Trends-in-Medicine

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by Lynne Peterson

SUMMARY

Total joint implants have not ***yet*** been affected by the recession, but for 2009 the outlook is for volume to be ***down*** 5%. There continues to be hospital pressure on implant prices, but no increase in that. ♦ Industry was a bit circumspect in marketing at AAOS this year, but business was getting done, though no share shifts were apparent. Zimmer, in particular, seemed "back to normal." ♦ Orthopedic surgeons are likely to be slow to abandon warfarin for newer anticoagulants, but Bayer/Johnson & Johnson's Xarelto (rivaroxaban) and Boehringer Ingelheim's Pradaxa (dabigatran) may replace LMWH quickly. ♦ Robotic systems like Mako's Rio are fascinating, but hospitals are not expected to spend nearly a million dollars for such technology in the current budget environment. ♦ Spine surgeon use of BMP is decreasing, but surgeons are hopeful about stem cell products for the future. Artificial discs are slowly gaining acceptance. ♦ Smith & Nephew is now competing with Kinetic Concepts in negative pressure wound therapy. ♦ CMS will continue to pursue value based purchasing, with an emphasis on patient outcomes. ♦ The FDA is concerned about several off-label orthopedic practices.

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Stephen Snyder, Publisher
2731 N.E. Pinecrest Lakes Blvd.
Jensen Beach, FL 34957
772-334-7409 Fax 772-334-0856
www.trends-in-medicine.com
TrendsInMedicine@aol.com

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS (AAOS)

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The AAOS focus this year was ***not*** on new technology or devices but on practical things like how obesity impacts orthopedics, when patients can return to activity after a sports injury, new agents to prevent deep vein thrombosis (DVT) during and after orthopedic surgery, osteoporosis, new treatments for hand and wrist pain, and the academy's new guidelines for osteoarthritis of the knee. In fact, asked what's new in technology this year, surgeons couldn't point to anything particularly exciting except perhaps for a small uptick in artificial discs.

THE ECONOMY AND ORTHOPEDICS

Forty-two orthopedic surgeons and four industry sources were interviewed about how the economic recession is affecting the orthopedic industry. Orthopedic surgeons were generally optimistic that the economic recession will have little impact on them, but joint surgeons painted a worse picture for implant procedures than the industry overall. One surgeon said, "Companies and doctors are delusional if they think orthopedics won't be affected by the economy." Most of the drop is in elective procedures and in younger (40- to 60-year-old working) patients. On average, doctors said overall procedure volume:

- 4Q08 ***flat*** compared to the same period in 2007. Many surgeons reported a slight to moderate uptick in volume in 4Q08, but they all insisted this was a typical seasonal effect as patients seek to get procedures done before insurance deductibles start over in the new year.
- 1Q09 ***flat to slightly down*** compared to 4Q08. A few surgeons said there was a dip in January, but, again, they described this as a typical seasonal phenomenon.
- 2009 vs. 2008 ***down*** 4% from 2008.

Looking at the procedure volume outlook over the next year, there is a difference by subspecialty, though surgeons said hip and knee volumes have tracked – and continue to track – exactly the same.

- **Total joint procedures** were flat in 4Q08, are tracking down very slightly in 1Q09, but are expected to be down an average of 4% for 2009 vs. 2008. Industry, on the other hand, is predicting 4%-6% procedure growth in 2009.
- **Spine procedures** were up 4% in 4Q08, down 2% in 1Q09, and expected to be nearly flat for 2009.
- **General, shoulder, and sports orthopedic surgeons** reported procedures down slightly in 4Q08, flat in 1Q09, and likely to be down a whopping 10% for 2009.

Orthopedic Procedure Outlook

Specialty	4Q08 vs. 4Q07	1Q09 vs. 4Q08	2009 vs. 2008
Hip and knee surgeons	Down 0.3%	Down 1.8%	Down 4.5%
Spine surgeons	Up 3.6%	Down 2.0%	Up 1.2%
General, shoulder, and sports orthopedic surgeons	Down 1.3%	Flat	Down 9.5%
TOTAL	**Up 0.2%**	**Down 1.6%**	**Down 4.2%**

Other hip and knee surgeon comments about the economy included:

- *Michigan #1:* "Procedure volume is down because of insurance. People are unwilling to pay out of pocket, so they are putting procedures off or waiting to see on insurance. There was a little rush before people lost their insurance at the end of last year, but January was down, and I suspect volume will remain down until the economy picks up."
- *Kentucky #1:* "I am in an underserved area, so my volume has not been affected by the economy."
- *Ohio:* "Volume in the bigger cities hasn't changed, but as people's insurance changes and their copays go up, people are deciding on the timing of the surgery more carefully. We have a big General Motors population, and a lot of them are getting surgery now – while they can."
- *Kentucky #2:* "People are scared of losing their job and insurance, so they have a 'do it now' attitude. There has been a subtle bump up in procedures in the last few months, but I expect it to flatten out this year unless there is a change in what the government is willing to pay."
- *New York:* "Our (implant) volume is down. Patients are more concerned with how much time off they need because they don't want to put their job in jeopardy. There has been an increase in worker's compensation patients, and we are seeing more motor vehicle accident victims with pain."
- *Kentucky #3:* "In the real world, people are delaying elective surgery without a doubt. By next year, I think even university settings like ours will feel it."
- *Oklahoma:* "Elective procedures are down, such as removal of cysts, rotator cuff repairs, and I think the decline will continue in the working population. People who have to meet a deductible are not having elective surgery."
- *Virginia:* "There hasn't been any impact yet, but there will be this year."
- *Alabama:* "I'm seeing more people trying to get on disability. They lose their job, and they want a way to get medical coverage – and a disability gets them coverage. People I operated on five years ago are coming back seeking a disability claim…And we are seeing more people taking care of things (having surgery) before they lose their insurance."
- *Illinois:* "People still in the workforce are afraid of losing their job. If they can put off a knee replacement, they will to keep their job. And they are concerned with the copay."
- *Arizona:* "A lot of people will lose their insurance and go to Medicaid over the next year. And people are already not doing things because of the copay. Over the next year, I expect procedure volume to fall 10%."
- *Massachusetts:* "There was a slight increase in volume in 4Q08, but that was typical for the end of the year. In the first quarter, volume is lower than in 4Q08, but, again, that is typical. The economy hasn't hit our volume yet, but it will. Orthopedic surgeons doing young patient procedures are being more affected than hip and knee surgeons."
- *North Carolina:* "Our volume is steady because the number of patients with knee arthritis is skyrocketing. We are seeing more patients who lost their insurance, but I have enough paying patients to fill the room…What we are seeing at the university is patients who had a total knee arthroplasty three years ago, then the knee goes bad, and the patient has no insurance now, so he comes to the university. If a patient absolutely needs the procedure, we have to do it. The hospital loses money, and the doctor loses money. Orthopedic surgeons who wanted to work at a university are leaving. Who will train the next generation? Half the fellowship positions remain unfilled. The government says AARP is not complaining (yet) about supply side issues, though."
- *Florida #1:* "Patients don't bring their copay anymore; they ask us to send them a bill in the mail, which means they don't pay us."
- *Michigan #2:* "A lot of patients are worried about losing their insurance, so they are pushing things (procedures) forward. We're seeing that in 1Q09. But for the rest of the year, if the auto industry is not bailed out, then our volume will go down. A lot of people are losing their jobs and money."
- *Texas:* "Our volume has been down because people don't have the money for their copays, but if the economy gets better, more people will have elective procedures. People need to walk."
- *Washington:* "I had three patients cancel in the last month because they were afraid if they took time off work, they would lose their job…And meeting the copay is difficult for some patients."
- *Pennsylvania:* "There was a small burst in the fall as people got procedures done while they had insurance. When their benefits run out, we will see a dip in our procedure volume…We had a big local recession in the 1970s, and I know what happens with the closure of two major plants – procedure volume goes down."

- *Florida #2:* "There will be a decrease in younger patients who will put it off. In previous downturns, people put off elective surgery if they were working, and we are seeing the same thing now."
- *Georgia:* "We are limiting some procedures because of a lack of proof they help patients. In 2009, I think volume will be down. We have so much volume that we are happy if volume goes down."
- *Maine:* "Our insured population will be down 20% this year compared to 2008. Orthopedic surgeons who don't expect a decrease are not being realistic."

The story was the same with other orthopedic surgeons. Dr. Scott Blumenthal, a spine surgeon with Texas Back Institute, predicted that their procedures will be flat to down 2% in 2009 vs. 2008, noting, "Flat is bad. Elective procedures are affected for two reasons: disposable income is down, and there is a trend in PPO health insurance – which is what most of our patients have – of going to higher deductibles. There is no question that in surgery, but also in hospitals, there is at best a flat year ahead…There was a push (increase) at the end of 2008, but that happens every year. The first quarter of the year is always slower than the fourth quarter of the previous year, but this year it is more pronounced." A Minnesota shoulder surgeon said, "We are only just starting to get impacted by the recession. Farmer loans are just starting to get hard. But the new money from the federal government will fix the Minnesota budget issue. However, over 2009 I expect procedures to be down 5%-10%." A North Carolina spine surgeon added, "There has been an increase in disability seekers in the last year…A bad economy precipitates decision-making." Dr. Richard Guyer, president of Texas Back Institute, said, "February is down a little, too. March looks like it is coming back, but there is definitely a downturn…And some insurance companies have started making patients pay the full amount of their deductible before they can just pay copays for an office visit." Dr. Guyer also said some patients are skipping MRIs or shopping MRI prices – even negotiating with imaging facilities on the MRI price – to save money.

Most surgeons said they continue to have a backlog of patients that is buffering any economic impact on their total joint procedure volume, but those backlogs are shrinking somewhat. A Michigan doctor said, "Before the economic crisis, I was scheduled a month in advance, and that hasn't changed." A New York doctor agreed, "Our backlog is unchanged at about a month." A Georgia surgeon said, "We are seeing a decrease in the waiting period from 3-6 months to 1 month."

Hospitals

Even though hospital capital budgets across the country are basically frozen, hospitals have not yet increased their pressure on orthopedic surgeons to choose cheaper implants or identify a preferred vendor so the hospital can negotiate lower pricing. Surgeons pointed out that this was tried 7-8 years ago and failed, and they said hospitals have not started any ***new*** push in this area. Over the past few years many hospitals have been getting more aggressive on pricing and, thus, in trying to influence the choice of implants used, and some have been more successful than others, but doctors said this effort has not accelerated recently. Gary Henley, CEO of Wright Medical, said, "(Hospital aggressiveness in trying to direct implant use) ebbs and flows, comes and goes. They are always looking for better pricing. But I haven't seen anything (significant) yet."

Surgeon comments about the hospital environment included:

- "Hospitals were pressuring us on implant choices 7-8 years ago, but they aren't doing it anymore. They understand not to tread on the surgeons who bring in good money. But custom things might be in discussion…And hospitals have gotten tougher on negotiating on price with all the vendors."
- "Hospitals have been trying to direct our implant choice for a while, and the effort continues. Doctors push back, but the hospitals continue to think implant companies make too much money, and I think the hospitals have had some success. But the manufacturers are tough because they want to continue innovation."
- "Our hospital feels empowered. They try to go to the lowest bid, but we (orthopedic surgeons) still have a little control."
- "Our hospital has categorized implants by demand – low, medium, and high. The hospital then set a price, and vendors had to lower their prices to sell to us – and they did…In some situations, higher priced implants are beneficial for the hospital and make them more money; in other situations, the opposite occurs."
- "Our implant choices are becoming more limited. There will be a lot of jockeying to get us to 2-3 providers. And I think that will cause the smaller companies to get bought or get run out of business."
- "Our hospital has a purchasing group, and I can choose J&J, Biomet, or Smith & Nephew – any of those. There hasn't been any pricing change yet, but I'm sure that is coming."
- "Our hospitals have gotten more aggressive, but smart hospitals have been negotiating tough for some time."
- "Pricing is fairly steady. Blue Cross has 85% of the market in our area, and their reimbursement is already low."
- "Our hospital wants us to use a cheaper cement. They haven't focused on implants yet, but they may set a maximum price for implants…In the bid process, they limited higher knees, but I haven't pushed that issue yet. And the hospital will start saying what nails we can use for trauma."
- "Our hospital set the price, and any vendor that meets the price can be used."

- "My hospital put a price cap on, and only one company met the cap. Then, when the hospital told us to change, the other companies met the price."

Obama administration

Surgeons expect the Obama administration and the Democratic Congress will be ***negative*** for doctors in general and orthopedic surgeons in particular. They offered a list of things they expect to happen, but one surgeon cautioned, "Washington won't do anything. There will be a lot of smoke, noise, and money spent but no change. They can't get national insurance without a policy on abortion, and that will be a big roadblock."

- Significantly lower reimbursements.
- Universal healthcare. One surgeon said, "I think we will end up with a single payer system, probably by the government, with patients able to opt for a higher tier but everyone covered…Before that, I'm seeing a trend of physician and physician groups going to work for hospitals and having the hospital be the employer. This is occurring more on the East Coast than anywhere else."
- More government control and intervention.
- Fewer Medicare providers.
- More regulation.
- Higher taxes.
- Socialized medicine.
- More unreimbursed mandates.
- Comparative effectiveness, which some doctors predicted could have a "big influence" in orthopedics.

Specific Companies

Last year ethics and the Department of Justice investigation of Zimmer and Stryker were hot topics at AAOS, but this year things seemed to have calmed down, and doctors were focused more on the nuts and bolts of their profession. However, a spine surgeon had a different perspective, "This year even more than last year the whole compliance issue of surgeon-industry relations is under the microscope. I've never seen so much tension in a meeting as I'm seeing now – even more than last year. Some of the big orthopedic companies forbid any employee from taking a doctor to dinner at this meeting. That is how on edge the companies are. I think it is over-reacting now."

Which orthopedic company is gaining most share in this economic environment? Talking to orthopedic surgeons you wouldn't think there are any shifts going on. Among the doctors questioned, the recalls at Stryker and Zimmer over the past year didn't affect their implant choice, and none became less loyal to their current vendor as a result of the recalls or the Department of Justice investigation. A North Dakota surgeon said, "Zimmer may have lost some share to Biomet's Oxford partial knee. Once doctors started using the Oxford knee, they may have switched to more Biomet products overall."

Wright CEO Henley said he doesn't believe the economy is making orthopedic surgeons more willing to change implant providers, but he said changes are occurring, "It is hard to change a doctor, but they are changing…Given our performance over the past year or two vs. the overall market, the assumption is that we are gaining market share."

None plans to change vendors in the near future, and only one surgeon has recently changed implant vendors. That surgeon explained, "We used to use Smith & Nephew, but we had failed components (in our state), and the company did not support a doctor (not at his hospital but in his state) in court when it was a product failure, so we switched providers." A Midwest doctor said, "The rush to market – and the subsequent recalls – has been a problem, so I think orthopedic surgeons are now more open to new products. If you can't trust a company, it's a problem."

Which orthopedic company has best product lineup currently? Surgeons generally believe it is the vendor they are using.

What was getting attention at AAOS? Porous metal – Zimmer's Trabecular Metal and Wright's BioFoam. The two products are made differently, but the results are similar. Of course, each company claimed their product was superior. A New York surgeon said, "Zimmer's Trabecular Metal is very innovative, but it is a niche market. The company should develop it further. I think it will help with revision work." A North Carolina surgeon said, "Trabecular Metal is awesome. All of the other companies have clones, but they are not tantalum." A Michigan surgeon said, "Trabecular Metal is a niche. It is exciting technology, but it is expensive. I would use it in a revision knee but not a shoulder." Another doctor said the advantages of Trabecular Metal are the immediate stability and very rigid fit that rarely requires a screw and its biocompatibility. The disadvantages are that there are no metal-on-metal or ceramic-on-ceramic implants yet.

Comparison of Zimmer and Wright Porous Metals

Feature	Zimmer's Trabecular Metal	Wright's BioFoam
Metal	Tantalum	Titanium
Hardness	Very hard	Softer
Resistance	More	Less
Resistance to compression	More	Less
Clinical trial data	Longer	Accumulating
Bone ingrowth	Comparable	

What is the outlook in this environment for smaller companies? Surgeons and industry officials alike predicted that smaller companies with me-too products will fall by the wayside but innovative ones are likely to be acquired by the larger companies and perhaps for bargain basement prices. There were no specific acquisition rumors floating around AAOS, though.

Asked to rank the sales reps for each of the implant companies on quality and effectiveness, surgeons said Johnson & Johnson/DePuy and Stryker tied for No. 1, followed by Zimmer, and then Biomet. A surgeon commented, "Biomet is at the bottom of my list because of a lack of knowledgeable service." Another said, "They are all about the same."

Other company news:

➢ **JOHNSON & JOHNSON/DEPUY.** The rumor at the meeting was that J&J plans to spin off DePuy, but company officials had nothing to say about that.

➢ **SMITH & NEPHEW.** The emphasis at AAOS was on its wound care products (*see page 10*).

➢ **STRYKER.** Surgeons indicated the recall of the Trident hip is no longer an issue, and "squeakiness" has stopped haunting the company.

➢ **WRIGHT MEDICAL.** CEO Henley said the company's BioFoam "got a warm reception" from surgeons, and the company got more leads for its foot and ankle portfolio on the first day of AAOS than at all of the meeting last year. Asked about interest in acquiring smaller companies, Henley said, "We've done 14 deals in the last two years, not huge deals, and we are still looking." Wright introduced several new products at AAOS, including:

- **G-Force,** a foot and ankle tenodesis screw system for soft-tissue fixation procedures with high fixation strength and a radiolucent PEEK Optima implant material.
- **Stature Modular Hip reconstruction system.** Zimmer has the "gender knee," but Wright took a different tack: a hip implant based on a patient's stature, not gender. The Stature system expands on the Profemur system.
- **A next-generation radiolucent instrument set** for use with Micronail, the company's popular plate for wrist fractures.
- **Prophecy Pre-Operative Navigation Guides** knee replacement, which will be launched this spring. These use advanced imaging technology to help surgeons plan precise implant alignment before they enter the operating room (OR) and then in the OR to enable accurate alignment.

➢ **ZIMMER** was "back to normal" at AAOS this year. The theater-in-the-round in its booth was back after a one-year hiatus, and the speakers in the theater were again telling the Zimmer story. There were rumors that some high volume doctors and "consultant" doctors had left the Zimmer fold, but none of the surgeons questioned had made a switch. One surgeon said, "I'm no longer a Zimmer speaker, but I still use Zimmer implants. Zimmer had a grand mal seizure and is just waking up. They have great products, and the cream will rise to the top. I don't know any Zimmer speaker who dropped them."

The Stryker, Smith & Nephew, Biomet, and Wright Medical booths did not ***appear*** as busy as Zimmer's booth, but if you counted the number of surgeons in each company's booth at any given time, it seemed comparable. Unlike Zimmer, several other companies, including Stryker, Smith & Nephew, and Wright banned their sales reps from taking doctors to dinner, lunch, or out for entertainment. Johnson & Johnson/DePuy had a very large, two-story booth with a lot of activity.

Zimmer sales reps also had resumed taking doctors to dinner, though a company official said they were supposed to be "educational, modest, and not in an elaborate setting." The booth looked very busy, but the design, with the theater taking up a lot of room in the middle, made it look busier than it was. And Zimmer had 600 people at the meeting, so there were always a lot of sales reps in the booth and in the theater audience.

The Durom hip "recall" in July 2008 was not a big topic at AAOS, and doctors asked about it generally said it is behind the company. Zimmer suspended sales of Durom after reports of an excessively high failure rate.

At AAOS, Zimmer introduced:

- **Patient-specific knee instruments.** They weren't on sale yet – that was to start in March 2009 – but they were being shown at AAOS. The instruments are made individually for each patient from the patient's MRI data.
- **DeNovo NI**, an orthobiologic juvenile stem cell product for defects that is new in the last six months.
- **Advanced Trabecular Metal.**

There has been some turnover in the Zimmer sales force, but surgeons did not see this as disruptive, and the sales reps themselves – at least those attending AAOS – did not appear disgruntled or unhappy. Rather, they indicated they were happy to be getting back to normal, though under some strict new ground rules. The general feeling was that the new CEO, David Dvorak, got them through a tough time, but there appeared to be some questions (not really concerns) about whether he could really lead them into the ocean once the shoals are navigated.

A Zimmer customer commented that the NexGen knee is "a little old" while there is newer technology from the competitors. So, what does Zimmer have in the pipeline? An official pointed to the DeNovo ET, a new hip cup system coming in late 2009, and a "lot of instrumentation and materials refinements."

ANTICOAGULATION

Dr. Fred Cushner of the ISK Institute in New York City said orthopedic surgeons have problems with both of the sets of guidelines for venous thromboembolic (VTE) prophylaxis, "There is no consensus on what we should do or what is

important…Are we more concerned with a blood clot, under diagnosis of pulmonary embolism, or the perceived risk of bleeding…All of us would like to prophylax high-risk patients and not those at less risk…Should we prophylax everyone aggressively with low molecular weight heparin (LMWH) – generally Sanofi-Aventis's Lovenox (enoxaparin) – or should we risk stratify and perhaps give patients with lower risk aspirin or compression…There is no consensus among surgeons on whether we should give warfarin in the hospital or at home, how long to give it, how long to use compression devices. We do know 99% of orthopedic surgeons prescribe prophylaxis, but only ~50% meet guidelines."

Dr. Paul Lachiewicz of the University of North Carolina, Chapel Hill, said the concern orthopedic surgeons have with the American College of Chest Physicians (ACCP) guidelines is that their "only interest is if the patient got a clot, not how the patient did."

- Asymptomatic (duplex scan or venogram) thrombi are the outcome measure and are considered as important as symptomatic VTE.
- Drainage and bleeding relevant to the surgeon or patient may be under-reported.
- Patient outcome – re-operation, infection, poor range of motion – is ignored.

Dr. Lachiewicz said the bottom line with the AAOS guidelines is that "each patient should be treated as an individual and assessed before surgery for PE risk and bleeding risk." Among the new AAOS guidelines are:

- Every patient should have mechanical prophylaxis, either interoperatively or immediately post-op (compression).
- Patients should be done under regional anesthesia (where possible). "The literature supports the opinion that that is associated with a lower incidence of blood clots."
- A vein scan before discharge, which was commonly done in the 1990s and 2000s, is no longer recommended.
- Arthroscopy with debridement or lavage should not be performed in patients with a primary diagnosis of symptomatic osteoarthritis (OA) of the knee. (Level of evidence I and II, Grade A)
- Arthroscopic partial meniscectomy is an option in patients with symptomatic OA of the knee who also have primary signs and symptoms of a torn meniscus and/or a loose body. (Level V, Grade C)
- A free-floating interpositional device is not recommended in patients with symptomatic unicompartmental OA of the knee. (Level IV, Grade B)
- The use of glucosamine and/or chondroitin sulfate or hydrochloride, needle lavage, and custom made foot orthotics are not recommended.
- No pro or con recommendation was made with respect to acupuncture, bracing, or intra-articular hyaluronic acid (e.g., Genzyme's Synvisc).

AAOS Guidelines for VTE Prophylaxis

Type of patients	Aspirin	Warfarin with INR ≤2	LMWH	Pentasaccharide
Standard risk patients	Yes	Yes	Yes	Yes
Higher risk of PE, standard risk of bleeding	No	Yes	Yes	Yes
Standard risk of PE, elevated bleeding risk	Yes	Yes	No	No
Elevated PE risk, elevated bleeding risk	Yes	Yes	No	No

New anticoagulants

Dr. Richard Friedman of the Medical University of South Carolina said almost all orthopedic patients in the U.S. receive at least some form of prophylaxis. Compliance with guidelines is achieved in 47% of total hip replacement (THR) patients and 61% of total knee replacement (TKR) patients. However, compliance with warfarin is much lower than compliance with LMWH (TKR 48% vs. 72%, THR 33% vs. 63%).

The mean length of hospital stay for total joint patients is 3.1 days, and 25%-30% are discharged at 2 days. Furthermore, the mean time to VTE is 9.7 days after total knee arthroplasty (TKA) and 20.5 days for total hip arthroplasty (THA). Thus, DVT prophylaxis is mostly an outpatient issue. The hope is that the new agents will improve compliance because they are oral, once-daily, require no monitoring, and have a low potential for food/drug interaction.

Thus, there is significant interest in alternatives to warfarin, and the closest to market are **BOEHRINGER INGELHEIM's Pradaxa (dabigatran)** and **BAYER's Xarelto (rivaroxaban)**, which will be marketed by Johnson & Johnson/Ortho-McNeil.

However, Dr. Lachiewicz sounded a note of caution, "What happens in pharmaceutical company studies and in the real world are 2 major issues…These (clinical trial patients) are very carefully selected patients…They are not real-world patients with multiple medical problems. It is a whole different ballgame…I personally think this (rivaroxaban) is a wonderful, promising drug. It will be interesting to see in the real world if bleeding will be a major issue."

Asked how he would choose between dabigatran and rivaroxaban, "Dr. Lachiewicz said, "There isn't enough information yet to make a decision." Dr. Friedman added, "There probably is room for more than one agent. I think orthopedic surgeons look critically at safety and efficacy, and if those are equal and the dosing schedules are equal, then it comes down to cost. If it is a choice between BID and QD dosing, they would probably go to QD dosing."

Asked how quick the uptake of dabigatran and/or rivaroxaban is likely to be, Dr. Cushner said, "I would expect it to be slow. In orthopedics, even the best of drugs take a long time to change practice. The big debate is who will switch…My personal opinion is injectables will be the first to go (vs. warfarin)." Dr. Friedman said, "People using LMWHs for a long time will switch quickly because the new drugs have the advantages of LMWH in a pill. I think warfarin users will keep a close eye on their LMWH colleagues, dip a toe in with high-risk patients, and gradually evolve over time." Dr. Lachiewicz said, "I think it will be an evolution. With all the Cox-2 problems, I think everyone is a little scared of new pharmaceutical agents. I think (uptake) will be a little slow, except for those (doctors) who were in the studies (for the new agents). I personally will use them in just high-risk patients."

ROBOTICS: MAKO SURGICAL's Rio

Mako has developed an interesting robotic technology, but at $895,000 it is likely to be a tough sell to hospitals in the current economic environment. A company official said 17 systems had been "placed" as of December 31, 2008, adding, "Hospitals are at least interested and looking." In this environment, president/CEO Dr. Maurice Ferré said some are being leased, "We arranged leasing before the economic crisis started, and we still have credit available. And hospitals are finding other ways to finance Rio, including third party leases. And Rio pays for itself with 70 procedures a year."

Rio is a robotic arm that enables doctors, using the company's Restoris MCK MultiCompartmental Knee System, to do Makoplasty – a partial knee resurfacing procedure for patients with osteoarthritis. The robotic arm allows precision resurfacing on either or both the medial and patellofemoral portions of the knee.

This surgeon-interactive robotic system integrated with computer assisted, 3D planning and haptic guidance, provides real-time visual, tactile, and auditory feedback. It allows a surgeon to resurface the damaged portion of a knee through a small keyhole incision, with an implant screwed in the joint to provide smooth knee movement. A surgeon described this Makoplasty as "almost like an arthroscopy, where you don't need to look in the knee but you are getting feedback from your eyes and hands."

Surgeons who use Rio to do Makoplasty have to use Mako's implants; the robotic arm only works with the company's implants. In addition, Mako has developed implants with special features to aid in working with the robotic arm.

However, Makoplasty doesn't decrease surgical time; it increases it. Users said that even after they get familiar with the robotic approach, it almost doubles their procedure time – ~65 minutes vs. 35 minutes with Biomet's Oxford knee. Not surprisingly, users like it. Dr. Martin Roche of Holy Cross Hospital in Ft. Lauderdale FL said, "The robotic platform has brought a new technology with a lot of safety, and I think we will find it more accepted than just computer-assisted surgery …A unicondylar knee replacement is more technically demanding than a TKR and more unforgiving, with lack of accuracy leading to poor outcomes…We feel this (Rio) will allow patients to maintain normal ligaments and have better function…This robotic-enabled surgery improves surgeon satisfaction with reproducible results, improved patient satisfaction and outcomes, with a short recovery, more natural knee kinematics, and improved implant longevity."

Surgeons who are not speakers or consultants for Mako find the technology interesting but not compelling. A Washington DC surgeon said, "I have yet to decide if it is worth doing. It may have a role in younger patients without significant deformity, but elderly total knee patients won't get a benefit because they have too severe deformity. It is probably a niche market for 40-60-year-olds who can't live with knee pain." A New England surgeon said, "Our chief is interested in Makoplasty, but I don't know if we will spend the money."

A Mako engineer said the haptics with Rio are more sophisticated than the haptics in Hansen's Sensei stereotactic system for cardiology, and he insisted there are no intellectual property issues between Hansen and Mako.

Dr. Thomas Coon from St. Elizabeth Community Hospital in Red Bluff CA, another Makoplasty user and a Mako consultant, said, "I feel the recovery for (Restoris MCK MultiCompartmental Knee System) falls somewhere between unicompartmental and total knee replacement…One thing we can do with the robot that we can't do with a traditional system is cut compound curves – sculpt the anatomy to fit the implant…I call this customized fit with off-the-shelf components…We designed our implant surfaces to be friendly to the robot. We can do an entire operation with minimal burr changes…We (now) have a new tool, and it enables new technology and a novel approach – eventually tricompartmental resurfacing."

Dr. Coon said he has only done tricompartmental knees in the laboratory so far, but those experiments were "very successful." There are no lateral applications yet, but Dr. Coon said those are in development and will probably be available in 3-6 months.

Dr. Stefan Kreuzer from Foundation Surgical Hospital in Houston TX commented, "What excites me so much about this technology is we can do an ACL/PCL preserving knee with their implants, which is very difficult to do with conventional instrumentation."

Asked when there will be a mobile bearing knee line, Dr. Kreuzer said, "There has to be an IDE for that, so I don't think it will happen anytime soon."

SPINE SURGERY

AAOS is not a big spine meeting, but there were some spine topics, and several spine surgeons were interviewed. Dr. Blumenthal of Texas Back said getting devices FDA-approved in spine has gotten harder, "The FDA is not 510(k) approving many spine devices anymore. They want studies. And there will be more of that. Nationally, we are seeing CROs (contract research organizations) getting involved, both new CROs and existing firms. It is turning into big business to do these studies." He also believes there will be a shakeout in the industry, "Up until 2009 when monies ran out, there was a huge influx of small boutique companies that engaged the surgeon at a very personal level to help them develop and use products…I think it is small companies that cut into all the big companies. The problem is most of them were not profitable yet, and the current economy and the current attention to industry/physician relationships will kill 90% of the small companies…Medtronic or J&J will wait it out and gain market share back."

Vertebral fractures

On the first day of AAOS, ***The Lancet*** published an article on a study proving the effectiveness of minimally invasive surgery to treat spine fractures. The results came from a 300-patient, international, multicenter, randomized study sponsored by Medtronic, which found that balloon kyphoplasty improved quality of life, function, mobility, and pain more rapidly than non-surgical management, with significant differences in improvement seen at just one month. However, at 12 months, the differences between kyphoplasty and non-surgical care diminished.

Kyphoplasty Safety and Efficacy Study

Measurement	Kyphoplasty n=149	Non-surgical care n=151	p-value
Results at 1 month			
Patients completing follow-up	138 patients	128 patients	---
Primary endpoint: Change from baseline in SF-36 physical component summary	+ 7.2 points	+ 2.0 points	<0.0001
Improvement in quality of life by EQ-5D questionnaire	More with kyphoplasty		0.0003
Days of restricted activity	2.9 fewer with kyphoplasty		---
Back pain score	2.2 fewer points with kyphoplasty		<0.0001
Results at 12 months			
Any adverse event	130 patients	122 patients	Nss
Device-related serious adverse events	1 hematoma 1 urinary tract infection	---	---
Roland-Morris score	Better with kyphoplasty		<0.0001
Days of restricted activity	Not significantly different		0.0678
Back pain score	0.9 fewer points with kyphoplasty		0.0034
New or worsening radiographic vertebral fractures	33%	25%	Nss, 0.220

Artificial discs

There was not a lot of excitement about artificial discs at AAOS, but there was a little increase in enthusiasm. It appears the key reason for the heightened interest is the entry of **SYNTHESE's ProDisc-L** to compete with **JOHNSON & JOHNSON's Charité.**

Reimbursement also appears to be improving, and the devices are gaining some traction with payers. An Alabama spine surgeon said, "Cervical discs are gaining steam. There is more public knowledge about them, and the results are better than lumbar discs, but I'm disappointed in the reimbursement which is about half of an ALIF (anterior lumbar interbody fusion)." A North Carolina surgeon said, "It is technically difficult, and revisions are an issue. I don't expect a real pickup before the North American Spine Society (NASS) meeting (in San Francisco in October 2009), but there will probably be slow growth." Dr. Guyer said, "It is cheaper to do an artificial disc than fusion, and there are good, unpublished data, that show the rate of reoperation is much less with discs than fusion...Getting the use of discs going will take insurance companies paying for it. (But) only Aetna and Cigna pay, though Blue Cross pays in selected cases, and I heard United Healthcare may start covering them."

Doctors who were trained early on Charité but didn't really start using them may need to be retrained if they want to start now. Dr. Guyer said, "We'll have to see if DePuy has the stomach to retrain folks. They spent a lot of money training people the first time around. Synthese has taken a slower, a much slower, approach to training."

Indeed, company marketing may play an important role in how successful these discs are in the near future. An expert said, "The reason adoption has been slow is 90% insurance reimbursement and 10% physician income. Because of the lack of insurance coverage, it lost momentum, and the company (J&J) stopped marketing it. If you did a business case study on how not to roll out a product, this would be it. I think when Sofamor Danek (Medtronic) gets its disc approved, they have a way to energize the market because they have such a strong sales force."

Asked how he would choose between Charité and ProDisc, Dr. Guyer said, "If they are put in perfectly, I don't think it makes a difference. Personally, I do both. Sometimes, a patient asks for a specific one."

Other spine companies/products

NUVASIVE. Sources generally praised the company's products. One surgeon said, "They have really been a game changer…I'm still in the beginner phase. It does have a role, and it is neat technology. I really think it is mature enough now."

SYNTHESE. Though the company was described as "a little behind with percutaneous pedicle screws," it is developing an anti-adhesion patch for lumbar spine to make revision easier that looks interesting, and it got N-Hance with the purchase of N Spine, which experts predicted would find a niche.

ORTHOBIOLOGICS

Surgeons questioned at AAOS about bone morphogenic protein (BMP) use generally indicated their use is down. Why? An expert said, "It doesn't fuse."

What spine surgeons are more interested in – but still consider a few years away – are stem-cell products. One surgeon said, "My use of BMP is down because there are alternatives out there – like mesenchymal stem cells – that appear good enough at a lower cost." Another commented, "Our hospital took a very, very strong line against off-label use. I don't use Infuse (Medtronic, BMP-2) at all. I use OP-1 (Stryker, BMP-7) for revisions, but the data are not very strong. The future is stem cells, but most of the technology is just new iterations." Another spine surgeon said, "People are looking for alternatives to BMP." Dr. Guyer said, "Biologics make a difference. If I had anterior fusion, I would pay for it myself out of pocket if insurance didn't cover it…Stem cells are probably the most exciting area. They will compete with Infuse, but it will take awhile – 5-6 years. The future is tissue engineering, or whatever you want to call it, but that is maybe 10 years away."

A new, privately funded, international society dedicated to the evaluation and use of new biologic treatments for orthopedic conditions has been formed, the Biologic Orthopaedic Society (BOS), which held its inaugural meeting at AAOS. BOS is a collaborative effort of several eminent scientists who wanted to share what they learned in their own labs, to compare results, and to collaborate on promising treatments – and then to disseminate the information to the orthopedic community. Among the society's current interests: stem cell therapy for OA and other musculoskeletal conditions; platelet-rich plasma injections for chronic tendonitis, disc regeneration, and accelerated healing; BMP to repair fresh fractures; and molecular and cell biology and biomaterials for tendon-to-bone healing.

MEDTRONIC's Infuse (BMP-2)

An expert estimated that >90% of Infuse use is off-label since the product is FDA-approved only for use with the company's LT cage for lumbar spine procedures. Another expert said, "Off-label use in the cervical spine is where people got the complications. No one worked out the dose response curve in cervical. There are surgeons who use a bunch of it and swear by it. But no one knows the right amount in the neck."

In this environment, sources agreed that Medtronic has been and is continuing to lose market share in spine – but they agreed that the company will turn that around in the future. One said, "I think the smaller companies are nipping at their toes. There has been turnover in their organization from the CEO on down…We've seen sales rep turnover in our area. They are reassessing…Then, there were all the lawsuits about how much doctors were making, and surgeons had to change how they were operating. All those things have an effect."

Dr. Steven Glassman of Leatherman Spine Center in Louisville KY presented data from a prospective, randomized clinical trial conducted at – and funded by – his hospital system on the use of Medtronic's Infuse (BMP-2) for postero-lateral lumbar fusion without interbody fusion in patients over age 60. He found Infuse and iliac crest bone graft (ICBG) similarly improved health-related quality of life, but there were lower fusion rates, more complications, and more revisions with ICBG. Over two years, the mean cost was "equivalent or maybe better" with Infuse when the cost of revisions was included. He said, "Our conclusion was, in this specific group studied, BMP is both as safe and effective as iliac crest bone graft replacement in these older patients."

2-Year Efficacy of Infuse in Patients >Age 60

Measurement	Infuse n=50	Iliac crest bone graft (ICBG) n=52	p-value
Mean OR time	248 minutes	270 minutes	0.024
Hospital length of stay	5.0 days	6.0 days	0.039
Hospital readmission	28 patients	37 patients	---
Days in rehabilitation	7.4 days	8.6 days	---
Perioperative complications	8 patients	20 patients	0.014
Clinical outcomes			
Health-related quality of life	49	51	Nss
Additional surgery	4 patients	11 patients	---
Mean CT grade	4.3	3.4	---
Costs			
Initial admission	$ 34,235.26	$ 3,650.56	---
Treatment of complications	$ 1,815.54	$ 1,885.71	---
Total cost	$ 42,573.66	$ 4,131.09	---

ORTHOFIX's Trinity

Trinity is an implant alternative to autologous bone, consisting of bone matrix containing adult mesenchymal stem cells. Doctors are interested in stem cells, but most doctors questioned at AAOS were not aware of this product. A spine surgeon said, "They have good people. I think they are a player… They are one notch below the big players…and they have a lot of work to do. Their products are fantastic, but they have to rebuild their sales force. They had a predominantly distributor network, and that didn't fit well with the corporate culture… They have really, really good engineers, so their products are very, very well engineered. And top management is terrific…

The science on Trinity looks really good. They will be a top player in stem cells."

Shortly after AAOS, Dr. Shannon Rush of Mountain View CA reported at the American College of Foot and Ankle Surgeons in Washington DC that Trinity promotes bone healing in patients who have undergone foot and ankle operations. The findings were based on a 23-patient study in patients with non-union foot or ankle fracture. Bone union and healing was achieved in 21 of the patients, and they were able to walk in regular shoes with little or no pain ≥6 month post cast removal.

STRYKER's OP-1 Putty (BMP-7)

In 2001, the FDA refused to approve OP-1, but in 2004, the FDA gave it a Humanitarian Device Exemption (HDE) for new posterolateral spinal fusions in patients who had a failed posterolateral spinal fusion and who are unable to provide their own bone or bone marrow for grafting because of a condition such as osteoporosis, diabetes, or smoking – or in patients whose broken leg or thigh bones failed to heal properly. The HDE limits use to <4,000 patients a year. In April 2008, the FDA slapped Stryker for using OP-1 in a clinical trial of an off-label use without an IDE, and the Department of Justice has been investigating off-label promotion of OP-1. Then, in July 2008, the government reported potentially fatal complications associated with off-label use of OP-1 in the cervical spine. Reportedly, patients developed difficulty swallowing, breathing, or speaking and required surgery. Just after AAOS, two former Stryker sales reps pled guilty to off-label promotion and agreed to cooperate with the investigation.

An FDA advisory committee later this month is expected to consider the approval of OP-1. OP-1 failed to show radiographic healing in clinical trials, but a speaker at AAOS argued that this is because the product "tends to be pushed medially by paraspinal muscles," so the fusion can't be adequately seen in x-rays, only by CT scan. Dr. Jeffrey Fischgrund, a Michigan orthopedic surgeon, said that CT scans at 36+ months of follow-up on the 295 patients in a prospective, randomized, non-instrumented study started in 2001 found that there was bone formation, and the fusion was sustained out to 4.5 years.

Infuse vs. OP-1

Asked why there appears to be less fusion with OP-1 than Infuse, Dr. Fischgrund blamed it on a tougher patient population, "My goal was to find the most difficult model (to test OP-1). I knew the fusion rate with autograft was 50% in these patients…and I figured if it worked in that situation, I was confident I could expand that to use with pedicle screws…I think, from a scientific point of view, we accomplished our goal, but the numbers I got were what was expected."

Demineralized bone matrix (DBM) products

A study of 10 production lots of each of three different DBM products (which weren't named) found extreme variability from lot to lot in the concentrations of BMP. The pg/mg varied tremendously from lot to lot, though the averages were similar across the three products. The speaker suggested that BMP-2 and BMP-7 assays might be used to screen and optimize DBM products for greater osteoinductive potential prior to clinical use.

Asked how doctors should respond to a project that "if it was a food or drug would be taken off the market for variability of content," the speaker said, "Now DBM copays realize that with so many companies on the market they really have to, perhaps for marketing purposes, screen their products…The companies are having difficulties as well…The general trend is in the right direction, but that is one of the trade-offs with DBM and BMP. DBM is a lot cheaper, but BMP has its own issues. It's kind of a trade-off."

NEGATIVE PRESSURE WOUND THERAPY

Negative pressure wound therapy (NPWT) was basically the province of Kinetic Concepts (KCI) until September 2008 when Smith & Nephew got its Renasys system approved by the FDA for in-hospital use. One estimate is that 21% of NPWT use is related to orthopedics (including trauma).

Thomas Dugan, president of North American business at Smith & Nephew's advanced wound management division, sees NPWT as a growth area for his company, with the goal of taking market share from KCI; he doubted that Smith & Nephew's entry into the market would expand use of NPWT, "It is a huge market – more than $1 billion in the U.S.… Clinicians will finally have a choice about the type of interface – KCI's foam or our gauze dressings…Our goal is not to expand the market. I think our goal is to get in and show clinicians that our products are viable alternatives and that they will get similar outcomes. We will focus on that initially …The net effect may be expanding the market. I hope so. But that is not our main objective. KCI has done a nice job of expanding the use."

Dugan said Smith & Nephew's Renasys gauze interface has advantages over foam, "Because clinicians only had a foam choice, that is clearly what most use and with good results, but there are a lot of clinical reasons to use gauze for certain types of wounds – irregular wounds, fistulas – that are not particularly well-suited to foam…For plastic surgery, you get a smoother surface with gauze than foam. So, we are seeing a lot of interest in having a choice…We have a lot of capabilities in products for basic wounds. That was the genesis of Smith & Nephew, and we are very, very good at that. And we have a lot of sophisticated products for taking care of that."

Another reason Dugan believes Renasys will cut into KCI's market share is that Smith & Nephew "has a broader line" of wound care products, "We will talk about using Renasys, and maybe transition patients to another advanced wound product without negative pressure, and we have other products…KCI can't do that."

What was the reaction to Renasys at AAOS? Dugan said, "Very good. We've had a lot of clinicians who were not aware we had the product, found out through orthopedic interactions, and came over and asked the sales rep to call."

How does the pricing of the two companies' products compare? Dugan said the initial pricing is similar, but the total costs of Renasys may be less, "By the nature of gauze, it tends to be less expensive. Foam is changed every 48 hours, and gauze every 72 hours. So, there is some economic benefit to hospitals and healthcare systems."

KCI announced during AAOS that it had been subpoenaed by the Office of Inspector General (OIG) regarding its Medicare billing practices. KCI indicated that the government investigation is in its initial stages. In its 10K filing with the Securities and Exchange Commission (SEC) recently, KCI indicated the OIG "initiated a study on negative pressure wound therapy, or NPWT, in 2005. As part of the 2005 study, KCI provided the OIG with requested copies of our billing records for Medicare V.A.C. placements. In June 2007, the OIG issued a report on the NPWT study including a number of findings and recommendations to CMS. The OIG determined that substantially all V.A.C. claims met supplier documentation requirements; however, they were unable to conclude that the underlying patient medical records fully supported the supplier documentation in 44% of the claims, which resulted in an OIG estimate that approximately $27 million in improper payments may have been made on NPWT claims in 2004… The OIG report…does not constitute a formal recoupment action."

Just after AAOS, the FDA approved Smith & Nephew's Renasys GO, a smaller, mobile, lightweight version of NPWT, and the company plans to launch it this month. Renasys GO can be used at home, on the go, in a long-term care facility, etc. A study conducted in Ontario, Canada, by Nursing Practice Solutions found that the average total cost of treating wound patients was 55% less with NPWT than with conventional dressings, and the wounds healed faster with NPWT. There was no difference in healing time between wounds dressed with foam and those dressed with gauze.

VALUE BASED PURCHASING (VBP)

Value based purchasing – where value equals quality divided by cost – is an important topic and increasingly is affecting orthopedic surgeons as well as other physicians, but a session at AAOS on VBP was only lightly attended. A speaker noted, "It is hard to make the case that the quality of (orthopedic) care has increased over the past 10 years, but the cost of total joint replacement has doubled."

Dr. James Robinson, a professor of health economics at the University of California, Berkeley, pointed out, "The biomedical industries have long enjoyed unsophisticated purchasers (hospitals and insurers) and cost unconscious demand (patients and companies). This has permitted extensive innovation but also consistently high prices, inefficiency, and unjustified variations in use…Orthopedic surgery is a main area of focus (by the government, hospitals, and insurers)…The U.S. healthcare system is moving towards a greater role for consumers/patients in choosing and paying for care. Cost-sharing is rising and will directly impact patient care. Hospitals want to be able to benchmark the prices they pay against those paid by other hospitals but are hampered by contract clauses that prevent disclosure to third parties. Proposed federal legislation (favored by Sen. Charles Grassley) would force price disclosure."

Dr. Robinson said the key components of VBP are:

- Integrated data systems that measure performance across the care continuum.
- Payment methods with incentives among all contributors and reduce conflicts of interest, such as bundling.
- Organizational structures that support, coordinate, and foster a culture of cooperation.

The challenges to surgeons from VBP are:

- Downward pressure on surgical fees.
- Rising adverse publicity (for consulting and specialty hospital/ASC self-referrals). "What's real doesn't matter; the public is increasingly disenchanted."
- Concerns over quality and appropriateness. "There are unexplained geographic variations in hospital readmissions and 'never events.'"

In the short term, Dr. Robinson predicted VBP would mean hospitals will assess new technology and devices prior to purchasing them; share data on device prices and performance – transparency, which means hospitals will need to eliminate price confidentiality clauses; seek physician leadership in deciding which functional level of device is needed for which patients; and collaborate on negotiating device prices – limiting use of contract "list price" devices. Doctors will still be able to pick what is best for patients but should understand what their choice is costing the hospital. In the longer term, VBP will lead to some form of bundled (episode of care) pricing to support joint accountability.

The CMS perspective

Dr. Mark Levine, chief medical officer of the Denver region for the Centers for Medicare and Medicaid Services (CMS), called VBP important and "evolving."

What does VBP mean to CMS? Dr. Levine said, "(CMS wants to) transform Medicare from a passive payer to an active purchaser of high quality, more efficient healthcare…We have a number of initiatives – all variations on value based pricing …and we are continuing to evolve them…Increasingly, the politicians are aware something must be done…The business of medicine in the future will not look like the business of medicine in the past…Basing value based purchasing on just a procedure (e.g., surgery for osteoarthritis of the knee) and not the well-being of the patient is short-circuiting our ability to look at value based purchasing from the perspective of the patient, which is where I think we need to put more and more of our energy in VBP."

While e-prescribing is a big federal initiative, Dr. Levine noted that it probably doesn't apply much to most orthopedic surgeons. He urged orthopedic surgeons to adopt e-prescribing.

The employer point of view

David Lansky, PhD, a consultant with Pacific Business Group on Health, said the questions employers are asking are: "Is the enormous increase in device costs leading to improved outcomes, or why are we implanting these much more expensive devices? Can you show us the gain for our employees for the money we are spending?...Is there a particular rationale that this discipline doesn't lend itself to more uniformity in (device selection)?"

Dr. Lansky said that in orthopedics employers are primarily interested in functional improvement, though clinical stability (revision rate) and perioperative outcomes are also a concern. But he said there are little data available on functional improvement, and what data there are suggest a high variability, "U.S. practice looks like technology and marketing drive decisions in orthopedics rather than continuous feedback."

He said the 2008 orthopedic guidelines are not very useful and wondered why the U.S. doesn't have more registries like the Swedish knee and hip registries, which he thinks are very good. He urged orthopedics to follow the example of cardiology, where there are staged levels of appropriateness and payment.

OFF-LABEL DEVICE USE

At a session on off-label use of orthopedic devices, Mark Melkerson, an FDA biomedical engineer, told surgeons that the FDA concern is that devices used off-label are not subject to premarket evaluations so the safety for human use is not known. Among the off-label areas he indicted the FDA is particularly concerned with are:

- BMP.
- Spinal fusion hardware used as a dynamic stabilization (non-fusion) system for adjacent level protection.
- Unapproved combinations of joint prostheses from different manufacturers.
- Spinal staples used to treat pediatric scoliosis in non-fusion procedures.

Melkerson urged orthopedic surgeons planning to use a device off-label to be well-informed about the product, base their decision on "firm scientific rationale and sound medical evidence," maintain records, report any related adverse events, and participate in clinical trials and registries, including post-market surveillance studies.

Tanisha Carino, PhD, of Avalere Health, a former CMS analyst, cited several issues to be watched during the new administration, including:

- Will the new CMS administrator draft new guidance on "reasonable and necessary"?
- Will the new administration take a more activist approach by initiating national coverage decisions on high-cost technology and off-label use of drugs and devices?
- Will CMS's Clinical Trials Policy (CTP) be opened for reconsideration?
- Will the comparative effectiveness proposal affect orthopedics? She said a comparison of hip resurfacing and hip replacement is likely to be one area examined.

Patrick Hurd, an attorney with LeClairRyan in Richmond VA, warned that Sen. Charles Grassley "hates" the FDA's decision not to consider manufacturers' use evidence-based science as off-label promotion, and he said Sen. Grassley "wants to tighten" that up. He said another piece of "not so good news" is that the Agency for Healthcare Research and Quality (AHRQ) is questioning the compendia used to justify off-label uses of oncology drugs, and U.S. Attorneys have been targeting doctors directly in Medicare fraud investigations. But Hurd told orthopedic surgeons, "Don't get too spooked."

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