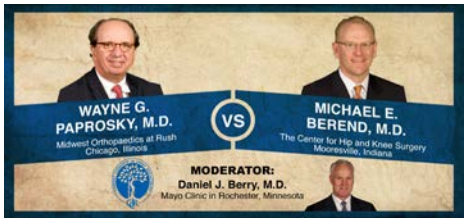
VOLUME 9, ISSUE 7 | MARCH 5, 2013

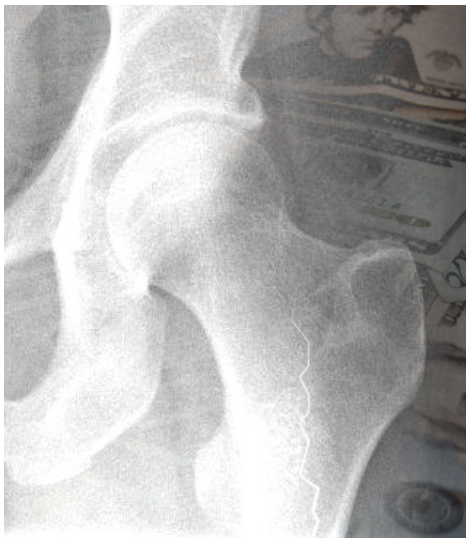
Orthopedics This Week

week in review

4 Drama and Fireworks at DePuy ASR Trial ♦ The DePuy ASR hip trial has reached the halfway point as plaintiff's lawyers rest their case. Now the defense takes its turn. DePuy has taken its lumps, but maintains it did nothing wrong. Read the evidence the jury has heard and what it might mean to the other 10,000 cases pending against DePuy.



8 Paprosky Takes on Berend Over Stem Modularity ♦ "I'm no fan of modularity, but dislocation is the number one cause of revisions. So that's the only reason I'm using it," states Wayne Paprosky. Mike Berend says, "One piece implants are appropriate for the vast majority of stem revisions. It's quicker and easier, and is proven out into the second decade."



12 New Study Shows How to Drive Savings in Hip Surgery. New Billion Dollar Knee Biggest Launch in History. And much more… ♦ Ken Egol, M.D. discusses his new study showing that matching the right implant to the right patient can both save money and obtain excellent outcomes. Rumor is Zimmer and DePuy each spent $1 billion on new knee designs making them the two biggest knee launches in history.

breaking news

14 FDA Recalls **DePuy Revision Knee** Product

Burtons are Back…With ISO Certification

Medtronic Gets First-Ever **Early Feasibility Study Approval**

New **Financial Disclosure Guidelines** from FDA

Sequestration to Cost Half Million Health Care Jobs

Vitamin D and Calcium Pills: **Not Enough Proof?**

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Three spine companies, GMED, NUVA and ATEC, are top gainers in the Power Rankings this week. Alphatec surprised Wall Street analysts with better-than-expected earnings and appears to be on track to outperform the rest of 2013. Les Cross, ATEC's CEO, pulled off a remarkably similar turnaround at DJO about 10 years ago. ATEC debuts at #6 on the Power Rankings this week.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Globus Medical	28.9%	13.19%	Globus beat estimates with 14% sales growth and $29 million in operating profit. And seems to be accelerating.
2	5	NuVasive	7.08	10.96	NuVasive added $80 million in new sales in 2012, up 15%. On expanded margins. Awe inspiring performance.
3	4	Stryker	23.68	2.40	Wraps up the Trauson deal in China and starts buying back $250 million in stock. Shareholders should be pleased.
4	6	Johnson & Johnson	25.58	3.52	The largest orthopedic company in the history of medicine, JNJ/DePuy now generates 56% of sales—OUS!
5	3	Zimmer	25.45	0.75	Can Zimmer's new Persona knee energize recon sales? It has the look of a major new knee replacement platform for Big Blue.
6	NR	Alphatec	(4.29)	10.00	We've been to the Les Cross rodeo before. Cost cuts plus acquisitions equal earnings turnaround. Déjà vu all over again at ATEC?
7	2	Exactech	8.64	(5.38)	Buyers seem to have cooled on EXAC. For now anyway. Outlook is for 7% sales growth this year.
8	8	Conmed	10.51	6.52	3% sales growth to end 2012—hurt by CNMD's patient care sales. More positively, earnings jumped 13%.
9	7	Medtronic	28.65	(3.06)	Medtronic spine is stabilized—that's the good news. Bad news—the young turks (GMED and NUVA) keep pressing.
10	10	Integra LifeSciences	13.73	(3.45)	IART undergoing an interesting re-org process right now. Can it deliver stronger sales growth in 2013? Maybe.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MAKO Surgical	MAKO	$12.75	$602	14.45%
2	Wright Medical	WMGI	$23.83	$946	14.40%
3	Globus Medical	GMED	$14.25	$1,299	13.19%
4	NuVasive	NUVA	$19.24	$847	10.96%
5	MiMedx Group	MDXG	$4.79	$416	10.37%
6	Alphatec Holdings	ATEC	$1.87	$170	10.00%
7	Conmed	CNMD	$31.20	$876	6.52%
8	Tornier N.V.	TRNX	$17.94	$749	3.70%
9	Johnson & Johnson	JNJ	$76.70	$214,401	3.52%
10	Stryker	SYK	$64.90	$24,695	2.40%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	$0.87	$37	-37.41%
2	RTI Biologics Inc	RTIX	$3.65	$204	-18.71%
3	TranS1	TSON	$2.22	$61	-12.94%
4	Smith & Nephew	SNN	$53.40	$9,667	-7.93%
5	TiGenix	TIG.BR	$1.13	$114	-7.12%
6	Exactech	EXAC	$18.28	$243	-5.38%
7	CryoLife	CRY	$6.13	$168	-4.96%
8	Integra LifeSciences	IART	$40.86	$1,144	-3.45%
9	Medtronic	MDT	$45.23	$45,744	-3.06%
10	ArthroCare	ARTC	$35.27	$989	-2.54%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$37.58	$730	12.40
2	Medtronic	MDT	$45.23	$45,744	12.56
3	Smith & Nephew	SNN	$53.40	$9,667	13.26
4	Zimmer Holdings	ZMH	$74.99	$12,700	14.10
5	Johnson & Johnson	JNJ	$76.70	$214,401	14.98

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$23.83	$946	216.64
2	NuVasive	NUVA	$19.24	$847	56.59
3	Symmetry Medical	SMA	$10.50	$386	31.82
4	ArthroCare	ARTC	$35.27	$989	23.05
5	CryoLife	CRY	$6.13	$168	20.43

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$37.58	$730	0.99
2	Globus Medical	GMED	$14.25	$1,299	1.23
3	Conmed	CNMD	$31.20	$876	1.32
4	RTI Biologics Inc	RTIX	$3.65	$204	1.35
5	Exactech	EXAC	$18.28	$243	1.36

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$23.83	$946	21.39
2	CryoLife	CRY	$6.13	$168	5.11
3	NuVasive	NUVA	$19.24	$847	4.61
4	Symmetry Medical	SMA	$10.50	$386	2.65
5	Johnson & Johnson	JNJ	$76.70	$214,401	2.36

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.87	$170	0.86
2	Symmetry Medical	SMA	$10.50	$386	0.94
3	Exactech	EXAC	$18.28	$243	1.08
4	Bacterin Intl Holdings	BONE	$0.87	$37	1.09
5	Conmed	CNMD	$31.20	$876	1.14

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.13	$114	99.30
2	MiMedx Group	MDXG	$4.79	$416	53.54
3	MAKO Surgical	MAKO	$12.75	$602	5.86
4	Globus Medical	GMED	$14.25	$1,299	3.36
5	Johnson & Johnson	JNJ	$76.70	$214,401	3.19

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

Drama and Fireworks at DePuy ASR Trial

By Walter Eisner

Thomas Schmalzried, M.D. the lead designer of DePuy Orthopaedic, Inc.'s ASR metal-on-metal hip, "was almost shaking with rage," over comments made by Birmingham hip inventor Derek McMinn at a British Hip Society meeting. McMinn "implied that the testing of ASR was both incompetent and biased."

Derek McMinn, M.D., FRCS

Tom Schmalzried

That's according to an email written by DePuy engineer Graham Isaac in 2008 in one of myriad documents introduced by attorneys for Loren Kransky, the plaintiff in the DePuy ASR hip trial in Los Angeles.

The trial began on January 25, 2013 with opening arguments and the presentation of the evidence by Kranky's attorneys. The plaintiff has rested and DePuy began presenting its defense on February 20, 2013.

Morguefile and mconnors/RRY Publications LLC

Jurors were shown videotaped depositions of current and former DePuy employees and consultants telling what they knew about the safety and design of the ASR and when they knew it. Kranksy alleges that DePuy knew about safety issues long before making them public and recalling the product in 2010.

The defense argues the device did not have a design flaw, the company did not withdraw the device from the market for safety reasons and that Kransky was so sick from chronic ailments that the failure of his implant was due to his medical condition and improper implantation of the hips by surgeons.

Kransky's legal strategy will likely be played out in the other 10,000 cases pending against DePuy—IF they go to trial. Think of this case as determining a "market value" of each side's legal arguments before serious settlement discussions take place. DePuy has reportedly already offered $200,000 per case. That was rejected by the patients' lawyers. If DePuy allows this case to advance to a jury's decision, and they lose, that settlement offer is likely to go much higher. If DePuy appears to shake Kransky's case, settlement dollars will likely not move much from the $200,000, or $2 billion total.

Patients are not the only ones looking for a piece of DePuy's hide. Payers are getting into the act as Johnson & Johnson (DePuy's parent) disclosed in a February 22 regulatory filing that the Justice Department has requested documents

relating to whether the company may have submitted false claims to federal health care programs over the device.

Even members of the British Parliament have gotten into the act. *Bloomberg News* reported on February 22, 2013 that if testimony provided by DePuy engineer Magnus Flett is true that the company knew the device had a higher than average failure rate before being recalled in 2010 and didn't tell anyone, then there should be a criminal inquiry.

The public fallout has not been pretty for DePuy either as a February 10, 2013, *New York Times* Editorial stated:

[T]here is evidence that [DePuy] was aware of a serious problem with one of its models yet failed to alert patients or doctors and continued to market it aggressively. Court documents now show that DePuy buried the bad news… early as 2008, DePuy executives were told by a number of surgeons, including its own consultants, that the device appeared flawed. That was never disclosed to doctors who were putting the device into patients.

It ain't over till it's over and DePuy has yet to present its defense to the jury. For now, based on the daily reporting of *Bloomberg*, here are some excerpts from the first half of the trial.

Design and Safety Issues

A "higher than expected" failure rate prompted DePuy to recall 93,000 of the devices in the U.S., Isaac, the previously mentioned DePuy engineer who led the company's hip-development program, told the jury as a witness for Kransky.

Isaac told jurors that the device was pulled because of safety concerns.

Kransky's lawyer asked Isaac if the failure rate was a safety issue. Isaac said "yes" and acknowledged that DePuy did not disclose to patients that all hip designs generate ions. Under cross-examination by DePuy's lawyers, Isaac admitted that the company did more testing on the hip than any other product the company put on the market.

Earlier in the trial, Andrew Ekdahl, DePuy's current president and senior executive in charge of marketing the device at the time, testified that the company recalled the device because it "did not meet the clinical needs for the product," and not because they were unsafe.

James Anderson, a DePuy bioengineer testified that he spent three years studying a redesign of metal-on-metal hip devices because of their failure rate. He said he was disappointment that

the work dubbed Project Alpha ended in 2008 with no change to the device.

Earlier in the trial, Kransky's attorneys referred to a May 2, 2008, email in which Paul Berman, DePuy's head of U.S. marketing, said, "We will ultimately need a cup redesign but the short term action is to manage perceptions."

Randall Kilburn, Berman's boss, testified that he spoke to Berman after Berman sent him an email on March 14, 2010, expressing concern over the safety of the device. Berman said that he had "an obligation as an employee of J&J and DePuy to make it known when I do not feel comfortable." He also referred to four earlier emails he sent suggesting a possible recall.

Killburn said he made sure all complaints that Berman knew about were investigated internally and handed Berman's email to David Floyd, DePuy's president at the time.

Killburn was asked about March 2008 emails from Isaac discussing public ridicule by British orthopedic surgeon, Derek McMinn, of the ASR and its designers. McMinn developed the Birmingham Hip Replacement system in 1997.

Isaac wrote that McMinn gave a speech to the British Hip Society and attacked competitors, while "his main vitriol was reserved for ASR." This is where Isaac made the reference to Schmalzried's anger.

Berman wrote to Schmalzried and Thomas Vail, M.D. that is was, "Good to know the Society generally didn't give credence to what McMinn was saying. I suppose it is somewhat like Brittany Spears…nobody really respects her, but there is a lot of morbid curiosity…I am confident that McMinn will continue to dig his own grave here in the U.S."

Berman continued that he received 10 calls from surgeons after McMinn's "little performance." "We now have some surgeons asking what is wrong with ASR." He suggested a position statement to Schmalzried, but the surgeon wrote that the ASR design board preferred to avoid publicly rebutting McMinn.

Schmalzried also testified. Kransky's attorney asked him about an internal DePuy study in 2011 showing 35.8% of the devices failed within 4.57 years, requiring revisions. Schmalzried said of 66 ASR hips he implanted, 11 required revisions.

"If you knew it was going to fail and have to be revised 20% of the time within four years, would you as a designer

have recommended this product to be put on the market?" asked Kransky's attorney.

In what must surely have an impact on the jury, Schmalzried said, "I would not have put the product on the market."

Kranksy's Condition

Kranksy, who suffers from medical problems including diabetes, cancer, kidney disease, heart disease and vascular disease, claims that elevated ion levels were responsible for his failed hip. DePuy's lawyer showed jurors medical records from Tom Trotsky, M.D., Kransky's personal physician. The records show that when Kransky first complained of pain in his hips in 2008, Trotsky diagnosed it as bursitis.

Peter Wendt, M.D., the Montana surgeon who implanted Kransky's first hip in 2007, testified he stopped using the device eight months before the company recalled it because he was warned about problems with the implant by a DePuy sales rep named Dan Harrington.

Harrington, he said, told him "there are some problems with this, we are going to pull it. You really shouldn't be using it anymore."

He said DePuy never told him about patients who experienced debris from the cobalt and chromium devices and didn't know that DePuy studied a redesign to try to prevent the problems. Had he known either, he said, he would have stopped using the device.

Jurors also heard testimony from Christopher Hunt, another DePuy bioengineer, about an ASR surgeon design team meeting in September 2005.

The jury was shown his draft minutes of the meeting, which reported that the group discussed adding a toxicologist to "address the perceived risk of cancer due to metal ion release."

"Although it was agreed that would be a useful study to undertake, concern was raised that the information should be strictly controlled in the event of it showing a negative answer," the minutes said. No study was ever done and a toxicologist was never added.

Michael Rhee, a DePuy hip marketing manager, was asked about 2008 emails by San Francisco surgeon, Thomas Sampson, M.D., to Vail. Sampson wrote that he saw an ad on the cover of *Orthopedics Today* claiming 99.2% survivorship for ASR patients.

"It was difficult to read the ad considering my failure rate is in double digits... and other orthos I have talked with stopped using it all together because of pain and fibrous ingrowth." Sampson added "I don't believe the failures are due solely to technique."

Vail forwarded the e-mail to Schmalzried, who responded, "Using 'surgical technique' to explain failures to a surgeon is an uphill fight."

Jurors also saw an email chain involving Tom Fehring, M.D., a North Carolina surgeon who had advocated studying ASR patients. Berman sent marketing materials to Fehring about another J&J hip, the Pinnacle.

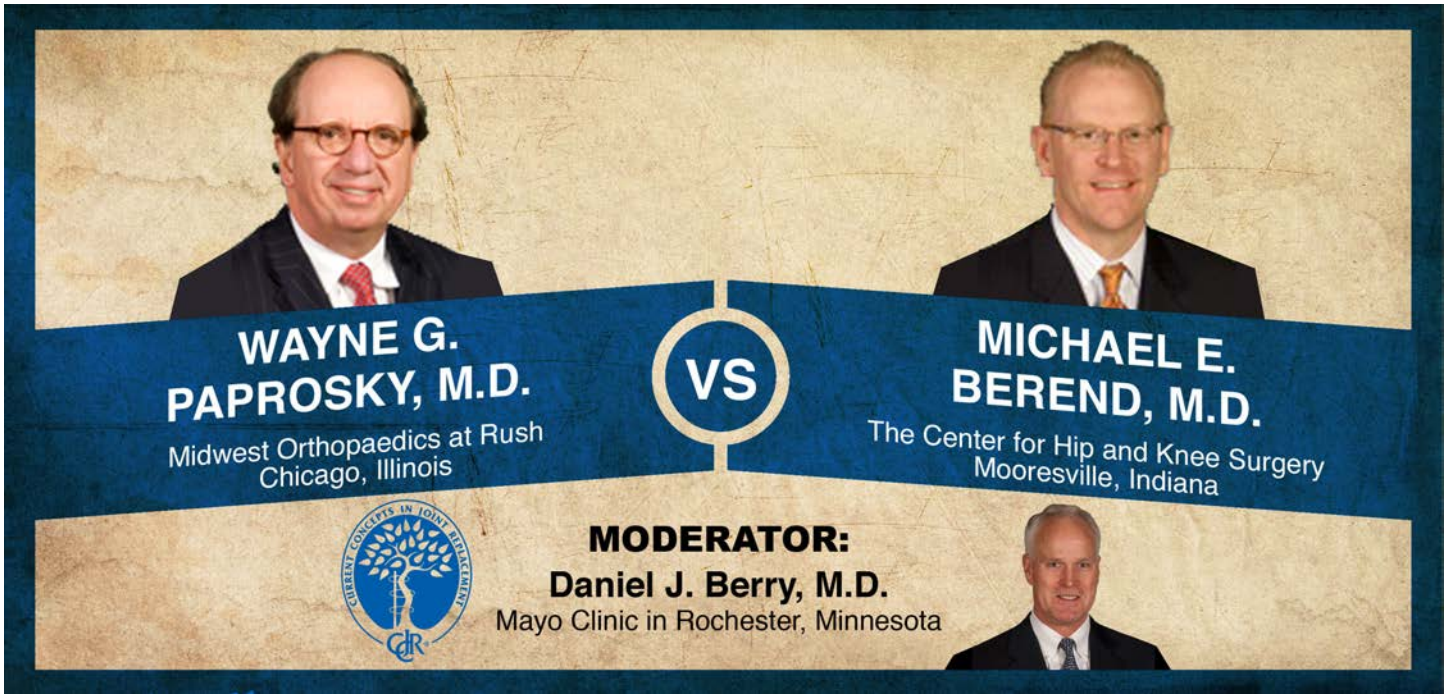
Berman emailed Rhee in January 2009 stating he had "sent all [Pinnacle] design surgeons the new brochure with a letter telling them we plan to continue promoting it. Should make them back off ASR a bit." Rhee replied, "Why r u getting in my s--- ?" Berman replied, "Keeping Fehring from recalling your product. You're welcome."

The videotaped testimony of depositions from the witnesses is likely to be repeated in the consolidated lawsuits in federal court if no settlement is reached.

DePuy now has the jury's attention and is making their defense. We'll report on that when the defense rests. A settlement may still be reached before the jury heads to the jury room. ♦

Paprosky Takes on Berend Over Stem Modularity

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



Current Concepts in Joint Replacement/RRY Photo Creation

"I'm no fan of modularity, but dislocation is the number one cause of revisions. So that's the only reason I'm using it," states Wayne Paprosky. Mike Berend argues against the proposition saying: "One piece implants are appropriate for the vast majority of stem revisions. It's significantly quicker and easier, involves fewer trays, and is proven out into the second decade."

This week's Orthopaedic Crossfire® debate is "Femoral Stem Modularity in Revision THA [total hip arthroplasty]: The Solution for all Seasons." For the proposition was Wayne G. Paprosky, M.D. from Midwest Orthopaedics at Rush in Chicago. Against the proposition was Michael E. Berend, M.D. of The Center for Hip and Knee Surgery in Mooresville, India¬na. Moderating was Daniel J. Berry, M.D. from Mayo Clinic in Rochester, Minnesota.

Dr. Paprosky: "Modularity is unnecessary in Type 1 and Type 2 femurs. The metaphyseal anatomy is relatively unaltered, monoblock stems are easily rotated into correct version, and in these cases there is no modularity advantage whatsoever. This is my perspective after having done revisions for 25 years."

"You're able to turn the implant in whatever version position you want. Even if you have a little bit of varus remodeling, you still are able to do this provided you keep the stem short (under eight inches). Breakage does occur in monoblock stems. The big concern with modular stems is breakage; there are reports of fractures of monoblock stems."

"In a study we did several years ago there were 18 stem fractures in 17 patients; the majority of the cases were in smaller diameter stems, but they can occur in larger diameter stems. When it does, it usually occurs when there's no proximal support. When we start to get into trouble is when the femurs get more deformed."

"About 10 years ago we found that porous coated stems didn't work in these types of cases, so we began advocating the use of tapered stems since we're able to get fixation over two centimeters when there was less than four centimeters of isthmus available. We got great rotational stability, and we were able to independently adjust the anteversion. Monoblock fluted tapered stems have shown a higher dislocation

rate…and there has been some subsidence early on. But I think as your learning curve improves subsidence will probably go down."

"As we get further down the femur and there's more damage, the femur starts to deform. The varus remodeling gets more severe; we go with longer stems and have to use curved stems. It's near impossible to adjust the anteversion in a curved stem. So what we find in Type 3 femoral defects is the more bone damage, the greater the torsional remodeling, the greater the difficulty with anterior mismatch. And without proximal landmarks it's difficult to adjust the height. With torsional remodeling you really don't have a good sense of what the anteversion of your stem should be."

"So the absolute indications for modularity are: when you have severe proximal torsional remodeling, altered anatomy of the lesser trochanter, severe proximal bone loss, and the lesser trochanteric landmark is gone (to determine version). And in cases with severe bone loss where curved stems are required, you can't adjust the anteversion."

"Anteversion optimization: why not use modularity…because there are reports of breakage and corrosion. The newer designs are stronger and there's no reported breakage yet. From 2000-2003 we looked at all patients undergoing femoral revision at Central DuPage Hospital using two different devices (modular devices with tapered stems). We had a minimum of eight year follow up, there was no proximal femoral support, and we had only one loosening and no dislocations."

"And there was the 2003 study by Louis Kwong that was similar to ours and was very successful. They had 143 patients, a 97% rate of component survival, and average subsidence of 2.1 millimeters."

"The dislocation rate that we've found overall is only 3% in modular stems; the dislocation rate with monoblock, including my series, was 8-14%. So dislocation rates can be reduced in femoral revision by using large diameter heads in conjunction with adjusting anteversion."

Dr. Berend: "I'd like to bring a Midwestern, simple country surgeon approach. We haven't gotten on the bandwagon for modular implants; we've used the same implant for all comers. Looking at a case of a Type 2 femur…a cemented implant removed with a femoral osteotomy where there was a fracture of the stem. I'm sure design improvements have helped reduce this; it's interesting that the final solution for this problem was to go with a non modular implant.

Perhaps we can skip the interval step of modularity and go straight to one piece implants."

"We have lots of things to choose from: fully coated, proximally coated (which is what we've most often used), one piece implants, and modular stems. It's a difficult inventory problem…how do you know when you're going to need it?"

"Wayne's work from 1999 had 170 hips and pretty good follow-up with excellent stem survivorship (95%). Six stems were revised to larger stems, and they observed stress shielding in larger bone diameters, so that's one case where we'd agree on modularity."

"Look at two quotes from this study: 'On the basis of the radiographic and clinical results at a mean follow-up of 14.2 years, we recommend the use of extensively coated femoral stems in revision hip arthroplasty…' and 'Proximally coated implants are not well suited to achieving these goals…'"

"We asked, 'Does defect determine the stem survivorship?' We have used the same stem since 1987; one of the designers reported 99.2% clinical survivorship after 14 years. It is coated only on the proximal one third, and is available in many lengths. The critiques are that it's not fully coated, it's non modular, and it doesn't achieve torsional stability… is a bowed implant after you reach the 220mm length. We've been able to use that in the vast majority of revisions."

"Our series is 461 hips with follow-up out to 21 years; overall survivorship for all revisions is 96.3%. If you look at femoral aseptic loosening it's 99%. There were no stem fractures in this cohort. Interestingly, stem survivorship on the femoral side was not correlated with femoral deformity, but overall complications of all reasons were correlated with deformity."

"From my work using the Paprosky Classification System: The majority of aseptic femoral re-revisions were Type 3 and higher; there were five femoral revisions (two for instability, one for periprosthetic fracture, one was not placed inside the femur at the index operation, and one patient returned for a follow-up at one year with a loose femoral component (and wearing an orange jumpsuit)."

"If you look at the overall complication rate, the dislocation was 6.7%, and a host of other problems that you see in all revision surgery about the hip. I do think that large head femoral diameters—which were not used in the majority of these cases—can reduce the dislocation rate."

"There's been critique of using a one piece proximally coated stem with an extended trochanteric osteotomy. We looked at our early experience in 45 hips; we had 98% union rate at the trochanter, 100% stem survival, excellent ingrowth of the implant. And, as Wayne pointed out, there was an 18% intraoperative fracture rate. In shorter femurs where there is a mismatch between the bow of the femoral implant and the bow of the femur, these folks may benefit from a modular implant."

"We're seeing increasing complexity, and the types of cases where you only have the distal femur I think a modular fluted stem is an excellent solution. So the goal here is torsional implant stability, and I think one piece implants are appropriate for the vast majority of stem revisions. It's significantly quicker and easier, involves fewer trays, and is proven out into the second decade. I would like to see long term data on modular stems, and I would encourage all of us to use large heads in these populations."

Moderator Berry: "Wayne, rebuttal?"

Dr. Paprosky: "There's probably cross-over of almost 90%. I looked at our data and the dislocation rate is higher as the defect gets more severe and there's more proximal remodeling. And without the landmarks—for someone who's not doing them all the time—you'd think that might be a reason, but for someone like me who's been doing this for 25 years, there is a difference and I'm able to fine tune the anteversion. When you don't have the proximal anatomy it's easier to think of doing two things separately…putting the stem in first and getting it solidly fixed, and then fine tuning the anteversion. But we're talking maybe 10% of cases. I'm not a fan of modularity because you have to put them together, there's a potential for particulates, etc. But dislocation is the number one cause of revision of revisions. So that's the only reason I'm using it."

Moderator Berry: "So you like the advantages of modularity, but don't like the biomechanical problems of modularity?"

Dr. Paprosky: "Absolutely."

Moderator Berry: "Mike?"

Dr. Berend: "Sometimes it's hard to decide offset, leg length, stability in these disaster type cases. We've chosen to do that with a one piece stem; we feel like we can adjust the anteversion even easier if the proximal femur is missing."

Moderator Berry: "Mike, is the reason you can deal with the anteversion more easily with a specific system you used because it's a calcar replacing one so you can rotate it a bit more easily than a monoblock?"

Dr. Berend: "Excellent point. When the bone is absent down to the level of the lesser trochanter you can pick your anteversion before you impact the final stem."

Moderator Berry: "Wayne, you said that you could handle 80% of revisions with a monoblock stem, but what do you actually do now?"

Dr. Paprosky: "Unfortunately I'm at the bottom of this sewer drain…so I'd love to be able to say that it is 85% because that's generally the breakdown in the literature of Type 1s and Type 2s versus 3s. But my practice is probably closer to two-thirds 3Bs and 4s. And in the 3As if I can get away with it I will use monoblock stems."

Moderator Berry: "Mike, you've made the argument for monoblock, but in a practice where you're seeing tough cases, how often do you actually go to modularity?"

Dr. Berend: "It's less than 2%; I think any time you're doing a femoral osteotomy transversely we'll use it for the splined element distally. Other than that, the case I showed is the only one we've done in 20 years."

Moderator Berry: "If you're going to make an argument about why you'd want to avoid it, you might say 'cost.' Also, there is the concern about how the modular junctions will hold up long term. Wayne, what do we know about how the modern tapers are holding up?"

Dr. Paprosky: "In every case where I use a modular stem there is no support. So when you go to some meetings [and] hear, 'Well, put a strut graft on.' That's kind of like kissing your sister. You do it at Christmas because your mother says you should. There's no benefit. I have some links out now—12 years—that have not broken. As for fretting and corrosion, these are low activity patients and I think because our dislocation rate is zero in these so far, it's a huge benefit. I wasn't able to achieve that with monoblock stems in severe cases."

Moderator Berry: "Thank you, gentlemen." ♦

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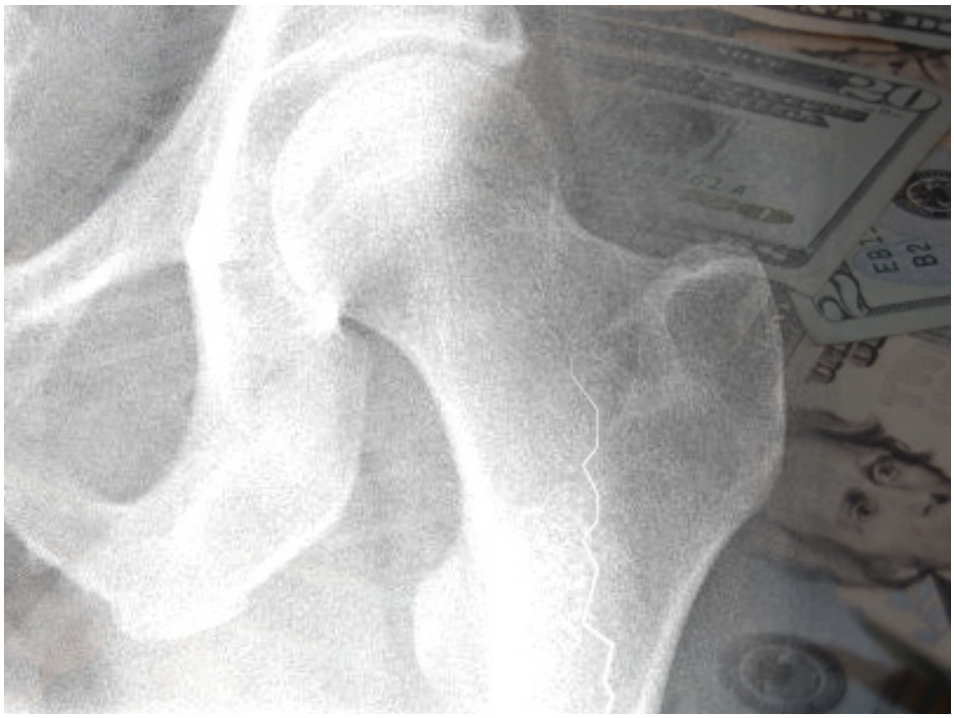
New Study Shows How to Drive Savings in Hip Surgery. New Billion Dollar Knee Biggest Launch in History. And much more…

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

New Study Shows How to Drive Savings in Hip Surgery. While the cost of orthopedic trauma implants has risen over the years, the fractures they are used to treat remain the same. Although some cost increases with improved technology is to be expected, indiscriminant use of costly implants when not needed should be examined. The orthopedic traumatologists are making progress in this arena that could benefit all their orthopedic colleagues…how to cut costs and maintain quality, that is. Ken Egol, M.D., is Professor and vice chair of orthopaedic surgery at the NYU Hospital for Joint Diseases at Langone Medical Center. He tells *OTW*, "We're looking at cost savings and quality measures, specifically, looking at ways to reduce hospital cost on the surgery side while still maintaining quality. In fracture care, we have looked at standardizing the type of fracture implants for the treatment of one type of hip fracture. Using the evidence-based literature as a guide to determine which implant to use for each specific fracture pattern, we examined 220 cases and found that it was possible to have significantly lower costs per operation without a reduction in quality. In fact, we had a lower readmission rate and lower complication rates. These hip implants can range from $800 to $4,000. What we did was standardize the way of fixing these fractures; while all fractures received the appropriate implant, the less complex fractures received less complex and thus less expensive plates and the more complex fractures were treated with the required more expensive nails. We determined that just by implementing these measures we were able to save an average of $700 per hip fracture surgery."



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"While this should be a 'no-brainer,' the fact is that some doctors may have an implant 'bias' based on their training or potential conflicts of interest. This pilot study has already been submitted for publication. The next step is to look at other fractures types and see if a similar algorithm can be applied."

Knee Redesign Prompts Biggest Product Launch in History. While we may never reach 100% patient satisfaction, a recognized knee and hip surgeon says that the release of the two newest knee platforms may hopefully get us to about 90% patient satisfaction. He tells *OTW*, "Only about 85% of people who undergo total knee surgery say that they are satisfied postoperatively; perhaps this is because conventional knee components are too mechanical and lack options to match the components to the specific size and shape of each patient's anatomy. With the release of the Zimmer Persona Knee and the DePuy Attune, however, we should be able to close that gap and more accurately match the components to the patient's anatomy…this will hopefully get us above the 90% satisfaction rate. Now that we know how the patella tracks and have more specifics on the

knee kinematics, things are progressing with the design of these new knee systems. Soft tissue balancing is easier, and there are more sizing options so we can customize these for patients. In older knee platforms there were five or six size options and only 2/3 mm incremental polyethylene thickness options; the new ones have 10 or 12 options on the on tibia and femur—and 1 mm incremental poly spacers."

"These have probably been the two biggest launches in history as far as a complete redesign of a knee line; I've heard that each company spent approximately a billion dollars each to develop these systems. Time will give us more information, of course. The Persona has been out six months, while the Attune was just released to research centers (and is not yet commercially available). Although this will likely help us narrow the gap, I do not think that we will get to the same patient satisfaction rate as we have had in the hip (about 95%)."

Spinal Deformity: Follow the Data To obtain the most relevant, accurate data, says a veteran spine surgeon, we need to look at the right questions and have massive numbers of patients. Tom Errico, M.D. is chief of the Division of Spine Service at NYU Langone Medical Center and Hospital for Joint Diseases. He shares his take on spinal deformity research: "We have done a lot of papers looking at a large national inpatient sample database and I am starting to realize that most researchers are satisfied with just analyzing a small issue, i.e., 'This procedure yielded a higher fusion rate' or 'This procedure is good at getting patients out of the OR sooner'. The world and payers are interested from a 35,000 foot level to see if they are getting enough bang for their buck. There was a recent *New York Times* article about a study from Barcelona about the Mediterranean diet. The smart thing was that the authors measured the final outcomes, i.e., were people less likely to die of a heart attack or have a stroke. That is why this paper was on the front page of the *New York Times*. So often in orthopedics—and perhaps especially in spine—we measure an isolated outcome measure alone in a small fractionated group."

"But since we should really be focused on final overall outcomes we need look at larger numbers of patients. There are two recent groups that have done great work on spinal deformity: the International Spine Study Group (which looks at adult deformity patients) and the Harms Study Group (focusing on childhood patients). When starting to look at 'bang for the buck' we need large amounts of patients, and these groups have been very successful at multicenter collaborative research and therefore getting abstracts into the important societies and expanding our knowledge base. What is most relevant is that people are pushing the envelope and enhancing their knowledge by joining other centers to collaborate on data collection. There have been a number of efforts over the years to do this, but these two groups stand out in my mind as being highly successful. The future comes when large groups like this can associate with each other to collaborate and create even larger databases. This effort has started but is in its infancy.

Accelerate Fracture Repair in a Single Injection! Statistically significant healing attained…nothing fancy needed. Scott Boden, M.D. is director of The Emory Orthopaedics & Spine Center and Professor of Orthopaedic Surgery at Emory University School of Medicine. He is excited about his team's recent work. "We are continuing to develop small molecules that may play a role in skeletal regeneration for the spine and possibly the disc. Thus far, we have identified four families of these molecules that we think will enhance local bone formation, and possibly enhance cartilage and soft tissue regeneration. They may also enhance bone void fillers in that category of less active graft materials."

"Next month we have a study being published showing that one of those compounds can accelerate fracture repair in a single injection. It is truly striking that we only need a single injection of a small molecule—without any fancy drug delivery—to obtain a statistically significant increase in healing properties. I would have thought that it might require a time release delivery or some type of gel, but we just squirted it into a fracture hematoma. It's a nice proof of concept experiment; the main thing is to be able to get to clinical trials. Emory finalized a license agreement for this technology to a company called SkelRegen, and they will assemble strategic and financial partners to move the project forward."

Daniel Cooper, M.D. Wins NFL Award. ESPNDallas.com is reporting that Daniel Cooper, an orthopedic surgeon and team physician for the Dallas Cowboys, has received the Jerry "Hawk" Rhea Award from the National Football League ("Cowboys' team physician honored" Todd Archer, February 26, 2013). Dr. Cooper, who practices at the Carrell Clinic, has been the Cowboys' head physician for the last 13 years. Dr. Cooper attended The University of Texas Southwestern Medical School, then did an orthopedic residency at the University of Texas Health Science Center. He then completed an Orthopaedic Sports Medicine Fellowship at Cornell University's Hospital for Special Surgery in New York City. Dr. Cooper is past president of the Texas Society of Sports Medicine. ♦

company

Burtons Are Back… With ISO Certification

Two veterans of the medical device industry have returned to give it their all. Mary Burton, along with her son Ed Burton, is back in business after a three year absence from the industry. They have a new facility dedicated to the production of orthopedic and spinal implants…and, they have just achieved ISO 13485 Certification of their new venture, MDI, LLC. Mary Burton is now in the role of Vice President of Sales & Marketing for MDI and Ed Burton is leading the new company as President.

"ISO Certification validates everything we've put into place over the past several months," said Ed Burton in the February 22, 2013 news release. "It puts us in the position to once again become a superior, quality supplier in the marketplace."

"We are so excited to be back," said Mary Burton. "We felt we owed it to our customers and to our employees to rebuild the tremendous relationships we had in the past."

"MDI has exceeded our expectations for delivery and quality. We have been extremely impressed with their talented team, which began manufacturing for us quickly and efficiently. We are looking forward to establishing a long term relationship that will produce great success for both companies," said Mahmoud Abdelgany, CEO, Custom Spine, Inc.

Asked what they have learned in the intervening years that will allow them to better meet the needs of their customers, Mary Burton told *OTW*, "We didn't really leave the market intentionally. Our former companies had grown to such a point, that in order to take them to the next level, we agreed to sell to another major medical device supplier. The company moved operations out of the area, and with the loyal employees who were left behind, their experience and our extreme knowledge of this business, we realized this wasn't a chance we could pass up. It was time to start-up again. This time, we are more focused. We used to do work in various industries; now we are focusing strictly on medical device and implants (thus the name of the company). This will allow us to stay more closely focused on our core group of customers; to provide even better service, superior quality, and lightning-fast turn-around time. By focusing on one industry, we were able to invest our money wisely, to purchase equipment specific to the industry we serve. We decided to focus on performing critical finishing operations in-house. We invested heavily in equipment for finishing operations such as titanium anodization, laser marking, passivation, electro polish, micro deburring and vacuum heat treat. We are now also in the process of completing our validated cleaning certification. Offering these expanded services allows us to offer better prices and faster lead times, and stay in control of the quality of the parts being made."

—EH (February 28, 2012)

MDI, LLC

FDA Recalls DePuy Revision Knee Product

The FDA initiated an "urgent" Class 1 Medical Device Recall of DePuy Orthopaedic, Inc.'s LPS Diaphyseal Sleeve on February 15, 2013. The agency made the recall public on February 22, 2013.

The sleeve is intended for use with the LPS System which is an end-stage revision knee product that allows surgeons to reconstruct severe soft tissue and bony defects. The diaphyseal sleeve is intended to enhance the fit and fill of the diaphyseal femoral canal with femoral and tibial replacements.

This product was recalled because the sleeve to sleeve base taper connection may not be sufficient to accommodate potential physiologic loads that may be transferred to the junction during normal gait activities by some patients. This may result in fracture of the sleeve at the taper joint which may also lead to loss of function or loss of limb, infection, compromised soft tissue or death.

The agency informed hospitals and surgeons of the problem on January 4, 2013 and asked providers to immediately stop distributing or using the recalled lots. If a medical facility has the affected product in stock, it should be returned to DePuy.

The sleeves were manufactured from 2008 to July 20, 2012. The product codes and lot numbers for the recall are as follows:

1987-20-018; 1987-20-020; 1987-20-024 and 1987-20-028.

DePuy is not recommending revision or additional follow up in the absence of symptoms of patients with this implanted device. However, DePuy is encouraging surgeons to communicate with patients who received these implants and discuss the risks of the implant fracture and the method for detecting implant failure if the patient begins experiencing symptoms.

The FDA has received a total of ten reports (six fractures and four reports of loosening that may or may not be attributed to the same device design issue) of incidents in which the device has malfunctioned.

Questions should be directed to DePuy Orthopaedics at 574-372-7136.

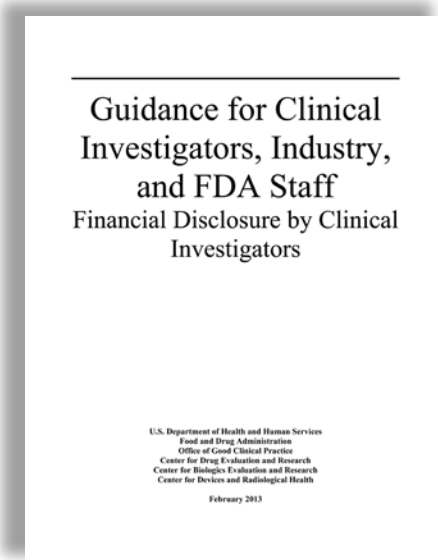
—WE (February 25, 2013)

FDA.gov

legal

New Financial Disclosure Guidelines From FDA

If you own shares in a mutual fund that includes a company for whom you are a clinical investigator for an FDA-sponsored investigation, do you have to disclose that? Can a literature report be considered a covered clinical study?


Guidance for Clinical Investigators, Industry, and FDA Staff

Financial Disclosure by Clinical Investigators

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Good Clinical Practice
Center for Drug Evaluation and Research
Center for Biologics Evaluation and Research
Center for Devices and Radiological Health

February 2013

FDA/Financial Guidance Disclosure

The FDA's got the answers for you in a new guidance.

The "Guidance for Clinical Investigators, Industry, and FDA Staff - Financial Disclosure by Clinical Investigators," was issued in February and is a revision of 2001 guidance.

Applicants who submit a marketing application for a drug, biological product or device are required to submit

certain information concerning the compensation to, and financial interests and arrangements of, any clinical investigator conducting clinical studies. This guidance is intended to assist clinical investigators, industry, and FDA staff in interpreting and complying with the regulations governing financial disclosure by clinical investigators. They must certify the absence of certain financial interests and arrangements of clinical investigators that could affect the reliability of data submitted to FDA, or to disclose those financial interests and arrangements to the agency and identify steps taken to minimize the potential for bias

The FDA issued a revised guidance in draft form in May 2011 for public comment. Comments were received from 13 individuals and entities, which were considered in preparing this final guidance.

Financial disclosure requirements go back to June 1991, when the Inspector General of the Department of Health and Human Services submitted a management advisory report to the FDA stating that FDA's failure to have a mechanism for collecting information on "financial conflicts of interest" of clinical investigators who study products that undergo FDA review could constitute a material weakness under the Federal Managers' Financial Integrity Act.

To get your copy of the 35 page guidance document, click here: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf?source=govdelivery

—WE (March 1, 2013)

Medtronic Gets First-Ever Early Feasibility Study Approval

It's not for an orthopedic medical device, but Medtronic, Inc. has received landmark FDA approval under new draft guidance to conduct an early feasibility study.

The approval to study Medtronic's Native Outflow Tract Transcatheder Pulmonary Valve (TPV), represent the first-ever FDA approval of an investigational device exemption (IDE).

Investigational Device Exemption

The intent of the FDA`s draft guidance, "Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, including First in Human (FIH) Studies," is to foster early-stage development of medical devices within the U.S. It is a new approach to clinical studies conducted in the early stages of development, and is designed to facilitate early clinical experience with investigational medical devices to reach patients sooner and create incentives to innovate in the United States.

This new approach is intended to allow studies to start earlier in the device development process than previously allowed, while still providing appropriate human subject protections. It also permits sponsors (manufacturers) and FDA device reviewers more flexibility to make device modifications once the study begins.

The FDA hopes that early feasibility studies allow for early clinical evaluation of devices to provide proof of principle and initial clinical safety data. These studies may be appropriate early in device development when clinical experience is necessary because nonclinical testing methods are not available or adequate to provide the information needed to advance the developmental process.

The agency says it recognizes the value of encouraging medical device innovation to address clinical needs and improve patient care, particularly when alternative treatments or assessments are unavailable, ineffective, or associated with substantial risks to patient safety. This guidance has been developed to facilitate the early clinical evaluation of medical devices in the United States under the IDE regulations, using risk

Logos courtesy of FDA and Medtronic

mitigation strategies that appropriately protect human subjects in early feasibility studies.

Qualifications

To improve the likelihood of IDE approval, the following questions should be addressed by the sponsor, with supporting materials, in the original early feasibility study IDE application:

- What is the clinical condition to be treated or assessed by the device?
- What is the standard of care for the clinical condition and expected clinical outcomes associated with the standard of care?
- Does the information included in the Report of Prior Investigations (Section 5) support initiation of the study?
- Does the Investigational Plan include a thorough risk/benefit analysis, sufficient risk mitigation strategies, adequate human subject protection measures, and an appropriate clinical study protocol (see Section 6)?
- Is initiation of the clinical study justified based on the responses to the aforementioned questions?

"The approval of this study is an excellent example of how the FDA and manufacturers can work together to advance medical innovation by studying initial device design and functionality, with the long-term goal of delivering novel therapies to patients in need," said John Liddicoat, M.D., senior vice president of Medtronic and president of the Medtronic Structural Heart Business. "In this case, the early feasibility study will help us develop a minimally invasive therapy for patients whose only current treatment option is open-heart surgery."

The Native Outflow Tract TPV is a minimally invasive therapy for patients with congenital heart disease who don't have a right ventricle-to-pulmonary artery conduit, and need a pulmonary valve to maintain adequate blood flow from the right ventricle and the pulmonary artery. Delivered in a minimally invasive procedure using a catheter (small tube) funneled through the veins, the valve is designed to restore pulmonary valve competency without invasive open-heart surgery.

To learn if your device qualifies, click here: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm277670.htm

—WE (February 26, 2013)

reimbursement

Sequestration to Cost Half Million Health Care Jobs

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March has arrived and Congress hasn't passed an alternative deficit-reduction package. That means Medicare provider payments began being cut by 2% on March 1, 2013 as required by the Budget Control Act of 2011 (Sequestration).

The health care industry will be impacted by government program spending reductions of $3 billion in the current fiscal year, according to updated estimates released by the Congressional Budget Office (CBO).

The cuts will undoubtedly affect job growth in the health care industry, reports *MedicareNewsGroup*. The direct loss in the health care sector is estimated to be 330,127 jobs by 2021, according to a joint study released by the American Medical Association, the American Hospital Association and the American Nurses Association.

496,000 Jobs Lost

The report says job losses would ripple across the economy. In just the first year of the sequester, it is estimated that health care and its related industries will lose more than 496,000 jobs, These numbers include those employed in the health care sector, as well as those affected by the purchases made by health care organizations and their employees. The analysis estimates the number of lost jobs will reach 766,000 by 2021.

The top five industries with the most job losses in 2013, because of sequestration are, from highest to smallest: hospitals; physicians' offices, dentists and other health practitioners; nursing and residential care facilities; medical and diagnostic labs, and outpatients and other ambulatory care services; and home healthcare services.

Skilled Nursing Care Hit Hard

The Alliance for Nursing Home Care, which analyzed the effect of the sequestration cuts and the cuts mandated by the Affordable Care Act, found that more than one-third of nursing facilities that responded to a survey said they were planning to lay off direct service staff such as registered nurses, licensed practical nurses, certified nursing assistants, therapists and other staff. More than one-half of respondents said they had plans to reduce benefits, while about three-quarters of nursing home operators said they will change wage rates. Altogether, Medicare payment reductions could results in at least 20,000 layoffs industry-wide.

Cuts to Provider Payments

According to *MedicareNewsGroup*, the cuts will be applied to provider payments for services administered under Medicare Hospital Insurance (Part A) and Medicare Medical Insurance (Part B) and contractual payments to Medicare Advantage Plans (Part C) and Medicare Prescription Drug Plans (Part D), according to the CBO.

Low-income subsidies and additional subsidies for beneficiaries whose spending exceeds catastrophic levels in Part D are exempt from sequestration. The sequestration percentage is capped at 2% for payments for individual services under Parts A and B and for monthly contractual payments to Part C and Part D providers.

Other mandatory program spending for benefits and administrative costs are subject to the same reduction rate as non-exempt mandatory spending, according to the CBO.

That means, reports the *NewsGroup*, that about 90% of Medicare spending is limited to 2% in cuts and 8% is completely exempt from sequestration. The remaining 2% of Medicare spending would be subject to a 7.6% cut in 2013 because it falls under non-exempt non-defense mandatory programs, according to the White House Office of Management and Budget (OMB).

$11 Billion Cuts in 2013

Under the sequestration process, Medicare providers will consequently see $11.085 billion in reimbursement cuts in 2013, according to preliminary OMB estimates. The CBO estimates that Medicare budgetary reductions will total $123 billion from 2013 to 2021.

The CBO also predicts that the sequestration will generate about $31 billion in outlays between 2013 to 2021 as a result of reductions in Medicare Part B premiums and other changes in spending. Since Part B premiums are set to cover a fraction of the program's cost, the CBO estimates that receipts from premiums will decrease due to reductions in budgetary resources and subsequent lower program costs.

In a letter to Congress sent September 12, 2012, the American Medical Association and more than 100 other provider lobbying organizations wrote, "The combination of the sequestration cut and looming Medicare Sustainable Growth Rate (SGR) payment cut would not only impede improvements to our health care system, it could lead to serious access to care issues for Medicare patients as well as employment reductions in medical practices."

—WE (February 28, 2013)

trauma

Vitamin D and Calcium Pills: Not Enough Proof?

The American Society for Bone and Mineral Research (ASBMR) is wondering about the new recommendations by the U.S. Preventive Services Task Force (USPSTF) that address the use of the combination of vitamin D and calcium supplements to prevent bone fractures. The USPSTF statement suggests that there is not enough evidence, one way or the other, about how supplements affect bone fractures for men and premenopausal women.

The ASBMR indicates that the USPSTF's recommendations differ from the 2010 Institute of Medicine's (IOM) findings, primarily because these recommendations are based only on fracture outcomes, while the IOM included an examination of the underlying biology of the impact of calcium and vitamin D.

"The ASBMR continues to support the recommendations of the IOM because they are based on a broader evaluation of the data rather than only fracture outcomes," says Sundeep Khosla, M.D., in the February 25, 2013 news release. Dr. Khosla is past president of the ASBMR and a practicing endocrinologist and research scientist at the Mayo Clinic at Rochester, Minnesota.

The ASBMR has long supported that calcium and vitamin D are important to bone health and the best way to get them is through food that is naturally rich in these supplements. Calcium and vitamin D are the most crucial, yet simple, first steps in promoting good bone health.

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"Research has shown us that healthy adults who are receiving the recommended amount of calcium and vitamin D in their diet and through sunlight exposure, need not take supplements for bone health," says Cliff Rosen, M.D., Past President of ASBMR and Director of Clinical and Translational Research and a Senior Scientist at Maine Medical Center's Research Institute in Scarborough, Maine. "But the report leaves out a crucial and large population—the elderly, especially those at high risk for fractures in assisted living and nursing home facilities. This population has less exposure to sunlight and is at high risk for hip fracture. They should be receiving supplements. The evidence generally supports benefits of calcium and vitamin D for building strong skeletons and preventing fractures and bone loss in high risk, elderly individuals."

—EH (February 26, 2012)

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