage too much healing and get an overgrowth of tissue and bone."

*—EH (June 18, 2009)*

## extremities

### Salamander Legs Anyone?

Are you smarter than a salamader? While not a primetime TV show anytime soon, some are beginning to wake up to the possibility than we humans could learn a (critical) thing or two from the lowly salamander. Can ultimately the leap be made from the creature that naturally re-grows severed appendages to helping humans who have lost limbs? To pursue such questioning, Tulane

*Photograph by Stephen Dalton/Animals Animals - Earth Scenes*

University Professor Ken Muneoka, the John L. and Mary Wright Ebaugh Chair in Science and Engineering, will use a $6.25 million U.S. Department of Defense grant, and will lead a team of researchers from the University of California-Irvine and the University of Kentucky to identify the genes that trigger regeneration in the axolotl, a Mexican salamander.

Our genetic cousins the mice will then brought into service, with researchers attempting to determine how the same genes are regulated in response to injuries in mice—who share similar genetic characteristics with humans.

"The hope is that once the genetic signals for regeneration are identified, therapies can be developed to enhance the regenerative response in humans," Dr. Muneoka said in the news release.

Regeneration of tissue in humans is a long-term goal of Muneoka who, like

## extremities

his colleagues, has conducted research in this area for many decades.

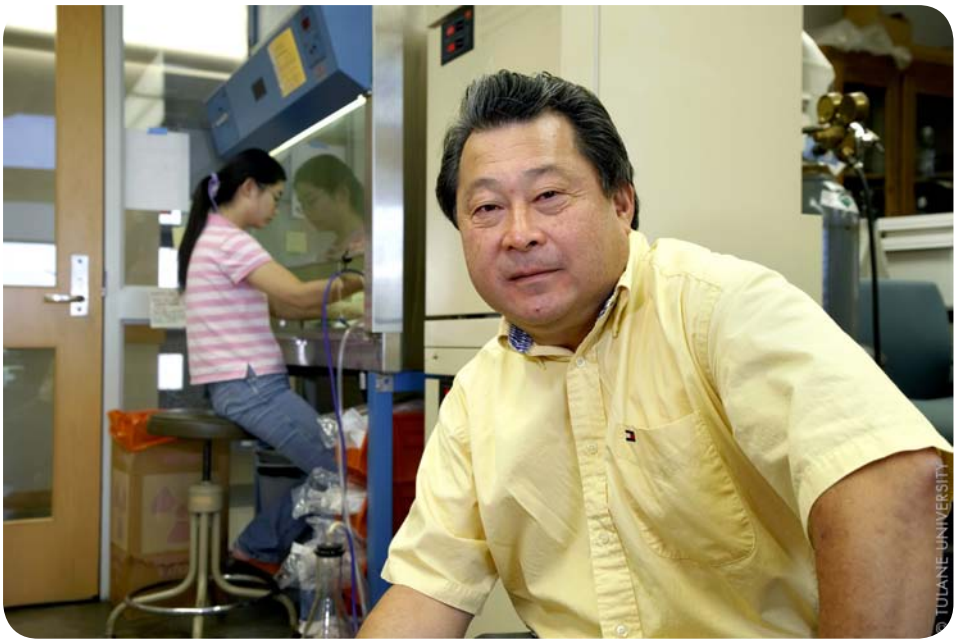
The shorter term goal is to modify the body's natural healing process to transition from a scar-forming response to the initiation of a regenerative response. Muneoka says this might involve cell-based therapies with regeneration-promoting cells, and/or factor-based therapies, such as providing a specific growth factor, to initiate and/or sustain the regenerative response.

While the salamander is the only animal capable of regenerating lost appendages, a child can grow back the tip of a severed finger, and, even in adults, bone, muscle, cartilage and skin can independently undergo a healing and regeneration response.

"What's missing is a way to coordinate these events so complex structures can be restored," Muneoka said in the news release. "By establishing a comprehensive database that identifies all the genes involved in regenerating a salamander limb, we will essentially create a genetic blueprint of how to do the same in humans."

The grant that will fund Muneoka and his colleagues' research is the result of a competition the Army Research Office, the Office of Naval Research and the Air Force Office of Scientific Research conducted under the Department of Defense's Multidisciplinary University Research Initiative (MURI) program.

Through the competition 69 academic institutions were awarded $260 million over the next five years to perform multidisciplinary basic research.



*Tulane University Professor Ken Muneoka*

Regarding the gene identification process, Dr. Muneoka told *OTW*, "Axolotl gene identification is from sequence analysis of cDNA (Voss lab, U. Kentucky) that is made from RNA collected at various stages of limb regeneration (Gardiner lab, UC Irvine). The sequence information will be used to develop a unique microarray chip (Voss lab) that contains a listing of all genetic changes that occur during limb regeneration. This chip will be used to probe the sequence of gene expression during axolotl limb regeneration stage by stage (Gardiner lab). This will result in a complete documentation of gene expression patterns during wound healing and limb regeneration."

Dr. Muneoka commented to *OTW*, "Meanwhile the Muneoka lab (Tulane University) will be documenting gene expression patterns during regeneration of the mouse digit tip using a microarray chip that is already available for the entire mouse genome. We will also establish gene expression in non-regenerating amputations of the limb to establish a baseline for studies aimed at inducing a regenerative response."

*—EH (June 24, 2009)*

## spine

### SpineJet Gets Workers Back to Work

Doug Daniels, HydroCision's CEO, announced on June 15 that the company has launched its new SpineJet Percutaneous Access Set for use in herniated disc procedures. The

spine

company is calling this the "Walk in/Walk out" option to get people back to work quicker.

"The procedure is performed under local anesthesia and on an outpatient basis—my patients return home the same day with no more than a Band-Aid on their back and can return to work much sooner than with traditional surgery," says Gabrielle Jasper, M.D., Director, Center for Pain Control in Brick, New Jersey.

She continues, "HydroDiscectomy also reduces the need for pain medications. The HydroSurgery approach made possible by the SpineJet Percutaneous HydroDiscectomy System provides physicians with great new tools, empowering us to perform truly minimally invasive percutaneous discectomy procedures that lead to improved clinical outcomes and faster patient recovery."

The system uses a high velocity water jet to simultaneously cut and remove nucleus to decompress herniated (bulging) discs, quickly, safely, and effectively. It does this without the collateral thermal or mechanical trauma of other surgical modalities, providing relief to patients suffering from back and/or leg pain, according to the company.

Daniels said that a large driver of procedural growth has been patients who seek out surgeons who perform minimally invasive procedures to reduce down time from work in these tough economic times. "This has led to rapid adoption of this new and evolving technique for the treatment of lower back pain by a growing number of neurosurgeons, orthopedic surgeons and interventional pain physicians. This trend has created the need for new instruments that can work through very small incisions."

Lower back pain is the second most common neurological ailment in the U.S. and is the most common cause of job-related disability and a leading contributor to missed work and reduced work productivity.

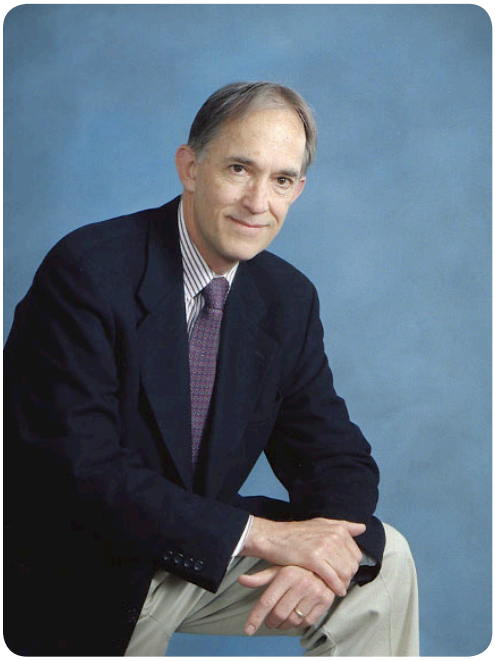
Walk in/walk out and get back to work with minimal disruption to your job and body.

Workers' comp boards should like that.

—*WE (June 22, 2009)*

# The Picture of Success: Dr. John P. Fulkerson

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



You could say that the knee has its own private eye. Dr. John Fulkerson, an orthopedic surgeon with Orthopedic Associates of Hartford in Farmington, Connecticut, is particularly taken with problems of the patellofemoral joint. Was there a car accident? What is the family's knee history? How is the patella tracking?

This sense of scientific inquiry runs in the family. Dr. Fulkerson: "I grew up in Levittown, New York in a diverse working class neighborhood. My dad was a general practitioner who sometimes let me tag along on house calls. He was a wonderful, kind man with an impeccable ethic of scientific inquiry, honesty, hard work, humor, study and athleticism. My grandfather and great grandfather were physicians as well, so I grew up with a strong sense that medicine was where I belonged."

## Medical School

Like many students who poured over textbooks in the late '60s, John Fulkerson had the Vietnam War in the back of his mind. "While at Williams College in Massachusetts, I worked hard to get into medical school. My thought was that if I were to go to Vietnam, it would be as a doctor. I studied very hard and played varsity tennis and squash, while also working as a DJ on the college radio station. While working as a YMCA camp counselor after sophomore year, I met my wife to be, Lynn; we are still married. During those years, I was inf uenced by Paul Tillich's 'The Courage to Be,' a book that emphasized the importance of a purposeful, positive life."

"Athletics played an incredibly important part in my life," continues Dr. Fulkerson. "After winning shotput and high jump in the Gardiner's Avenue School Olympics, feats which gave me great confidence, I thought I was ready for any challenge. So I went on to high school football, wrestling and tennis. But it was tennis that got hold of me, and I managed to make the Williams College tennis team, working my way up from number 27 to number 2 on the freshman tennis ladder…then on to the varsity squad as a sophomore. Tennis continued to be good to me and brought me many friends and opportunities over the years."

John Fulkerson also had the opportunity to meet new friends and mentors when he entered Yale Medical School in 1968. "I worked with Dr. Robert Handschumacher, a professor of pharmacology, who was really inspirational. A friendly person and great scientist, 'Dr. H' emphasized meticulous honesty about data and its analysis. In my senior year, I did an orthopedic surgery rotation, and really liked the positive, reconstructive nature of the field. I worked with Dr. Peter Jokl, the head of sports medicine, who had an exemplary lifestyle and stressed the same values that I was raised with, namely honesty, hard work, athleticism and integrity. Peter has been a career-long mentor and friend."

His life imbued with a sense of service, Dr. Fulkerson had no problem signing on the dotted line. "I had received a grant from the U.S. Public Health Service for medical school, so it came time to honor that obligation. After a general surgery internship at Yale New Haven Hospital, I went into the Indian Health Service as a general medical officer and ran the surgical service under the direction of Dr. Jim Ritter at Fort Defiance, Arizona. Having never worked outside the northeastern U.S., this was an exciting experience for me, and one which entailed treating people with a lot of health needs."

"I also learned quite a bit about Native American spirituality," adds Dr. Fulkerson. "One patient had a cyst the size of a grapefruit in his chest, and, as we were preparing to operate, his family decided that he should have three days of treatment by a medicine man first. They held a ceremony in his room during which time the medicine man drained the cyst and it went away; I never had to operate. I

really don't know exactly what went on, but I was impressed by the power of Native American spirituality in this and many other instances."

## Real-World Training

Armed with real world experience, Dr. Fulkerson was more prepared than many to get the most out of a residency program. "I began my orthopedic surgery residency at Yale in 1975, during which time I got to know Dr. Wayne Southwick, the Chairman of the department. He had an incredible intellect, a terrific breadth of knowledge, and took such joy in his job. The venerable Dr. Augustus White taught me the wonders of research. For a while, he had us read about 10 articles a week and then reviewed them with us. He imparted an appreciation for the critical understanding of orthopedic literature. Dr. Donald Chrisman also impacted my career. He was a true scholar who took a day each week out of his private practice to drive from Northampton, Massachusetts to New Haven to do research. He taught me that there is a close relationship between basic science research and clinical practice; I began to seriously consider an academic career. I was drawn in by the blend of science and medical practice, and fascinated by the way things work—especially cells. At this point in time, I was also very inf uenced by Lewis Thomas's book, 'The Lives of a Cell.'"

Dr. Fulkerson then followed his residency with a travelling feast of orthopedic study. "In 1979 I did a traveling fellowship sponsored by the Orthopaedic Research and Education Foundation. This enabled me to learn from many 'greats' in orthopedic surgery, such as Dr. John Marshall at Hospital for Special Surgery, Sir John Charnley, inventor of the total hip replacement, in England, and Dr. Jack McGinty in Boston. I also travelled to Sweden to study with Drs. Lars Peterson, Per Renstrom, Ejnar Eriksson and Jan Gillqvist. Sweden has a strong heritage of ACL reconstruction going back to Dr. Ivar Palmer in the early '30s."

## Professional Success

His travels ultimately helped him find his focus: "I had been searching for an area of interest that needed study and better understanding. It was the traveling fellowship that helped me settle on the patellofemoral joint as something I wanted to pursue. I had begun a full time faculty position at the University of Connecticut in 1978, then in the early '80s, I devised an operation known as an anteromedial tibial tubercle transfer."



Dr. Fulkerson explains, "This evolved from a concept I learned as a resident from Wayne Southwick, who had described a biplane osteotomy of the hip to treat slipped capital femoral epiphysis. We would literally sit on the f oor of Wayne's office and play like kids with the instruments for doing this complex osteotomy. Wayne Southwick had an uncanny ability to make the complexities of orthopedic surgery fun. I figured, 'Why not a biplane osteotomy of the knee to help unload and realign the patella?' This operation has since been called the Fulkerson Procedure by many, and is now a mainstream orthopedic operation that has helped thousands of people with breakdown of the lateral and distal patellofemoral joint."

Dr. Fulkerson then continued his investigations into the knee with more research. "I wanted to know why patients had pain around the patella so I undertook a study of the lateral patellofemoral retinacular structure. Margaret Grunnet and I discovered that some people with pain had histologic evidence of small nerve injury in the lateral retinaculum of the patellofemoral joint. We reported this in the literature in 1985. Steve Schutzer, Gale Ramsby and I then examined the mechanics of the joint using a new technology at that time–computerized tomography, by which we differentiated the alignment patterns of patella tracking."

No one is successful without the help of others, says Dr. Fulkerson, who

adds that he was fortunate to have been surrounded by the best young people imaginable. "In 1980 I started the Division of Sports Medicine at the University of Connecticut Health Center, and ran the resident education and selection programs in the department of orthopedic surgery there for many years. I worked with some brilliant students and residents who helped me with my studies."

Dr. Fulkerson's detailed knowledge of the knee would then benefit athletes who engage in full body contact…hockey players. "I covered Trinity College hockey and football, and received an award from their athletic department for consistently supporting their programs. After that I was asked to be team doctor for the NHL's Hartford Whalers, which was a lot of fun. We had a terrific medical group there with an extraordinary trainer, Bud Gouveia. I got to know Gordie Howe, Kevin Dineen, Paul Holmgren, Ron Francis, and even Ivan Lendl (who was on the Whalers Board). I exchanged stories with Wayne Gretzky in our training room, reduced Al Macinnis's dislocated hip, and reconstructed Adam Burt's knee."

"In 1993," adds Dr. Fulkerson, "I was honored to be appointed team doctor to the '94 U.S. Olympic ice hockey team, and had the pleasure of traveling through Finland and Sweden on their pre-Olympic tour. Hockey players are exceptional people who often grow up in strong families. As you might imagine, they are tough and don't let things get them down. Many of the guys are also very down to earth, and most have great senses of humor."

His leadership skills sharpened, Dr. Fulkerson then undertook the creation of a new society in 1994. "Jean Yves-Dupont and I launched the International Patellofemoral Study Group to provide a forum for surgeons worldwide to meet and further our understanding of how this joint works. Then in 2002 I started the Patellofemoral Foundation to raise funds for research and education on this topic. Part of our success has been the ability to link up with some major orthopedic organizations to sponsor traveling fellowships for outstanding academic orthopedic surgeons worldwide. In addition, we present awards for exceptional research on the patellofemoral joint. Some of my long time friends, including Peter Jokl and Eric Dahlinger, helped me with this from the beginning. Ivan Lendl also lent a hand in the early days."

Having explored every nook of the knee, Dr. Fulkerson wanted to find a more effective method for reconstructing the ACL. "In the mid '90s I learned about the central quadriceps tendon from Hans Uli Staubli, a Swiss surgeon. It is thicker and wider than the patellar tendon and is a better alternative for reconstructing the ACL. My primary finding and contribution here is discovering the 'central quadriceps free tendon graft' for ACL reconstruction. I did the research to establish that the quadriceps tendon, without bone attached, is a safe, optimal autograft for ACL reconstruction."

After being elected to a prestigious sports medicine group, the Herodicus Society, Dr. Fulkerson was named President of the organization in 2002. He explains, "The Herodicus Society is an academic sports medicine society that brings together leaders in the field to share new ideas and information in an informal setting. I am proud to say that during my tenure as President, the membership was expanded to incorporate a larger number of young, accomplished surgeons into the group."

A man of the OR *and* the land, John Fulkerson and his wife live amongst the vines. "We have a full vineyard with over 200 grape vines, enabling us to make our own wine…an area where my science background comes in very handy. Finally I have found the old college organic chemistry useful!"

Dr. Fulkerson: "Given that we're in Connecticut, we specialize in cold weather varieties, including a number of hybrids such as Saint Croix, Foch, Cayuga, and Vidal Blanc. We exchange it with friends who make different things; I have traded wine for everything from canned goods to

manure. Harvesting the grapes and making the wine is a blast with special friends coming over to pick grapes and join in the fun (and work). We make a party out of it with plenty of food and, of course, wine!"

At home in the natural world, Dr. Fulkerson is a committed land preservationist and President of the Litchfield Land Trust, an organization dedicated to preserving quality land in northwest Connecticut. He also enjoys the outdoors while participating in a number of sports: "Skiing, biking, flyfishing and tennis are some of my favorite pastimes. I also love spending time with my wonderful wife of 41 years, Lynn, who has been so helpful and supportive over the years. We are so proud of our two children, Brad the dentist and Phoebe the artist, who have achieved great things in life. Our family has been very fortunate; much of this I attribute to hard work, friends, caring and mutual support."

Dr. John Fulkerson…expanding scientific inquiry and creating opportunities for future generations.

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