

# Orthopedics • This Week

## week in review

**05 Advancing Pediatric Clinical Trials** ♦ In fall 2009 the FDA held the Pediatric Clinical Trial Workshop, where attendees discussed the most efficient ways to advance clinical trials for pediatric devices. Our interviewees discuss how the traditional ways of thinking about clinical trials are shifting.

**09 Yes, Virginia, You Can Resurface Hips** ♦ The FDA asked for ten years of follow-up data when the Birmingham hip was approved. It didn't take ten years. Data is streaming out and guess which component is posting up the better scores? Yes, it's that *other* Memphis company!

**14 Health Care Reform and Orthopedics** ♦ The health care reform bill will make everybody a winner. So says Bill Frist, the cardiologist, hospital owner, and former leader of Republicans in the U.S. Senate. It also means more patients, more units sold, longer wait times, and more "Sunshine." We have the key orthopedic issues here.

**18 Hatching a Joint Pain Relief Solution** ♦ What began as a way for one egg producer to cut down on waste has blossomed into a entire line of joint and bone supplements, all based around the common chicken egg.



## the picture of success

**31 Dr. Kenneth DeHaven** ♦ Years ago he found a way to combine sports and orthopedics. Dr. Kenneth DeHaven, an orthopedist with the University of Rochester Medical Center, is a pioneer in arthroscopy, and prefers repairing menisci, as opposed to removing them.



## breaking news

- 22 Medicare Cuts April 1, Don't Panic** .....
- New Study on "Tommy John" Surgery .....
- Berwick to Head CMS .....
- Special Tissue Sends Cell Growth to New Heights .....
- Device Helps Locate, Avoid Nerves .....
- Orthopedics: Hospitals' Golden Goose .....
- FDA Managers Cleared by Inspector General .....

**For all the news that is Ortho, read on.**

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- Associated procedures
- Private payer and Medicare data
- Patient demographics
- Regional and State charging data
- Associated diagnoses
- State reimbursement data
- Comorbidities

Spine Procedure U.S. Market Reports	Code
<i>Spine Fusion</i>	
Anterior cervical fusion	81.02
Posterior cervical fusion	81.03
Anterior dorsal and dorsolumbar fusion	81.04
Posterior dorsal and dorsolumbar fusion	81.05
Anterior lumbar fusion	81.06
Lateral lumbar fusion	81.07
Posterior lumbar fusion	81.08
<i>Spine Refusion</i>	
Posterior lumbar refusion	81.38
<i>Other Spine Procedure</i>	
Discectomy	80.51
Decompression	03.09

Large Joint Reconstruction	Code
Total Hip Replacement	81.51
Total Knee Replacement	81.54
Revision of Hip Replacement	81.53
Revision of Knee Replacement	81.55
Excision of Semilunar Cartilage	80.6
Cruciate Ligament Repair	81.45
Synovectomy of the Knee	80.76
Removal of Implanted Device Tibia/Fibula	78.67
Hemiarthroplasty	81.52
Hip Resurfacing	00.85

Extremity Market Reports	Code
Ankle Fusion	81.11
Triple Arthrodesis	81.12
Subtalar Fusion	81.13
Total Shoulder Replacement	81.80
Partial Shoulder Replacement	81.81
Rotator Cuff Repair	81.63
Total Ankle Replacement	81.56
Open Reduction of Fracture Radius & Ulna w/ Internal Fixation	79.32
Open Reduction of Fracture Humerus w/ Internal Fixation	79.31
Open Reduction of Fracture Tarsals & Metatarsals w/ Fixation	79.37



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# Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

**This Week:** Economic news was upbeat this past week and the health care reform legislation is now law. As expected, insurance companies raised rates. What does it mean for orthopedic companies? Simple, we think. More units sold at lower prices. Who wins, who loses? Most vulnerable, we think, is the distribution system.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	11.00%	8.40%	We think the path to every investor's heart is cash flow. OFIX is all about rising cash flows.
2	6	Stryker	24.71	7.4	Big jump this week for SYK. Could SYK be best positioned to ride health care reform?
3	2	Integra LifeSciences	15.37	6.89	Now the least expensive ortho stock as measured by a blend of P/E, PSR and PEG.
4	7	Alphatec	-0.44	22.31	Consensus among analysts is that ATEC will earn \$0.08 per share this year and \$0.25 next year. Up 3 more spots this week.
5	3	Johnson & Johnson	27.1	3.75	Flat earnings expected for the March quarter. The only good news is that R&D spending is robust.
6	5	Medtronic	31.37	3.98	Investors are starting to look at smaller market cap companies. MDT down 1 spot this week.
7	9	Symmetry	11.48	16.69	Big jump this week as investors look past this quarter, next quarter—heck the whole year.
8	4	Exactech	12.61	0.1	Up 30% in the last six months. Could EXAC be running out of steam? Analysts looking for a flat year in 2010.
9	8	CONMED	7.73	9.87	Investors are betting that hospital purchasing will rebound with health care reform. CNMD should benefit.
10	10	Zimmer	27.71	3.02	Investors still not enamored with ZMH. Analysts expecting just 6% sales growth this year.

## Robin Young's Orthopedic Universe

### Top Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg
1 Regen Biologics	RGBO.PK	\$0.45	\$4	66.7%
2 Alphatec Holdings	ATEC	\$6.36	\$344	22.3%
3 Symmetry Medical	SMA	\$10.28	\$368	16.7%
4 ArthroCare	ARTC	\$30.07	\$810	13.3%
5 Orthovita	VITA	\$4.28	\$328	12.9%
6 NuVasive	NUVA	\$44.24	\$1,720	11.1%
7 RTI Biologics Inc	RTIX	\$4.36	\$237	10.9%
8 CONMED	CNMD	\$24.37	\$711	9.9%
9 Orthofix	OFIX	\$37.29	\$653	8.4%
10 Stryker	SYK	\$57.65	\$22,950	7.4%

### Worst Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg
1 TiGenix	TIG.BR	\$3.64	\$112	-23.9%
2 Capstone Therapeutics	CAPS	\$0.92	\$38	-12.4%
3 CryoLife	CRY	\$6.53	\$186	-7.6%
4 Smith & Nephew	SNN	\$50.25	\$8,870	-2.8%
5 TranS1	TSO1	\$3.21	\$66	-1.2%
6 Mako Surgical	MAKO	\$13.33	\$448	-0.9%
7 Exactech	EXAC	\$19.96	\$257	0.1%
8 Wright Medical	WMGI	\$17.53	\$680	1.3%
9 Osteotech	OSTE	\$4.04	\$73	1.8%
10 Synthes	SYSTVX	\$123.81	\$14,693	2.6%

### Lowest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E
1 Kensey Nash	KNSY	\$23.72	\$259	13.46
2 Medtronic	MDT	\$45.67	\$50,310	14.09
3 Johnson & Johnson	JNJ	\$65.77	180,990	14.21
4 <i>Average</i>			\$11,941	14.65
5 Zimmer Holdings	ZMH	\$59.99	\$12,170	14.91

### Highest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E
1 Smith & Nephew	SNN	\$50.25	\$8,870	76.67
2 RTI Biologics Inc	RTIX	\$4.36	\$237	49.35
3 NuVasive	NUVA	\$44.24	\$1,720	42.52
4 ArthroCare	ARTC	\$30.07	\$810	27.80
5 CONMED	CNMD	\$24.37	\$711	24.50

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

Company	Symbol	Price	Mkt Cap	PEG
1 CryoLife	CRY	\$6.53	\$186	0.71
2 NuVasive	NUVA	\$44.24	\$1,720	0.79
3 Integra LifeSciences	IART	\$43.46	\$1,250	1.03
4 Smith & Nephew	SNN	\$50.25	\$8,870	1.08
5 Alphatec Holdings	ATEC	\$6.36	\$344	1.19

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

Company	Symbol	Price	Mkt Cap	PEG
1 CONMED	CNMD	\$24.37	\$711	9.91
2 Orthovita	VITA	\$4.28	\$328	7.13
3 Johnson & Johnson	JNJ	\$65.77	180,990	1.95
4 Symmetry Medical	SMA	\$10.28	\$368	1.82
5 <i>Average</i>			\$11,941	1.76

### Lowest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR
1 Osteotech	OSTE	\$4.04	\$73	0.76
2 CONMED	CNMD	\$24.37	\$711	1.00
3 Symmetry Medical	SMA	\$10.28	\$368	1.01
4 Orthofix	OFIX	\$37.29	\$653	1.20
5 Wright Medical	WMGI	\$17.53	\$680	1.39

### Highest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR
1 TiGenix	TIG.BR	\$3.64	\$112	108.90
2 Mako Surgical	MAKO	\$13.33	\$448	13.11
3 NuVasive	NUVA	\$44.24	\$1,720	4.64
4 Synthes	SYSTVX	\$123.81	\$14,693	4.33
5 Orthovita	VITA	\$4.28	\$328	3.51

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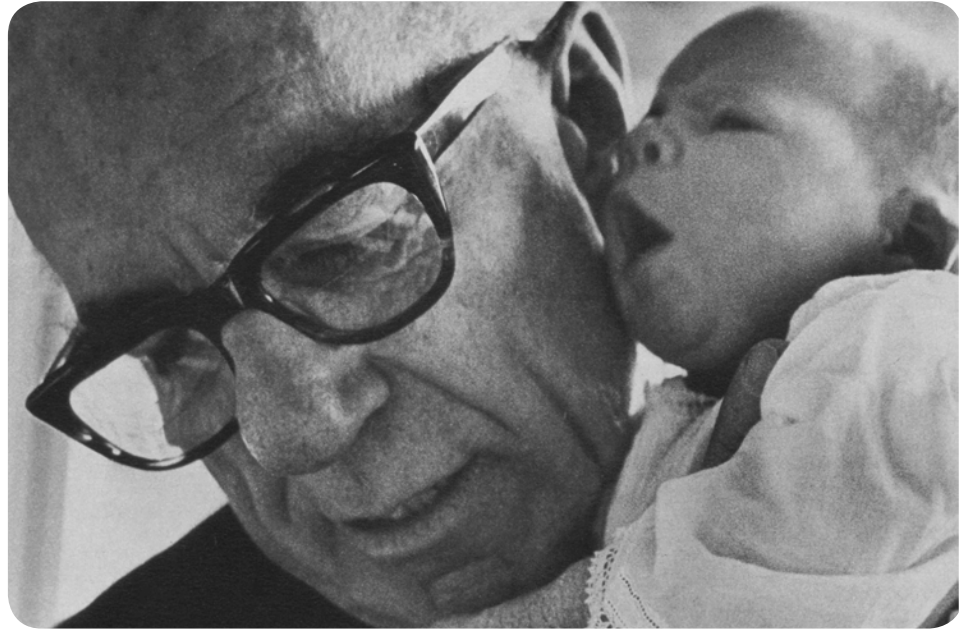
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## Advancing Pediatric Clinical Trials

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

**T**here is an old adage, “women and children first.” In orthopedics, the women are covered...the children, however, don’t always make it into the lifeboat.

In an effort to address the needs of children, in fall 2009 the FDA held the Pediatric Clinical Trial Workshop in Washington, D.C. Dr. Robert Campbell, who attended the event and is an orthopedic surgeon at Children’s Hospital of Philadelphia, said of the event: “This was the FDA’s first such conference and it offered attendees an assessment of unmet needs, study design, safety and effectiveness, and outcomes. In part this workshop grew out of a 2005 survey by the American Academy of Orthopaedic Surgeons



*Benjamin Spock, American pediatrician (with his first granddaughter, Susannah)  
LOOK Magazine, February 20, 1968*

(AAOS) which found that 33% of respondents had used adult-sized devices on children.”

The musculoskeletal panel set about detailing the unique needs of pediatric patients and how those special requirements translate into pediatric medical devices. Dr. Campbell: “There are two broad categories of need in pediatric surgery, namely, spinal deformity and trauma care. Pediatric surgeons need minimally invasive (MI) growth modulation devices and we are currently considering staples, MI tethers of the spine, and even animal work on magnet technology. This is timely because Axial Biotech has recently released a genetic test for adolescent idiopathic scoliosis, which will determine the genetic likelihood that early mild scoliosis will progress to surgical levels.”

Many of the trials and tribulations that come from using pediatric devices can be found in the literature and clinical trials. “Pediatric surgeons need to have growth modulation for scoliosis cases that are expected to progress, but this is not yet a reality. While there are promising initiatives, it is a substantial challenge for researchers and the FDA. One of the points made at the workshop was that the FDA and researchers must work together to find affordable regulatory pathways. It is tough to determine ways to have a device be both safe and effective, yet not be prohibitively expensive to develop and bring through the FDA approval process. The cost of a pediatric device may range from \$3,000 to \$ 10,000 per patient during a clinical trial, and can increase further if an issue arises during the trial—if, for example, the FDA wants the study



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investigator or company to repeat something. And the reality is that the companies involved are often startups and must answer to their investors.”

But Washington has begun to shift its thinking in a way that should benefit children. Dr. Campbell: “Laws were passed in 2007 that should ensure a more common sense approach. It is becoming clear that requiring perfection in device trials for safety and effectiveness is impossible for anyone. If we can let this ‘make it as safe and effective as possible, but make affordable’ philosophy sink into our work, then we can reign

in the expenses. One of the biggest cost issues is trial design. In the past we would get halfway into the trial and the regulations would change, which plays havoc with timelines and budgets. At the workshop Donald Berry, Ph.D., made a point of saying that the classic clinical trial with its large patient populations and extreme statistical power and controls may not be necessary in many instances of small pediatric patient populations, since other statistical approaches can support conclusions from smaller sample sizes. All of us have, in the past, been stymied by the thought that we needed matched controls for

pediatric device trials. Actually, robust clinical trials can still be designed for children with other types of controls.”

Dr. Campbell, inventor of the Vertical Expandable Prosthetic Titanium Rib (VEPTR), adds, “There are several companies working on developing devices with self expansion capability to power both growing rods and VEPTRs. At present, growing rod and VEPTR patients require surgery twice a year to lengthen their devices until skeletal maturity, with a significant cost and morbidity because of the limitations of the technology. But this can change once self-expansion



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is clinically proven. Self expanding devices are primarily magnet-based devices that a surgeon activates with an external fixed magnet or battery powered rotating magnets. The future is brighter because of these advancements.”

On the trauma front, says Dr. Campbell, “We have metal screws and plates to stabilize fractures, items which remain in the patient after healing and may be a problem later in life. Straightening and lengthening limbs with external fixation is also an area with a high rate of complication. There are plates and screws made of bioabsorbable materials which may be able to address these issues; the trick, however, is to make them strong enough to resorb without any adverse reaction. Also, we need more internally expandable implants

that can lengthen limbs or correct angular deformities near the joint and with fewer complications than our current methods. The most important consideration here is reliability; these devices need to get the job done with a low amount of force although there can also be problems with excessive reactive force from scarring. I would like to see a mechanical growth plate developed that would mimic gradual physiological lengthening of the long bone to normally lengthen the limb with time.”

Those in the pediatric device world know that to get on target you’ve sometimes got to go off label. “Physician directed (off label) devices are a reality in pediatric orthopedics. Pedicle screws are off label as are growing rods; we need to figure out how to get them officially FDA

approved as safe and effective. A major catch 22 is as follows: you may want to compare growing rods to another treatment, but the Institutional Review Boards [IRB] won’t let you perform a device trial because the rods are not FDA approved.”

More focus and funds are now flowing to pediatric device development. Dr. Campbell: “Three nonprofit pediatric device development consortia have just been established: one at Boston Children’s Hospital, one at the University of California, San Francisco, and one at the University of Michigan. These facilities have the resources in place to make a substantial impact in a relatively short amount of time.”

Dr. Michael Vitale, Chief of pediatric spine at Morgan Stanley Children’s Hospital Columbia University Medical Center, was the moderator for the orthopedic panel at the workshop in October. He notes, “The event was successful in that it opened lines of communication on issues and highlighted challenges in innovation. One of the things we covered was how to deal with the fact that it’s hard to spend prohibitive amounts of money on research and development on items that have such a small market. On the regulatory side of things, doing a premarket Investigational Device Exemption (IDE) requires a large multicenter study with very strict outcomes. You need tremendous participation by a large number of people around the country, something which can cost between 20 and 30 million dollars.”

Dr. Richard E. McCarthy, President of the Scoliosis Research Society, adds, “It is imperative that the FDA approve

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the use of pedicle screws and growing rods in children soon or further advances in this area will be thwarted. In its present status, the regulation does not allow us to prospectively study our patients to determine how effective these treatments are.”

The conference was eye opening for Dr. Brian Snyder, a pediatric orthopedist with Children’s Hospital Boston. “The single biggest thing that I was hoping to come away with was that the NIH and FDA think about the IRB problem. I propose that we develop universal IRB regulations specific to FDA studies...that would allow us to systematically investigate the ‘off label’ uses of a device. Also, we should establish requirements that allow the use of previously published high quality studies that establish the safety and efficacy of an adult medical device used in children.”

The visionary behind this multifaceted event was Dr. Barbara Buch of the FDA. Dr. Buch, a Deputy Director of the Division of Surgical Orthopaedic and Restorative Devices, at the Center for Devices and Radiological Health, states, “The meeting’s purpose was to gather information related to collecting sound scientific information in clinical trials for pediatric devices, and solicit information about various aspects of device clinical trials involving pediatric diseases and patients.”

As for the most important issues facing pediatric orthopedic devices, Dr. Buch notes, “Understanding the unmet needs, understanding

the regulatory requirements to get pediatric devices to market, communication between professionals, and FDA and industry support of good clinical data collection for pediatric diseases and devices. Physician-directed use of devices engineered for adult populations has been a problem for a long time. We would like to have future interactions and discussions such as this one to keep the lines of communication open and transparent as pediatric specific devices are being developed.”

And, says Dr. Buch, it is time for some creative—yet logical—approaches. “Pediatrics is largely a new area for devices. Since most children are well, the populations needing devices may be relatively small and so traditional ways of thinking about clinical trials may need to be reexamined and

tailored to the specific populations or subpopulations involved. Traditionally pediatric patients have been excluded from clinical trials for a variety of reasons and the scientific community has to think of ways to overcome the multiple barriers inherent in this population.”

And the prospects for little limbs? Dr. Buch: “The FDA is in an exciting period now with lots of changes in the works. Even more emphasis on good science and evidence-based decision making will benefit the development of safe devices for pediatric patients. The orthopedic review branches have always been proactive with current technologies so it comes as no surprise that the agency is anticipating medical device development in the area of pediatric orthopedics and wants to be prepared for the future in this area.”

“The audience was diverse,” states Dr. Buch, “and included clinicians, representatives of research societies, members of industry, members of various government agencies, venture capitalists, epidemiologists and researchers. The meeting drew interest from international stakeholders including participants from Australia, the United Kingdom and Canada. All told there were approximately 200 participants talking and sharing ideas in a ‘think tank’ atmosphere. It was really terrific, and I have received a lot of complimentary feedback about the FDA staff who participated in the event. We look forward to going forward with a team approach to helping children.”



## Yes, Virginia, You Can Resurface Hips

By Robin Young

**T**he hip resurfacing debate keeps raging. This technology category has had a target on its back since that warm day in September 2005 when the Orthopedics Advisory Committee voted 4 to 2 to recommend commercialization of the Birmingham Hip Resurfacing (BHR) system in the United States.

With the committee vote in hand, the FDA approved the BHR (marketed by Smith & Nephew) for U.S. sales eight months later. What surprised observers at the time and, we think, laid the foundation for today's debate was that the data set used by the Orthopedics Advisory Committee and the FDA to approve the BHR came from a retrospective study of, in effect, 124 X-rays. No randomized, blinded controlled prospective trial data.

Standing behind those 124 X-rays were, however, roughly 2,400 patients and documented revision rates that were essentially the same as traditional total hip replacements (THR). In the study, the method employed to determine patient outcomes was a telephone interview.

Why did the FDA approve the BHR on such comparatively light data? It is probably not an exaggeration to say that the FDA felt some pressure based on the European data to approve the first hip resurfacing system for the United States. At the time, hip resurfacing procedures were fairly common in Europe, Canada and Australia. In fact, hip resurfacing has been performed outside the U.S. since 1997. By 2009, we estimate, more



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than 90,000 patients have received a hip resurfacing worldwide.

But that was only part of the story. The FDA asked for ten years of follow-up study when they approved the BHR in 2005. It didn't take ten years. Data is streaming out from various studies now. They are confirming that hip resurfacing, is appealing for patients and surgeons alike, but they are also showing that hip resurfacing has some serious caveats—particularly regarding which prosthesis are employed in which patients.

At last month's AAOS (American Academy of Orthopedic Surgeons) annual meeting, Drs. Graves, Steiger, Davidson, Ryan, Miller, Standord and Tomkins provided the results of their eight-year follow up of 12,093 primary hip resurfacing procedures. Their conclusion: **“Outcomes of resurfacing hip replacement is very**

**dependent on both patient and prosthesis selection.”**

The researchers measured time to first revision using the Kaplan-Meier scale and, trumpets please:

1. Best results were achieved in male patients less than 55 years of age with a diagnosis of osteoarthritis and who required a femoral resurfacing component which is 50mm or greater in size. In this group the rate of revision for resurfacing hip replacement is comparable to primary total hip replacement.
2. Worst results were achieved in women of **all ages** who were diagnosed with anything other than osteoarthritis (in particular DDH) and received a femoral resurfacing component of less than 50mm in size had a significantly increased risk of revision.

3. Finally, but most importantly and certainly to fuel this debate further, there was considerable variation in risk of revision depending on the **type of prosthesis** (we added the emphasis). And the three most used prostheses in the study were the BHR (Smith & Nephew), ASR (DePuy) and the Durom (Zimmer).

However, as we discovered when we looked into this debate, the two most studied hip resurfacing systems in the United States are the BHR and Wright Medical's CONSERV Plus. The BHR was the first hip resurfacing system approved in the U.S. Fourteen months after the BHR was approved, the FDA gave Corin Group's hip resurfacing system the green light for the U.S. Conserve Plus was originally available in the U.S. (before BHR) as a large femoral head component. In 2009 it was approved for hip resurfacing.

The data supplied to the FDA for approval to commercialize in the United States.	
CONSERVE Plus (Wright Medical)	Birmingham Hip Resurfacing (Smith & Nephew)
11 clinical sites (Multi-center study)	One clinical site (Birmingham, UK)
1,366 procedures	2,385 procedures
1,366 patient X-rays in IDE	124 patient x-rays in IDE
Physician follow-up	Telephone follow up
4.90% Revision rate	3.20% Revision rate

Source: Wright Medical Corporation

Hip resurfacing is an alternative to total hip replacement . It has several advantages including less bone removal, potentially (and more about this later) fewer hip dislocations because of the larger femoral head size and, if a revision is required, potentially easier revision surgery since the surgeon has more bone stock to work with.

What could go wrong with hip resurfacing? Number 1 on the hit list is femoral neck fractures (rate of 0-4% according to the literature) followed by aseptic loosening, metal wear and squeaking.

Hip resurfacing is supposed to be for younger patients who have non-inflammatory degenerative joint disease, do not have an infection, and are not allergic to metals.

The goal of hip resurfacing is to facilitate a more active post-operative lifestyle.

The large size cap and cup are roughly the same size as a person's original femur bone and could

reduce or even prevent dislocations.

Then we found this study by Dr. Koen De Smet who'd performed roughly 3,000 hip resurfacing procedures since 1998 and had used the following prosthetic devices:

Hip Resurfacing Design	Procedures Performed
BHR (Smith & Nephew)	1,974
Conserve Plus (Wright)	628
ASR (DePuy)	55
Mitch	18
Adept	13
Durom (Zimmer)	12
Recap	9
ACCIS	9
Cormet 2000	2

Source: Dr. Koen De Smet, ANCA Medical Centre, Ghent, Belgium



Wright Medical Corporation

Dr. De Smet has been retrieving BHRs, Conserves and other components for several years and sending them out for wear measurements. He found that:

1. The BHR had “high wear; average of 60 microns on the femoral side, 53 microns on the acetabular side, n=17”.
2. The Conserve Plus had almost no wear data since acetabular malposition (a common reason for revision and therefore component retrieval) was rarely seen with this implant. But where the components were sent to the lab for testing on a coordinate measuring machine, the Conserve Plus had wear rates of 7.03 +/- 13.5 microns while the BHR had 54.7 +/- 49 microns of wear.

De Smet then measured the abduction angle, ion wear rates and on and on and on for the different components.

Bottom line: he found a clear performance difference between devices and attributed most of the difference to a greater and more forgiving head coverage angle (Wright Medical's Conserve Plus) and 2mm size increments (BHR is at 4mm size increments in the U.S., 2mm in Europe and elsewhere).

Here is his summary table which, since most of his experience was with the BHR and the Conserve Plus, only deals with those two implants.

According to De Smet's data, the Conserve Plus delivered significantly lower post-op complication rates including almost no squeaking.

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	BHR (All)	Conserve Plus 2004/2008
Number of Patients	1,884	667
Gender M/F	1,267 / 605	379 / 284
Average Age	52	54
<b>Etiology</b>		
Osteoarthritis	91.2%	93.65
Necrosis	5.4	4.80
Rheumatoid	1.1	0.45
CDH	1.5	0.75
<b>Outcome Stats</b>		
Revision	0.48	0.45
Reoperation	0.48	0.90
Pre-op Complication	0.16	0.15
Early Complication	13.44	0.75
Late Complication	0.80	0.30
Squeaking	5.15	0.75

Source: Dr. Koen De Smet, ANCA Medical Centre, Ghent, Belgium

Late in 2009, the AAOS Board of Directors approved a new technology overview (TO) study regarding hip resurfacing (HR) which was led by Kristy L. Weber, M.D., chair of the Council on Research, Quality Assessment and Technology. Here is a quick summary of their conclusions (details are on the AAOS website):

“Resurfacing arthroplasty is now offered worldwide as a treatment option in some cases of end-stage hip arthritis.” Modern total hip resurfacing implants have attempted to address many of the shortcomings of early resurfacing devices by incorporating cementless fixation principles on the acetabulum with material and manufacturing improvements to produce a durable, low-wear bearing surface.

The workgroup reviewed 786 hip resurfacing citations, 3,056 total hip prognostic citations, and data from seven joint registries.

### Revision Rates

Based on data from three of those registries, patients who'd received HR are at greater risk for revision than patients who receive total hip arthroplasty (THA). The Australian registry, however, suggests that younger males with osteoarthritis might have a lower revision rate after HR than THA.

The workgroup also concluded that the literature does not conclusively demonstrate predictors of better or worse patient-oriented outcomes (such as pain relief, patient satisfaction, or walking ability) for either resurfacing arthroplasty or THA.

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And then, looking at a direct comparison between HR and THA, the workgroup concluded that the disparate preoperative hip function scores and demographic characteristics between the groups enrolled in the relevant comparative studies “prohibit meaningful comparisons and confound the interpretation of the data.”

### Improving Outcomes

As to which technique, THA or HR, delivered better outcomes; the workgroup looked only at formal studies, not anecdotal reports. The group could only find low-quality studies and those studies suggested that outcomes after hip resurfacing can be improved by changes in technique and increased surgeon experience.

After literally tens of thousands of patients, there is little debate, we think, about the appealing aspects of hip resurfacing. Compared to all-



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Andrew Huth / Photographer

cemented, large head components of the early 1990s, newer metal-on-metal components are showing better long-term wear.

But debates around hip resurfacing rage on. Lest three key points get lost in the din, here they are again:

1. Hip resurfacing works and can be routinely successful for BHR, Conserve Plus and other products
2. **BUT**...different components have different outcomes independent of surgeon training or experience

and from the data it appears that Wright Medical's Conserve Plus is posting up the better scores

3. Patient selection is huge and may be as important as component selection

For more information we refer our readers to the AAOS site and the plethora of papers submitted over the past three years at its annual meetings.

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# Healthcare Reform and Orthopedics

By Walter Eisner



President Obama / Wikimedia.org

President Obama signed the Patient Protection and Affordable Care Act of 2009 into law on March 23, 2010.

The bill's \$940 billion price tag will, according to the Congressional Budget Office, trim the federal deficit by \$139 billion over the next decade and over \$1 trillion over the next two decades.

Thus came to an end the first round of fierce partisan debate where all physicians in Congress voted along party lines. Round two promises to spill over into next fall's elections and the federal courts.

Regardless of one's political leanings or the likelihood of repeal of parts of the new law before its provisions kick in, or, actions by the courts to strike down any parts of the law as unconstitutional, there are provisions in this bill that will have an immediate

impact on orthopedic surgeons and the orthopedic industrial complex that supports them.

Those provisions include 32 million new patients with money to pay for services, a new 2.3% device excise tax, new disclosures requirements of surgeon/industry relationships, additional resources for comparative effectiveness research, cuts to Medicare Advantage programs, and the establishment of a payment advisory board to help Medicare cut costs.

Who wins and who loses?

The day after the President signed the bill, two grown-ups from the health care industry went on national news programs to give their analysis.

Former Republican U.S. Senate Majority Leader and cardiologist, Bill Frist, M.D., told *MSNBC*, "Everybody's

a winner." He said, "Hospitals will do well. With an additional \$2 trillion going into the system, industry will be pleased."

Another grown-up, Stephen MacMillan, the dean of medical device manufacturing executives told the "Squawk Box" on *CNBC* that the new device tax will not keep his company, Stryker, from continuing to find ways to innovate. He said that everybody in the health care industry "took their piece" and the company realized it "needed to take some pain."

## 32 Million New Patients

What will over 30 million new patients mean to device manufacturers?

In a September 18, 2009, article in *OTW* entitled: "*Is This Tax Good for Business?*" our publisher Robin Young provided an analysis.

Orthopedic companies sold about \$30 billion of devices in 2008. Young predicted that if only 15 million new patients came into the system, orthopedic companies would sell 8% more implants. "That's \$2.4 billion of incremental revenues, about \$1.8 billion in incremental gross profits, and very likely, \$1.2 billion in incremental operating profits."

What will that number of newly insured patients mean to orthopedic surgeons?

Again, if only 15 million new patients came into the system, Young predicted there would be an increase of 300,000 new orthopedic patients.

## Physician Shortage

Leaders of AAOS and NASS have told OTW that there are not currently enough surgeons practicing to accommodate an increase in patients. Provisions in the legislation that raise reimbursement rates for primary care doctors and offers special loan repayment programs to students who choose primary care, don't help the specialty practices.

Stuart Altman, a professor of national health policy at Brandeis University, points to the recent experiences of Massachusetts. The state was facing a primary care shortage when its insurance reform law was implemented. By 2009, a survey by the Massachusetts Medical Association found that more than half of internists and 40% of family doctors were not accepting new patients, the lowest acceptance rates since the survey was started eight years ago.

Fitzhugh Mullan, a professor of health policy and pediatrics at The George

Washington University, said that in the long term, "it will cause us to increase and rebalance our workforce" to make it more efficient." He says the rebalancing will include an increase in the number of physician assistants and nurse practitioners, who can be trained more quickly than doctors, to fill the primary care gap and reduce wait times.

## New Excise Tax

To help pay for the cost of insuring new patients, device manufacturers will be assessed a new 2.3% excise tax with full deductibility and will cover all product classes with the exception of retail products like contact lenses.

The \$2 billion per year tax was reduced from an original proposal that called for twice that amount.

"I think at the end of the day, the excise tax reduces the ability of medical device companies to spend money on discretionary spending," said Biomet's Bill Kolter, to the *Times*

*Union* of Fort Wayne after the bill was passed. "That could have an effect on things like (research and development) and employment."

Zimmer issued a statement saying:

"We applaud expanded insurance coverage for millions of Americans...While we continue to disagree with a tax on medical technology innovations, we are pleased that the House refrained

from increasing the \$20 billion device industry tax. We are also pleased the tax will be delayed two years to 2013."

Medtronic said it estimates the impact of the tax will be roughly \$150 million to \$200 million annually beginning in 2013. The company said it had no immediate plans to eliminate jobs as a result of the device tax or health care reform. "We accept our shared fiscal responsibility for coverage expansion," said the company in a prepared statement.

Tax hits on other businesses and industries include:

- \$52 billion on companies that do not provide what the government deems "acceptable" or "affordable" insurance for workers
- \$60 billion on health insurers
- \$27 billion on drugmakers and importers



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## Let the Sun Shine

The Physician Payment Sunshine Act was passed as part of the bill. This provision has the potential to change the competitive dynamic between device companies because they will now be able to see which physicians are working with their competitors.

Beginning in 2012, drug and medical device companies will be required to disclose payments to doctors and teaching hospitals of anything over \$10, with the first report available in 2013. If an individual receives more than \$100 from a company in a year, then everything [even amounts less than \$5] must be reported.

There is nothing that physicians need to report and the materials can be reviewed by physicians and companies before the disclosures go public.

The government will establish rules for collecting information about payments from device and drug companies no later than October 2011.

## Comparative Effectiveness

The law creates a nonprofit "Patient-Centered Outcomes Research Institute" charged with examining the "relative health outcomes, clinical effectiveness, and appropriateness" of different medical treatments by evaluating existing studies and conducting its own. The institute will be governed by a 19-member board that includes patients,

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doctors, hospitals, drug makers, device manufacturers, insurers, payers, government officials, and health experts.

The law states that the institute does not have the power to mandate or even endorse coverage rules or reimbursement for any particular treatment. Medicare may take the institute's research into account when deciding what procedures it will cover, so long as the new research is not the sole justification and the agency allows for public input.

Last year, Congress approved \$1.1 billion in stimulus funding for effectiveness research. The new legislation appropriates at least \$500 million per year to fund the institute.

## New Payment Advisory Board

A new 15-member Independent Payment Advisory Board (IPAB) with significant authority with respect to

Medicare payment rates is created by the legislation. Beginning in 2014, in any year in which the Medicare per capita growth rate exceeded a target growth rate, the IPAB would be required to recommend Medicare spending reductions. The recommendations would become law unless Congress passed an alternative proposal that achieved the same level of budgetary savings.

By law the board, "shall not include any recommendation to ration health care, raise revenues or Medicare beneficiary premiums, increase Medicare beneficiary cost sharing (including deductibles, coinsurance, and copayments), or otherwise restrict benefits or modify eligibility criteria."

## Medicare Cuts

Medicare Advantage payments will be frozen in 2011 and lowered in 2012 until \$136 billion in spending on the program has been cut by 2019. The law also requires private Medicare Advantage carriers to keep their overhead to 15% or less.

Medicare currently pays private plans to administer Medicare benefits and pays them about 14% more than the per-patient cost of the traditional Medicare program

"You are going to start seeing companies dropping out," said Robert Moffit, a policy analyst at the Heritage Foundation.

Gross cuts in projected payments to insurers, hospitals and other providers



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total \$533 billion over ten years, according to a preliminary analysis by the Kaiser Family Foundation. About \$100 billion will be plowed back into Medicare, leaving a net cut of \$428 billion. Medicare spending will continue to grow under the law, just not as fast.

### Unfinished Work

The legislation clearly moves the nation along the road to making health care available to virtually every person. It leaves the job of finding a permanent solution to a flawed physician payment system and new

practice standards that will allow physicians to stop practicing defensive medicine, to the future.

Nor does it address the light at the end of tunnel...the onrushing train of \$38 trillion or more in unfunded Medicare promises to retiring baby boomers.



## Hatching a Joint Pain Relief Solution

By Jacqueline Rupp



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**H**atching chicks create a lot of leftover eggshells, but even more eggshells come from cracking eggs for the food industry. If you're one of the U.S.'s top five egg producers, like Norco, California's Moark LLC, you have literally a ton of eggshells at your disposal. Historically, these discarded shells were used either for agriculture or, more commonly, simply dumped into landfills. Moark's owner, Hollis Osborne, began to wonder several years ago if something could be done not only to cut down on the waste, but also to find a revenue stream for this under-appreciated resource.

To uncover the possibilities, Osborne started a company, Membrell in 2001 in his hometown of Carthage, Missouri. Osborne consulted with several scientists at local colleges to study the properties of the eggshell.

What they found was that the egg shell membrane in particular contains protein, hyaluronic acid, glucosamine, and chondroitin. Today, that entrepreneurial spark has transformed Moark into a pioneer in eggshells processing for bone and joint health. It also spawned the 2002 creation of another company, ESM Technologies, also based in Carthage, which is solely dedicated to the bone and joint health market.

But the company has progressed with its research and data since those first basic findings. Today, Hollis Osborne's grandson, Micah Osborne is president of ESM Technologies and the company has refined its processes, creating

a patented system to separate the membrane from the egg and process each part into powders.

The idea of utilizing discarded animal parts is actually quite primitive. "Bone broth," the humble stock made from bone, water, a touch of vinegar and assorted vegetable bits has served for centuries as a nutritional powerhouse, utilizing the beneficial elements of bone and cartilage. It has even been suggested that the addition of eggshell to the stock provides the benefits found in the eggshell membrane, namely protein, hyaluronic acid, (providing resilience to cartilage) glucosamine, and chondroitin.

Eggshells can also be cooked alone to create a liquid rich in hyaluronic acid. This is done simply by cracking eggs and washing out the shell to remove the remaining egg white, boiling in water for at least eight hours, adding water as needed and pouring the resulting



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Egg shell powder/ESM Technologies

mixture through a strainer. The liquid can be stored and used in cooking or as a drink by adding flavoring.

### Cracking Into a Better Joint Remedy?

Natural Eggshell Membrane (NEM) is processed into powder form by ESM and sold to pharmaceutical companies which then encapsulate it and distribute it as a supplement for the relief of joint pain and the restoration of joint health. But ESM hasn't left its presence in the market to being just one of supplier. Instead, the corporation has undertaken significant research and trials to determine just how effective NEM can be for joint health.

"We have conducted three human clinical trials on NEM to date," says Dr. Kevin J. Ruff, director of scientific and regulatory affairs at ESM. "These studies were published in *Clinical Interventions in Aging* and *Clinical Rheumatology* in 2009.

The most impressive finding to come out of these studies is that patients saw a clinically significant improvement in pain and stiffness in only seven to ten days, with just one 500 mg capsule per day. The rapid onset of efficacy combined with the small dose makes NEM the natural choice for arthritis and other painful joint conditions."

An independent study published in the journal *Clinical Rheumatology*, additionally found a 500 mg supplement of eggshell membrane provided a significant reduction in symptoms of joint pain in arthritis sufferers, over a 60-day period. Although it's important to note that 43% of participants left the study early, which means further trials could prove the supplement to be more or less effective.

Ruff adds that the mechanism of action hasn't been fully discerned, so it's not clear just why the egg membrane

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substance is effective. However, he points out that early studies are making a link to an anti-inflammatory mechanism. "NEM appears to reduce the production of pro-inflammatory cytokines, inhibiting inflammation early in the cascade. We are continuing to look into this topic, and we have ongoing studies to this end."

Ruff explains that NEM is derived from the thin membranes that line the interior of an egg. The membrane in fact contains a combination of many known joint repair substances. "It naturally contains a family of glycosaminoglycans including chondroitin sulfate and hyaluronic acid, and also collagen and other beneficial proteins that all work in concert to support healthy joints."

Michah Osborne says there are many benefits to NEM over other joint remedies, beginning with its organic properties. NEM is completely natural, in fact as Osborne points out, it comes from one of the most familiar, widely consumed foods on the planet. He adds other joint pain relief products are completely synthetic or processed with harsh chemicals. Ruff says another safety benefit that was found in the trials showed that even at 50 times the normal dose the product remained safe.

Osborne adds that NEM's biggest opportunity is in products where consumers are looking for fast relief from joint pain. "The combination of NEM's small 500 mg dosage and fast ten-day results makes it very consumer friendly," says Osborne. "In just ten pills (one per day for ten days) you can experience noticeable results with NEM. Contrast NEM's results against 90 pills (three pills per day for 30 or more days) like many other joint health products, and you can see the major advantage of NEM."

**Table 1** Single-arm trial mean values by category at baseline, 7 and 30 days post-treatment

	Days Post-Treatment	Mean ± SD	Percent Improve	P-value
<b>General Pain</b>	Baseline (n = 11)	3.6 ± 1.8	–	–
	7 (n = 11)	2.7 ± 1.7	25.8%	0.515
	30 (n = 11)	1.0 ± 1.2	72.5%	*0.007
<b>Flexion (ROM)</b>	Baseline (n = 11)	64.2° ± 36.5°	–	–
	7 (n = 11)	82.0° ± 41.4°	27.8%	*0.038
	30 (n = 11)	92.2° ± 38.4°	43.7%	*0.006
<b>ROM Pain</b>	Baseline (n = 11)	2.9 ± 2.6	–	–
	7 (n = 11)	1.7 ± 2.1	43.3%	0.112
	30 (n = 11)	0.7 ± 1.3	75.9%	*0.021

**Notes:** P-values were determined by pairwise, two-sided, t-test comparison, and represent treatment versus baseline.

\*P < 0.05.; Abbreviations: ROM, range of motion; SD, standard deviation.

### A Purer Form of Calcium?

Eggshells are after all made of calcium carbonate, just like chalk, limestone, cave stalactites, sea shells, coral, and pearls. About 5% of their composition is also attributed to calcium phosphate, magnesium carbonate, and soluble and insoluble proteins. So it would stand to reason they would offer a promising source for calcium supplements for bone health.

In fact Dutch researchers have reported very positive findings involving the use of eggshell calcium. In a double blind, placebo-controlled study, eggshell calcium with the addition of magnesium and vitamin D was given to a test group. Results showed a measureable increase in density of the hip bone after a year's time. These benefits are not exclusive to chicken eggs, but there may be an advantage to using certified organic eggs from free-range birds because these birds are generally better nourished, which translates into more nutrients in the eggshell.

The composition of the eggshell is in fact markedly similar to the make-up of human bone, with one whole medium-sized eggshell yielding about a teaspoon of powder out of which approximately 800 mgs of elemental calcium can be obtained. Other microelements, like magnesium, boron, copper, iron, manganese, molybdenum, sulphur, silicon, zinc, and ten other elements can be found in similar quantity to that found in bones and teeth.



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ESM's other product EggShell Calcium (ESC) utilizes the hard shell, which the company grinds up and encapsulates and markets in-house as a calcium supplement. With nearly 20,000 pounds of shells being processed per day, there obviously is no shortage of raw materials to use.

Ruff says that this form of calcium is different from other naturally occurring sources. "It is one of nature's purest and most absorbable forms of calcium. ESC naturally combines ultra-pure calcium carbonate with inherent transport proteins and essential trace minerals for increasing bone mineral density (BMD)."

Ruff adds that when taken in combination with magnesium and vitamin D, ESC has been clinically proven to increase BMD (bone mass

density) in osteoporotic women in under a year's time. Sourcing from eggshells also avoids the risk of impurities that can be involved in calcium that's mined in the ground.

### Expanding the Market

"We now have a good following of rheumatology and general practice doctors after presenting our clinical trials," says Osborne. "However, I am not sure the orthopedic community has been introduced to NEM and ESC until now. I believe the orthopedic community would be very interested in both products."

ESM Technologies is currently selling its ingredients to a number of partners who include the ingredients in their brands. "One of them is our sister company Membrell," explains Osborne. He says Membrell's

main demographic is really quite diverse and centers around anyone suffering from joint discomfort. "Joint discomfort is not just a part of life," adds Osborne. "It's not a natural consequence of getting older. And there is something you can do about it!" Currently the Membrell products line is being sold at natural health food retailers.

However ESM sees a future in expanding the line to fit into a new generation of seniors who lead active lifestyle. "Adding NEM to food products like bars would be an excellent next step," says Osborne. "There is still some development to do in this regard but we see it as a logical next step."

"We are always looking for new and innovative uses for our flagship ingredients, NEM and ESC," adds Ruff. "Whenever a new condition is identified, we will approach it with the same scientific manner that characterizes ESM Technologies' current quality products."



## legal &amp; regulatory

**Reader Mail:  
Post-ReGen FDA**

**M**ark DuVal, a private attorney with extensive FDA experience, commented on our recent article regarding the FDA's Orthopaedic Advisory Panel's rehearing of the ReGen knee device.

Writes DuVal:

The FDA with the IOM [Institute of Medicine] and internal working groups are now exploring the idea of new legislative authority to rescind 510(k)s. This would most certainly destabilize industry investment, especially among the start-up/venture community.

Overall, the FDA continues to look for more ways to be more deliberative and 'surround' the company with requirements that will **discourage investment and send more innovation outside the United States**. FDA continually escalates data requirements to PMA and even drug-like heights, takes an inordinately long time to conclude pre-IDE discussions, often doesn't stand by what it has agreed to in those meetings, often suggests additional performance work including clinical trials after the company's performance data/clinical program has been submitted, gives an SE with limitations letters and insists on post-marketing requirements, among many other opportunities to delay clearances and increase costs.



Wikimedia Commons / Leonid Dzhepko

Industry does want a strong FDA and believes we have a mutual and important obligation to prove the safety and effectiveness of our products.

We do not begrudge or want to deny this obligation. Industry simply wants scientific rationality and predictability—it is easy to ask for more and more data, but to what scientific end? It is too easy and safe for FDA as a regulator to always want more. FDA must take reasonable risks to ensure we do not deprive patients of valuable therapies. We are tired of seeing our products on the market in Europe being safely used by physicians and their patients two to eight years before the United States.

What can we look forward to from the FDA?

“Call me an optimist,” writes DuVal, “I am encouraged by the direction Dr. Shuren is headed. He seems to want to tackle all of these issues head on. Time will tell whether his legacy will be that he is known as the Center Director that contributed to the demise of this innovative, world-leading device industry or he helped to stabilize and grow investment and innovation by taking seriously the other half of FDA's mission; to promote innovation.”

—WE (March 31, 2010) 

## legal &amp; regulatory

**FDA Managers Cleared by Inspector General**

**F**ood and Drug Administration managers did not engage in criminal retaliatory actions against agency scientist “whistleblowers.”

That’s according to a report by Alicia Mundy in *The Wall Street Journal* on March 31. According to the story, the inspector general for the U.S. Department of Health and Human Services plans no criminal referrals to the Justice Department.

The “whistleblowers,” who have appeared to be using the *Journal* to make their case public, had alleged that the FDA review process had been “corrupted and distorted” and they had been retaliated against for going public.

The FDA’s Chief Counsel Ralph Tyler said the HHS inspector general informed the FDA of its finding about a month ago.

Mundy wrote that several members of the whistleblower group said this week they were notified by Tyler on March 29 about the inspector general’s report and the FDA’s intention to publicize it.

FDA spokeswoman Meghan Scotts said the FDA has hired a management-consulting firm to investigate workplace issues and allegations about management problems that weren’t addressed by the inspector general.

Tyler said the FDA decided to disclose the inspector general’s findings in light of the interest by the medical community and the media, but he said the agency wouldn’t release the report itself to the FDA scientists or the public.

Perhaps this will put an end to the internal FDA train wreck that has jeopardized approvals and clearances for devices that can help patients and foster medical innovation in the U.S.

—*WE* (April 1, 2010) 

from elsewhere in the body. Prior to this surgery, players with this type of injury were forever benched. Now, new research has found that 95% of skeletally mature high school pitchers were satisfied with their “Tommy John” elbow reconstruction surgery. Almost as many, (94.7%) returned to competitive baseball.

“High school kids have been a grey zone for this surgery,” said Michael J. Angel, M.D., of Premier Orthopaedics of Westchester and Rockland, in the news release. “Obviously, surgeons would avoid surgery on young patients whose growth plates had not closed. But this study can give surgeons the confidence to recommend this surgery to teenage skeletally mature athletes. It also gives the teen and their parents assurance that the surgery should go well.”

Researchers examined data from 20 high school baseball pitchers between 16 to 18 years old who had UCL surgery; 19 out of 20 reported being satisfied with the surgery (17 were very satisfied, 2 were somewhat satisfied). Eighteen of the 19 satisfied patients reported that they returned to competitive baseball. Of the 19 players, three reported that their highest level of competition was in the minor leagues, another 13 went on to play intercollegiate baseball and three returned to high school baseball.

With regard to further research, Dr. Angel told *OTW*, “Larger studies with longer term follow-up would help improve upon the efficacy of our results. Our patients were highly

## extremities

**New Study on “Tommy John” Surgery**

**I**n 1974 Hall of Fame pitcher Tommy John opened doors for injured athletes of the future. John was the first person to have a surgery where a damaged elbow ligament (ulnar collateral ligament or UCL) is replaced with a tendon



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## extremities




Pitcher's motion, Cincinnati Reds, 9/15/2004, by Rick Dikeman

satisfied from their outcomes and return to play baseball, but over time they're ability to play at a highly competitive level wanes. Perhaps comparing them with a control group would be beneficial. The most difficult point to address is whether these athletes stopped playing because of the injury to the elbow or because over the course of time, they weren't talented enough to play at the next level (i.e., college or professional) or even lost interest in playing competitive baseball. While there are statistical means to determine this, the most appropriate way to approach it would be with a larger series of patients, perhaps targeted based on level of play (baseball camps, travel teams, prep schools, etc.), ideally with a comparable control group, and with the statistical model that follows them over the course of time."

Overuse injuries account for nearly 50% of all sports injuries in middle school and high school students, according to the National Center for

Sports Safety. For high school athletes whose growth plates have closed, this study shows that the "Tommy John" UCL reconstruction is a successful option for teenage baseball pitchers who have sustained this type of injury.

—EH (March 31, 2010) 

## people

## Berwick to Head CMS

**I**t looks like the Centers for Medicare and Medicaid Services (CMS) is going to get its first permanent chief since Mark McClellan left the position in 2006.

An administration official reportedly confirmed that President Obama intends to name Massachusetts pediatrician Donald Berwick, M.D., MPP, FRCP, to the position in the near future.

CMS runs government health care programs for seniors, the poor and disabled. Benefits are provided to an estimated 100 million people.

### Comparative Effectiveness Advocate

Berwick is the president and CEO of the Institute for Healthcare Improvement, a nonprofit organization in Cambridge, Massachusetts,

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## people

that works to eliminate “needless” problems within health care systems across the globe, such as needless deaths, suffering, waiting for help, or waste. Berwick is also a professor of pediatrics and health care policy at the Harvard Medical School and a professor of health policy and management at the Harvard School of Public Health.

A new chief of CMS will have his hands full implementing components of the health insurance reform legislation recently signed into law. Having served as the chair of the National Advisory Council of the Agency for Healthcare Research and Quality from 1999 through 2001, it will particularly interesting to see how the agency makes use of comparative effectiveness data to make, or not make coverage and payment decisions.



Donald Berwick, M.D./photo courtesy of apqc.org

## “Sir” Berwick

Dr. Berwick was inducted as a Fellow of the Royal College of Physicians in London in 2004. In 2005, in recognition of his work for the National Health Service in the UK, he was appointed honorary Knight Commander of the Most Excellent Order of the British Empire—the highest award given to non-British citizens

## Congressional Approval

Congressional approval from a Congress ripped apart by the health care debate won't be automatic. The *Tribune Newspapers* reported a signal of concern, if not outright opposition from Republican Senator Tom Coburn of Oklahoma, a practicing obstetrician.

“One concern I have is that he's an advocate of cost comparative effectiveness,” said Coburn. “There may be one or two or three ways of doing something. I want to do what's best for the patient, not necessarily what's cheapest.”

Focus too much on cost effectiveness, and “all of a sudden you're rationing care,” Coburn said.

“It's way too early to tell” if Republicans will try to derail Berwick's nomination, Coburn said. “I think he's more than qualified...I want to sit down and talk with him.”

—WE (April 1, 2010) 

## reimbursement

## Medicare Cuts April 1, Don't Panic

When the Senate approved legislation on March 10 to postpone the scheduled 21.2% cut in the Medicare physician fee schedule (MPFS) that was to go into effect April Fool's Day, physicians had every right to breathe a sigh of relief. The cuts were to be postponed until the end of September.

Turns out that action was a figurative April Fool's Day joke, because Congress adjourned on March 26 for two weeks without taking final action of the bill.

The health insurance reform package passed by Congress and signed into law by the President did not address the fee schedule, so the statutory cuts will go into effect April 1.



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## reimbursement



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However, it's not time to panic...yet.

Medicare believes Congress is working to avert the negative update that will take effect April 1 and has instructed its contractors to hold claims containing services paid under the fee schedule for the first 10 business days of April. Medicare says the hold should have minimum impact on provider cash flow because, under the current law, clean electronic claims are not paid any sooner than 14 calendar days (29 for paper claims) after the date of receipt.

If Congress acts during the period of the hold, Medicare can begin processing claims for these services again.


### No Debt for Docs

Efforts to pass a permanent fix to the fee schedule failed because Republican and Blue Dog Democrat lawmakers

(including orthopedic surgeons in the House and Senate), said the fix would add to the national debt and refused to support the fix. Democrats didn't put it into the health insurance reform bill because it would have pushed the cost of the bill over \$1 trillion.

The last time we came this close to a Medicare payment melt-down was over the last Fourth of July weekend when former Senator Edward Kennedy left his hospital bed to cast the deciding vote in the Senate to restore Medicare payments.

That's quite a jump from Independence Day to April Fool's Day.

—WE (March 31, 2010) 

### Orthopods: Hospitals' Golden Goose

Orthopedic surgeons generate \$2.11 million in revenues per year for their hospitals. The average net revenue generated by 17 physician specialties for hospitals in 2008 was \$1.54 million, according to a recent survey conducted by Merritt Hawkins.

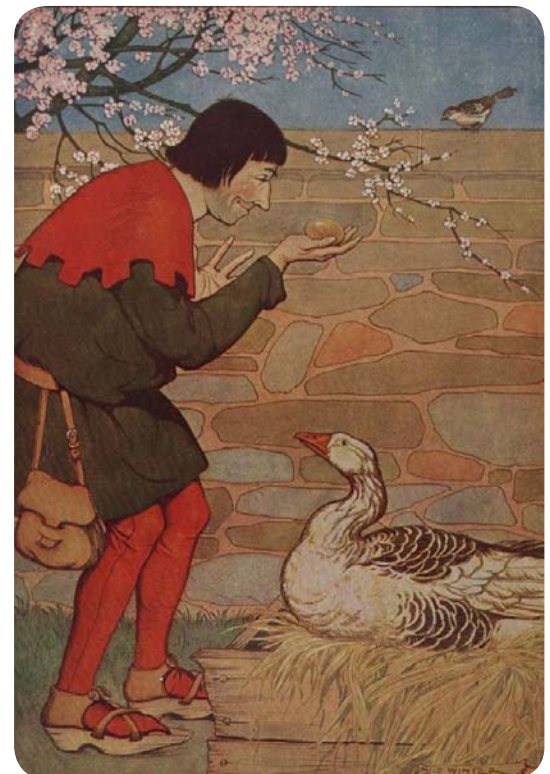
The overall revenue number was a 3% increase over 2007 and virtually the same as in 2002. The approximate \$1.5 million in revenues have proven to be a

benchmark number that hospitals use to assess the financial benefits that newly recruited physicians may bring to a hospital.

Income generated by orthopedic surgeons declined in 2010 relative to 2007, which, said the survey, could be a response to a recession-driven drop in elective surgeries such as joint replacements.

### Neurosurgeons Tops

Neurosurgeons topped the list of specialists. According to the survey, a single, full-time neurosurgeon generates an average of \$2,815,650 a year on behalf of his or her affiliated



The Goose That Laid the Golden Eggs / Milo Winter / Wikimedia Commons

## reimbursement

hospital. Other high revenue generating specialists include invasive cardiologists (\$2,240,366 a year), general surgeons (\$2,112,492 a year) and hematologists/oncologists (\$1,485,627 a year).

Revenue generated by other types of specialists increased over the time of the survey. One of the largest increases was seen in psychiatry. Income generated by psychiatrists increased from \$888,911 in 2007 to \$1,290,104 in 2010. Serious mental problems tend to be exacerbated by economic recessions and this may have caused more psychiatric hospital admissions, tests, etc. in the last 12 months than in previous years.

The survey said that income generated by pediatricians also increased, a possible result of the expansion of health insurance for children.

General surgeons generated more revenue in 2010 than in 2007, which could be attributable to the growing shortage in this specialty. General surgery, considered by many doctors to be the “primary care of surgery,” is declining in popularity among medical students because of income disparities with other surgical areas. A shortage of general surgeons may be increasing per-physician caseloads at hospitals and driving up per-physician generated revenue.

Merritt Hawkins mailed the Physician Inpatient/Outpatient Revenue Survey to 5,000 hospital chief financial officers (CFOs) nationwide in October 2009 and additional surveys were mailed in January 2010.

A total of 114 completed surveys were received. Merritt Hawkins noted that the volume of categorical responses varied by specialty. Not all returned survey forms included data for all specialties. In addition, the survey was self-selecting. Given these factors, average revenue generated per medical specialty cannot be expected to reflect the experiences of all hospitals.

—*WE* (April 1, 2010) 

## spine

## Device Helps Locate, Avoid Nerves

**R**emember the game “Operation?” Well, you could call this “Operation 5.0.” Researchers from Henry Ford Hospital in Detroit have found

that using an electronic device—mechanomyography (MMG)—is an accurate technique for locating and avoiding nerves during spinal procedures.

As indicated in the news release, MMG systems function by measuring the mechanical response of muscle following nerve stimulation, compared to traditional techniques that monitor the electrical response of muscle using electromyography (EMG). MMG has been widely used in laboratory settings, but this is the first time it has been applied as an intra-operative tool for locating nerves.

“We felt there was a safer and faster way to intra-operatively monitor the location of nerves and we wanted to test this theory by directly comparing MMG to EMG,” said Stephen Bartol, M.D., orthopedic spine surgeon at Henry Ford Hospital, in the news



U.S. Navy photo by Mass Communication Specialist 3rd Class Kristopher Wilson

## spine

release. “We found MMG to be extremely effective for detecting the presence of nerves during minimally invasive surgical procedures when the nerves could not be directly visualized.”

“Because conventional EMG systems monitor for subtle changes in muscle electrical activity, there is the potential for electrical interference. By using an MMG system, we are not worried about electrical interference since the response to electrical stimulation is measured through mechanical sensors instead,” added Dr. Bartol.

In an animal model, Dr. Bartol and his colleagues measured the EMG and MMG responses to electrical current. “We found that the MMG system had a faster response, indicating a higher sensitivity for detection of nerves at a lower threshold,” says Dr. Bartol.

In another study Dr. Bartol examined how the muscle response to electrical stimulus varies with the distance of the nerve from the source of the stimulus. “We need to know exactly how far away we are from the nerve. Working with different levels of current, we were able to establish a relationship between the current and distance, allowing the surgeon to determine precisely how far a nerve is from the stimulus probe,” he noted in the news release.

Dr. Bartol told *OTW*, “We were surprised to learn just how accurate the MMG system is in determining how close we are to a nerve. The information is not qualitative like

it is with EMG but rather quantitative, thus giving us a much higher level of accuracy.”

They found MMG detected the presence of a nerve on average 1.2 seconds earlier than EMG, using approximately half the amount of stimulating current. Since electrical resistance is highly variable, depending on the conducting tissue, EMG monitoring systems may utilize currents as high as 200 mA. The MMG system in this study has a maximum current output of 6 mA, nearly 35 times less than comparable EMG systems.

Regarding further work in this area, Dr. Bartol commented to *OTW*, “We are currently planning human trials to validate our results and we are looking at clinical applications such as lateral trans-psoas approaches and pedicle screw testing.”

—EH (April 1, 2010) 

## trauma

## Modeling the Perfect Bone

**T**he success of growing tissue-engineered bones for implantation is hinged on the accuracy of the design. Dr. Gordana Vunjak-Novakovic of Columbia University and her team have created a process to grow new bones in proper anatomical shape using stem cells, digital imaging, and a special kind of incubation device.



*In the Studio* by Marie Bashkirtseff / Wikimedia Commons

Here’s one instance where form and function play equal roles. Looks might not be everything, but the shape and proportion of a bone set for implantation is critical. Dr. Gordana Vunjak-Novakovic, a professor of biomedical engineering at Columbia University and her team have developed a system using stem cells that not only creates an accurate shape but also promises to grow larger bones than have been achieved before.

So far with this procedure Dr. Vunjak-Novakovic and her team have been able to grow two small jaw bones from scratch. The process begins by creating the digital image of what the new bone should look like. This image is then transferred onto a 3D scaffold that is made from bone material.

“We start from medical images of the patient. If a specific bone is seriously damaged, we take the contra-lateral side and make mirror images. The images were digitized and processed to obtain a 3D reconstruction of the bone to make.” She says these digitized

## trauma

images then become the basis for the creation of both a scaffold that the bone will grow around and the soft inner chamber of the bioreactor, the unit which will house the growing bone.


“The scaffold and chamber exactly match, like a positive and negative, so that the scaffold is fully enclosed by the chamber, and the culture medium is directed to perfuse through the scaffold and not around it.”

“The biggest challenge was to design the bioreactor so that you can have controlled perfusion of culture medium through anatomically complex grafts, which is the necessary condition for maintaining normal cell viability and function.” She says these clinically sized bones are centimeters in size (or more), in contrast to simple diffusion which can only support bone tissues that are a fraction of a millimeter thick.

The bioreactor’s conditions so perfectly match the internal environment, thanks to a constant flow of oxygen, growth hormones, sugar and nutrients that the stem cells are able to grow just as they would within the body.

“In the study published in PNAS we used human mesenchymal stem cells derived from bone marrow aspirates,” explains Vunjak-Novakovic. “We also use human mesenchymal stem cells derived from liposuctions (fat aspirates). In either case, the patient’s own cells or matching allogeneic cells (from another individual, or cell bank) can be used.”

The Columbia team is now in the process of working to add connections to the vascular supply of the host and the creation of complex tissues, like bone with cartilage. And Vunjak-Novakovic sees particular promise in the reconstruction of head and face tissues and along with other bones that require great precision.

—JR (March 31, 2010) 

### Special Tissue Sends Cell Growth to New Heights

The use of the extracellular matrix (ECM), harvested from a pig’s bladder has become a trusted method of encouraging healing in wounds, but the special biological scaffold could hold even better possibilities for the orthopedic community.

What if there was a magic powder that when sprinkled on a torn ligament could springboard and rebuild the rupture? Or what if such a powder could be used to regrow a limb? Sound too good to be true? Well it’s not that far from reality. The magic powder is actually extracellular matrix (ECM) a tissue extract that is already in use for wound and ulcer repair. Thanks to researchers with the McGowan Institute for Regenerative Medicine, the prospect of advanced orthopedic applications is much closer to reality.

Dr. Stephen Badylak, Deputy Director of the McGowan Institute for Regenerative Medicine at the University of Pittsburg and Director of the Center for Pre-Clinical Tissue Engineering at the Institute is quick to point out what ECM is *not*. “ECM does not create regeneration,” says Badylak.



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## trauma



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“It’s a facilitator, it changes the patient’s response and improves that response, assisting in the process of cell growth and healing.”

So ECM can be thought of as a biological catapult of sorts that sets off signals in stem cells, encouraging their specialized growth. ECM is actually a supporting scaffold that is secreted by cells. Harvested from the bladder of a pig, the special tissue is composed of a collection of protein fibers, including collagen, elastin, fibrillin, fibronectin and laminin, along with proteoglycans with their attached polysaccharide molecules. Processing begins by spinning the bladder cells and

subsequently drying and compressing them to create a powder. This powder can then be applied to a wound and the healing process is set into motion. Stem cells throughout the body quickly detect the powder because of its open matrix and are drawn to the site. The ECM signals the stem cells to grow specifically to fit whatever part of the body the powder is placed on. “With a biologic mesh like ECM, the cells that respond to it will actually turn into those of that location.”

“We’ve been working with this for 20 years now,” says Badylak. “ECM is categorized as a surgical mesh, has been FDA approved and is really

nature’s biologics scaffold. If prepared properly we could never do any better. When used properly ECM can change a patient’s wound healing response from inflammation and scarring to repair. It is constructive remodeling, we are changing the patient’s own response, the patient’s own stem cells do the work of re-growth.” Badylak adds that this technology can be very useful for treatment of Achilles tendon injuries and collateral ligament repair and is currently being testing by the U.S. military for the re-growth of lost fingers.

—JR (March 31, 2010) 

## The Picture of Success: Dr. Kenneth DeHaven

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



He hasn't done a history and physical on Big Ben, but he would if asked. The distinguished Dr. Kenneth DeHaven, a pioneer in the field of arthroscopy, is also trained in the mysteries of clocks and runs his own repair business. More on that later.

Born in small town Ohio, Dr. DeHaven, now part time at the University of Rochester Medical Center, grew up during the Great Depression. "My mom taught English and my dad taught math and physics and was the principal of the local high school. The school closed and we had to move in order for my parents to find new work. Each of the three kids had to do their part as well, with the family mantra being that you absolutely must work hard. When I was nine we lost my older brother to leukemia. That tragedy left a strong imprint on our lives."

With compassion as his compass, Ken DeHaven found his way to medicine.

"In part because of my brother's illness I decided to become a doctor early in my life—while in junior high school. The driving force was that I would be in a position to help people."

Although he attended Dartmouth, Ken DeHaven still needed a dictionary to look up a certain term. "I played football, basketball and ran track in high school... I also played football throughout college. I knew no matter what else happened that I was good at sports. I had academic problems initially because I had to take courses that I was not prepared for. When my advisor said I had to take calculus, I replied, 'Is that math?'"

His new sport? "Catch up." Dr. DeHaven: "I was unsure about being admitted to medical school and decided that plan B was to give the NFL a try, and to hope eventually go to medical school. I plowed through courses off season and got up to speed. Dartmouth Medical School was a two-year program and when it ended I headed to Northwestern in Chicago."

Then he pulled out a broad brush. "I felt that surgeons were jerks, and thus steered myself in other directions. The only exposure I had to orthopedics was a brief elective rotation in my fourth year (and among my fellow rugby players who were headed for orthopedics). I left medical school

considering either internal medicine or pediatrics."

Finding mentors who were comfortable in the scrum—of rugby and orthopedics—would begin to shift Dr. DeHaven's thinking. "I started an internship at Cleveland Clinic in 1965 and met Dr. John Bergfeld, also a rugby player. Another rugby fan was an orthopedic attending, Dr. McCollister Evarts. 'Mac' was a critical influence, and I started rethinking my direction after attending the anatomy classes he taught. Also important was Dr. Rupert Turnbull, a colorectal surgeon who was astoundingly talented. Puzzled that I had selected medicine, he said, 'You have an aptitude for surgery that I only see

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once every 10 years.’ The result? Cleveland Clinic added me to the first year surgery resident group for the next year.”

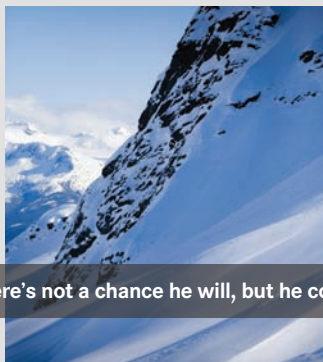
“Then came a two-year stint in the Navy. I went to sea and served as the only doctor on a ship of 1,000. Much of the year was spent in dry dock, but we had to maintain on board sick bay because sailors were working on the ship.”

Following this Dr. DeHaven got a taste of battlefield orthopedics. “I went to Camp Pendleton (during Vietnam) for a year of orthopedic work. That was an intense experience that cemented my desire to pursue orthopedics. When I returned to Cleveland Clinic as an orthopedic resident my compass was set. Shortly thereafter I became aware of the field of sports medicine, and was thrilled to see I could possibly combine my two loves, sports and orthopedics. I graduated in 1972.”

A big leader in small incisions would then change everything. “I headed to Toronto to pursue something that had peaked my interest—arthroscopy. There I saw that the esteemed Dr. Robert Jackson was having success, and was doing two or three minor things that we in Cleveland were not doing with arthroscopy. It was still tough, however. Dr. Jackson would move his head and try not to move his hand while I looked through the scope. And there were times when we couldn’t see anything.”

Standing astride sports medicine and arthroscopy, Dr. DeHaven wanted to have both feet firmly planted. “Along with Dr. Jackson, I was one

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of the first people to be engaged in both fields from the beginning. Part of my training was three months in Atlanta in 1970 with Dr. Fred Allman, the first orthopedist to dedicate his entire practice to sports medicine. By developing credentials in both fields I was able to show the established surgeons in sports medicine how much it could help them to use this new thing...the arthroscope.”

A self described “young pup” just out of residency, Dr. DeHaven had some nerve. “I told the senior surgeons that when they opened up the knee and didn’t find what they expected, that they had the experience to get the right answer on the spot. I said, ‘The arthroscope gives me the same opportunity to be correct about diagnoses even though I don’t have all

of your experience.’ It was not an easy sell with the older surgeons.”

In 1975 he took his boldness and talents to Rochester. “Several of us, including Mac Evarts, left for the University of Rochester. Dr. Evarts, the new Chair, laid the groundwork for me to become the doctor for school’s athletic teams...I would be a one-man band for the next 15 years.”

Lonely no more, in the late 1980s the new chair asked Dr. DeHaven to draft a proposal for growing the sports medicine program. “In 1989 we hired a second faculty member and continued to work closely with residents. Since 1989 things have changed dramatically and we now have six fellowship trained orthopedists, and four non-operative sports medicine specialists, including me.”

Meaning that Dr. DeHaven can be more selective about how he spends his time. “From 2004 to 2008 I was the Senior Associate Dean for Clinical Affairs and Director of the faculty practice group. I stopped operating in 2005. I was surprised to find that a major source of chronic stress was gone. I always felt that the OR days were less stressful than non-OR days, but there was dramatically less stress immediately—stopping surgery was the only thing that had changed. The stress was so suppressed that it ‘never saw the light of day.’”

Reflecting on a significant part of his life’s work, Dr. DeHaven says, “I have dedicated much of my time to learning how to repair menisci, as opposed to removing them. The old thinking was that even if you couldn’t find anything

wrong, just remove the meniscus because there was probably a tear in the back that you couldn't see. The red flag was that many people got arthritis after the removal."

"In 1976 I had a case involving the best heavyweight in the Olympic wrestling trials. His lateral meniscus was torn into two separate pieces. The medial meniscus had a peripheral tear, but the medial ligament complex was normal. I could always remove the meniscus but this was my only chance to save it, so I sutured it back to the capsule. It worked so well that I began doing the procedure somewhat regularly. As I traveled around the world the next few years I never found anyone else doing it. While it is now an established treatment, it remains a hard sell, and I am disappointed that repairable menisci are still being removed. I think people are afraid of failure; they also know that they can't do repairs as quickly as removals."

Moving forward, says Dr. DeHaven, we will see more of a temporary structure that is used in permanent soft tissue healing...the scaffold. "The future is in tissue engineering. Permanent synthetic materials don't last in the joints as menisci or ligaments, so what seems best is to put an absorbable scaffold into the defect of the natural tissue, or even to replace a missing ligament. This attracts cells that once in the scaffold, generate tissue that is similar to the original. After six months to a year, the scaffold is gone and you are left with the patient's new tissue. We are on the first generation scaffolds...they are only bound to improve."

Dr. DeHaven has a history of being a leader in both thought and action. Elected captain of every athletic team on which he ever played, he later was elected president of every society he joined. "I have had the pleasure and honor of guiding the activities of the Herodicus Society, the Arthroscopy Association of North America, the American Orthopedic Society for Sports Medicine, the International Society of the Knee (a parent of ISAKOS), and the American Academy of Orthopaedic Surgeons. These experiences have brought hours of learning and lifelong friendship."

But his best friend is his wife of 41 years. "Jean is an artist, skilled in portraiture and figurative oil paintings. Our daughter Kathleen lives in Colorado, and has just stepped down from being a clinical trials administrator for a pharmaceutical firm. Golf, skiing, and travel are some of my hobbies, along with snowshoeing and 'non-professional' reading."

Or, perhaps, clock manuals. "We had five old pendulum clocks in the family. When they stopped working we found a man who quickly got the clocks running. I peppered him with questions, and ended up spending a lot of time at his shop watching him take clocks apart (a four-year, part time apprenticeship). Then, after nine months of clock school, in June 2009 I launched 'Ken's Clocks', a mechanical clock repair service."

"Like patients, no two clocks are exactly alike. Also, there are similarities to orthopedics: you must

take a history of the problem, followed by a diagnosis, cleaning, fixing the problem, and putting the clock back together. (A surgeon's manual dexterity also comes in handy.) It is amazing that these clocks, some of which are over 200 years old, can run again and keep good time. I love the history involved, and enjoy seeing how much pleasure the owners derive from learning the background of their clocks."

Dr. Ken DeHaven...still ticking.



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