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ARTICLE

Sales Representative Credentialing...at what price?

By Jim R. Rogers

As the debate continues regarding certification and credentialing of medical device company sales representatives, the ultimate question is, at what cost? A secondary but critical question is this: as the cost increases, will it lead to an inevitable slowing of technological development and innovation?

Most medical device manufacturers support the ideas that are advanced with medical device sales rep credentialing. All device manufacturers would agree with the position of the Association of Perioperative Registered Nurses (AORN) that “the industry representative plays an incredibly important role in the clinical setting, in terms of training, support and guidance with new technology.”

At the same time, AORN wants to make sure that sales reps are trained in OR protocol, aseptic technique and do not provide any unneeded risk while in the OR. Furthermore, AORN has always viewed sales representative credentialing in the context of the organization’s overall mission, which emphasizes safety, optimal outcomes and professional support and collaboration.

As the debate rages, regulators continue to hammer out a statement of consensus on sales rep credentialing, or at least an effort at standardization, which was to be presented to the Joint Commission. The Joint Commission is examining credentialing standards for the entire industry.

While everyone would agree that sales reps should learn and observe any hospital rules and policies regarding appointments, check-in and patient privacy and safety, manufacturers’ concerns with continued pressure on credentialing have been well publicized. Such concerns

include: cost of credentialing, lack of credentialing company standards, impact to manufacturers and, more importantly, to end-users, on product innovation and ultimately, denial of access into hospitals.

Without a move towards standards, representatives can expect delays and roadblocks in their ability to provide technical support or innovation, as well as additions to the cost of care. With every hospital potentially using a different service or set of procedures, the patchwork of rules can be overwhelming for a sales representative trying to serve his or her surgeon customers.

Device sales representatives can develop close relationships with physicians because of the time spent training on new, innovative products and servicing surgeons during routine cases. Surgeons view most sales representatives as a valuable resource and in many cases ask for input and guidance on the use of products. It is the sales representative’s expertise, gained across countless surgeries and multiple surgeons, that often means the difference between a good, smooth surgery and one that has problems and complications.

Therefore, the relationship between the sales rep and surgeon is vital to patient care. The amount of work and time that goes into these relationships, and the need for them, can be easily overlooked by facility administrators. But a sales rep provides education, service and collaboration on all levels.

The main concern of all parties in this environment is ultimately the sacrifice of patient care. As hospitals tighten up on credentialing and limit the interaction between the sales

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Credentialing...

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representative and surgeon, it is easy to overlook its effect on device innovation. Medical device manufacturers, however, are keenly aware of what the extra costs and trouble mean to them.

The increased cost associated with credentialing is just the first of many challenges for device manufacturers. Device manufacturers' main mission has always been to improve patient lives with better devices. To do this, sales representatives need to be able to have meaningful conversations with surgeons about current products and future innovations.

With many sales representatives working through distributors, credentialing has become a financial roadblock and a very time-sensitive issue.

As a new representative, many times one is faced with bearing all the costs associated with credentialing. These can include immunizations, which can often run to more than \$300.

Many hospitals provide these services for a fee to a sales rep prior to acceptance, but the rep must complete the application process with the selected vendor credentialing service before he/she may be granted admittance to the OR.

Once immunizations are completed, then the sales representative must complete the required training in areas such as bloodborne pathogens, patient privacy and security (Health Insurance Portability and Accountability Act or HIPAA), aseptic techniques and hospital procedures.

Further, they often must register for the various credentialing services, which can increase the cost by \$250 per needed credentialing service.

All of this must be done in addition to whatever product training is required by the manufacturer and the hospital.

In a more recent series of developments, many hospitals are requiring all representatives to carry product and personal liability insurance that goes beyond the manufacturer's insurance

that has always been required. This also can be a direct cost to sales representatives and can become very expensive.

This all is done in order for the sales representative to service his customer, the surgeon. To avoid these burdens, sales representatives during the course of product introductions can attempt to see surgeons at their private offices. This too can present a challenge, however.

As surgeons find themselves seeing more and more patients, time constraints become a constant issue. At most offices, appointments for product introductions or innovations must be set months in advance.

In a few cases, it has been reported that some surgeons are actually charging a fee to see the sales rep. This will absolutely discourage the sales representative from presenting product developments and new innovation or training. More obstacles will equal a burden on innovation.

When people argue in the support of any regulation, they must remember the role of a professional medical sales representative.

Dr. Mark Domanski's telling letter to the editor of *The Washington Post* made the case eloquently. He said, in part:

"As a surgeon, I always want a company rep in the operating room.

Here's why:

Remember when you tried to assemble that desk you bought from a furniture store? We all know how to use a screwdriver, but when something is off, it's nice to know there is a number to call.

What if you needed to put that desk together quickly because you needed it for something important? It would be nice if the company sent someone to make sure all the parts were there and in good order. That's what a good rep does.

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As the cost increases, will it lead to a slowing of technological development and innovation?



Credentialing...

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As the surgeon, I make the diagnosis and decide the treatment. No company representative tells me how to use a knife. But

many products in the operating room are complex and change almost every year; they are getting better that fast.

When I am using a complex product, such as plating system for fixing a jaw fracture, having the rep in the room ensures that the system is functional. I know all the parts will be there. I know that the right screw and plate will be handed to me at the right time.

Sometimes we call in the rep for an operation, and it turns out that the fracture does not need to be plated. No rep has ever suggested that I plate a fracture that didn't need to be plated.

So, if you were having surgery that involved a complicated piece of equipment, wouldn't you like somebody from the manufacturer to be there? I know I would."

Mark Domanski, M.D., Arlington
The Washington Post, Letter to the Editor
January 5, 2010

At the American Institute of Medical Sales (AIMS), the goal is to train a more professional generation of sales reps than had previously existed. This begins with the concepts that credentialing attempts to cover: sterile technique, OR protocol and understanding of bloodborne pathogens. However, we attempt to train beyond these issues.

It is our belief that professional sales representatives should understand the world of the hospital and the world of the surgical team well enough to be valuable members of that team.

This begins with an understanding of how and when to present new products, technologies, instrumentation and concepts to surgeons and other hospital buyers. The training that goes into a good rep goes well beyond how to close the sale.

A professional sales representative knows how his or her implants work, understands the flow of a case and knows what options are available when everything does not go as planned during the surgery. They are an important part of the case when things are perfect, but an absolutely vital part of it when things go wrong.

Between his personal knowledge and direct access to his company's key employees and consultants, a well-trained, professional rep can literally mean the difference between success and failure in some cases.

When training, we strive to teach beyond the basics that are typically (and correctly) required for most credentials. We train reps to know how to think and act in a way that makes them indispensable, both to their surgeon customers and to the hospitals those surgeons operate in.

We at AIMS have not sided with either the medical device sales rep credentialing companies or device manufacturers, per se. Our process is to educate and prepare sales reps for their careers through training. Our biggest concern is with the quality, timing and availability of patient care.

Device manufacturers continue to provide innovative products that improve the quality of life for patients. It would be a shame to deny any patient the opportunity to partake in this technology due to roadblocks, bureaucracy or lack of efficiency within our medical system.

Jim Rogers is Founder and Chief Executive Officer of Denver based American Institute of Medical Sales, a provider of sales representative education and training (www.aimedsales.com).

Prior to AIMS, Jim spent over ten years as a sales rep for Stryker and Vice President of U.S. Corporate Sales for Wright Medical. He can be reached at jrogers@aimedsales.com.



YEARLY REVIEW

A First Look at 2009 Results

At press time, four of the major recon companies had reported 2009 financials. Their year-over-year growth is shown in Exhibit 1, and in the next issue, we will add in results reported during this month to present the fuller picture of 2009 market growth.

Performance highlights follow for all orthopaedic companies that have announced 2009 results to date. Also, we feature notes from Anika's recent conference call following its acquisition of Fidia Advanced Biopolymers.

ANIKA THERAPEUTICS

Acquisition of Fidia Advanced Biopolymers (FAB)

- Transaction details: ~US \$17.1MM in cash, ~2MM shares of Anika common stock
- FAB develops hyaluronic acid-based products, e.g. for tissue regeneration
- Orthopaedic line includes:
 - ◆ Hyalograft C Autograft
 - ◆ Hyalonect
 - ◆ Hyaloglide
 - ◆ Hyaloglide mini
 - ◆ Hyaloss
- HYAFF polymers may be formed into films, fibers, non-wovens and gels
- Hyalograft C has been used to treat cartilage injuries in >4,800 patients in >200 clinical studies in past 9 years
- Orthopaedic portfolio provides critical mass of products to sell in U.S. alongside MONOVISC, following regulatory clearance (cursory data on MONOVISC suggests strong performance)

- Many of FAB's orthopaedic products may only require FDA 510(k) clearance to begin commercialization – could have at least 3 available for sale in U.S. before end of 2010
- Pipeline products include some for spine, either close to CE Mark approval or CE Mark in progress
- Sales force should be substantially established by 3Q10, using hybrid sales model of reps plus contract sales organizations
- Will leverage FAB's distribution partners in Asia and Europe to enhance MONOVISC sales (including >100 reps in Italy)

BIOMET (for fiscal 2Q ended 11/30/09)

- \$695.6MM, +8%*
 - ◆ Reconstructive \$528.4MM, +9% (Hips +4%, Knees +12%, Extremities +27%, Other +2%)
 - ◆ Fixation \$57MM, -3%
 - ◆ Spine \$58.9MM, +6%
 - ◆ Other \$51.3MM, +8%

*Growth excludes dental.

General

- Excise tax could fall in range of \$25MM-\$30MM for company
- Expecting slightly better environment in Europe into next year as governments go to new spending budgets
- In U.S., slight negativity in price a little bit more than offset by mix, so net price mix was positive – expecting more of the same for the future
- Continue to see low single digit negative price in Europe

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EXHIBIT 1
ORTHOPAEDIC SALES¹ INCREASES BY PRODUCT SEGMENT: 2009 TO 2008

Company	Hips	Knees	Extremities	Fixation	SportsMed	Spine	Total
Biomet ²	7%	11%	20%	0%		11%	8% ³
DePuy	12%	9%			15%	9%	10%
Stryker	5%	6%		6%	-1% ⁴	11%	3%
Zimmer	-2%	2%	14%	6%		12% ⁵	2%

NOTES TO EXHIBIT 1

¹Orthopaedic products only; constant currency, pro forma growth

²ORTHOWORLD estimates for the year ended November 30, 2009; trauma includes stimulators; spine includes stimulators and orthobiologics.

³ORTHOWORLD estimate (excludes dental)

⁴Long bone (U.S.) and spine, respectively

⁵ORTHOWORLD estimate for pro forma sales without Abbott Spine



2009 Results...

(Continued from page 4)

- Impact of pricing in Japan should be known in 4/10, expecting enough volume growth to have significant positive growth in Japan, regardless of reimbursement pressure

Recon

- Hips driven by Ringloc and Regenerex Ringloc + cups, E1 Antioxidant Infused bearings, Biolox Delta ceramic heads, M2a-Magnum Tri-spike cups
- Metal-on-metal and E1 as a combined category still growing faster than ArCom
- Strong growth in Europe from Exceed ABT acetabular system
- U.S. advanced bearings recording higher growth than standard line of hip bearings
- Performed first cases with Arcos Modular Revision Hip, received very good feedback; clinicians can intraoperatively choose from a range of components with a single set of instruments; will be a critical growth driver for hips in FY2011
- Knees led by Vanguard primary and revision, E1 infused bearings, Signature Personalized Patient Care, Regenerex Primary Tibial Trays
- In “early innings” of total knee instrumentation, and in seeing how that technology can expand to other parts of business
- 8th consecutive quarter of double-digit global extremity sales growth (6th consecutive for U.S.)
- Extremities growth driven by Comprehensive Primary and Reverse (latter gaining “excellent market acceptance”), Comprehensive Fracture and Copeland Shoulder systems, as well as Discovery elbow
- Ex-U.S., T.E.S.S. Anatomical and Reverse shoulders performing well
- Courses for Comprehensive Shoulder continue to exceed capacity

Trauma and Spine

- U.S. fixation growth supported by Phoenix Ankle Arthrodesis Nail, Forerunner Plate, OptiLock Proximal Humeral Plates, Pediatric Locking Nail
- Released 175 sets of expansion inventory to boost U.S. internal fixation sales, will release additional 125 sets in 3Q10 including OptiLock, BioDrive Cannulated Screws
- Will launch TraumaOne in select ex-U.S. markets during 3Q10
- Seeing strong acceptance of OnPoint diagnostic system for temporomandibular joint

syndrome and Microfixation TMJ replacement system

- Legacy external fixation continues to decline
- Submitted Premarket Approval supplement for OrthoPak stimulation platform early in quarter, subject to 180-day FDA review
- Will launch lighter, smaller redesign of OrthoPak as well as revamped SpinalPak stim device in 4Q10, with EBI Bone Healing System to follow in 2Q11
- 5th consecutive quarter of global spine growth (8th consecutive for U.S.)
- Double-digit growth of spinal hardware offset by decline in spinal stim and biologic sales
- Continued strong acceptance of Polaris line; Polaris Deformity system now offered in titanium, stainless steel and cobalt chrome
- Cervical sales led by MaxAn Anterior Cervical Plate
- Ex-U.S. spine sales led by Synergy and Array systems
- Two-day technique and technology course for spacer, thoracolumbar and cervical products attended by ~100 surgeons
- Working on development program for lateral fusion market

Other

- Will launch Cobalt MV (medium viscosity) bone cement in second half of FY2010
- Biologics generates <\$100MM annually, continues to generate double-digit growth
- In second half of FY2010, will launch Bio-Q Platelet Concentration System
- Double-digit sports medicine growth partially offset by decrease in soft goods/bracing sales
- Sports med driven by ToggleLoc Femoral Fixation device, ComposiTCP interference screw, MicroMax flex suture anchors and new ZipTight Fixation system
- In second half of FY2010, will introduce Juggernaut soft suture anchor, a completely suture-based system for shoulder repair

CONMED

- \$413.8MM, -4%
 - ◆ Arthroscopy \$269.8MM, -4% (Single-use \$196.5MM, +2%)
 - ◆ Powered Instruments \$144MM, -4% (Single-use \$76.3MM, +1%)

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2009 Results...

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- Maintains cautious optimism that the worst is behind us, but notes potential impact of continued high unemployment
- Cost-cutting programs did not affect numbers in this quarter, but that could start in 2010
- Not necessarily counting on a big bolus of business coming through due to pent-up demand
- Both U.S. and ex-U.S., arthroscopy and powered instrument growth up sequentially
- Strong acceptance of Shoulder Restoration System and new products for arthroscopic repair of anterior and posterior cruciate ligaments

DEPUY

- \$5,372MM, +8% (US \$3,096MM, +8%; ex-U.S. \$2,276MM, +7%)
 - ◆ Hips +12%
 - ◆ Knees +9%
 - ◆ Spine +9%
 - ◆ Sports Medicine +15%
- Challenges of economic downturn continue to put pressure on hospital budgets, while unemployment constrains access to healthcare
- Saw continuing slight price declines of 1% quarter on quarter in orthopaedics
- Acquired Finsbury Orthopaedics, hip implant manufacturer
- Still awaiting final decision from FDA on Pinnacle CoMplete Acetabular ceramic-on-metal cup

KENSEY NASH (for fiscal 2Q ended 12/31/09)

- \$6.0MM, -16%
 - ◆ Spine \$2.8MM, -14%
 - ◆ Sports Medicine \$3.1MM, -16%
 - ◆ Other Orthopaedic \$0.1MM, -30%
- Orthopaedic royalty revenue +12%, includes \$1.5MM from Orthovita
- Will launch extracellular matrix product line with Synthes in second half of FY2010
- Expects to receive CE Mark Approval "very shortly" for cartilage product
- Has not initiated U.S. trial for cartilage product, but expects to commence before end of FY2010; confident in resources to take this product all the way through clinical trials
- Expects to report an improvement in sports medicine numbers in 3Q

MEDICREA

- \$18.8MM (€13.1MM), +45%
- Medicea USA \$8MM, +122%
- Medicea Europe Francophone +40%, just launched Granvia cervical disc
- Medicea U.K. \$1.3MM (€0.8MM), +700%
- These three distribution subsidiaries contribute 65% of sales
- Sales driven by PASS-LP thoracolumbar fixation system
- Product pipeline includes X-JAWS and L-JAWS, lumbar versions of the K-JAWS cervical compression staple
- Medicea USA is implementing a local sales team to complement current commission-based agents

ÖSSUR

- Bracing/Support \$161.7MM, -9.5%
- Discontinued third party supplier agreements continue to affect sales
- Within 2009, launched the HipTrick hip support and Miami Lumbar spinal orthoses for post-surgical immobilization and pain relief
- U.S. Bracing/Support stabilizing due to:
 - ◆ Access to hospital channel through new group purchasing organizations
 - ◆ Investment in increased number of sales representatives
 - ◆ Two minor acquisitions of distributors

STRYKER

- Total orthopaedic* sales \$6,271.1MM, +3%
- Orthopaedic Implants \$4,119.7MM, +4%
 - ◆ Hips +5% (U.S. +7%, ex-U.S. flat)
 - ◆ Knees +6% (U.S. +10%, ex-U.S. -1%)
 - ◆ Trauma +6% (U.S. +11%, ex-U.S. +3%)
 - ◆ Spine +11% (U.S. 4%, ex-U.S. +14%)
 - ◆ Craniomaxillofacial +9%
- MedSurg Equipment \$2,603.4MM
 - ◆ Instruments \$1,210.2MM, +2%
 - ◆ Endoscopy \$941.2MM, -1%

*ORTHOWORLD estimate; excludes medical. MedSurg includes patient handling and emergency medical equipment.

- Global total company price down ~1%
 - ◆ Still experiencing low single digit price declines in U.S. hip and knee
 - ◆ Trauma and CMF realizing price gains
 - ◆ Spinal implants has ongoing price pressure, second half more dramatic than first half of year, but 4Q vs. 3Q was substantially in line
 - ◆ Pricing flat ex-U.S. due to declines in Japan, offset by favorable dynamics in other regions

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2009 Results...

(Continued from page 6)

- ◆ Assuming that impact from Japan will be “less bad” than it was the last time
- Continuing to focus on ex-U.S. expansion in instruments and endoscopy
- Level of 510(k)s will start to turn around closer to 2011
- Accolade, X3 and Trident consistently driving hip growth
- Rejuvenate modular stem not 100% fielded to salesforce, but beyond 50% mark
- Metal-on-metal hips appear to have stabilized at ~1/3 of the market; will continue to monitor it
- Triathlon knee continues to gain broad acceptance ex-U.S.
- Trauma slowdown largely driven by the economy, as a “fair chunk” of trauma comes from construction-related and driving incidents
- Ex-U.S. trauma sales supported by sizable gains in Pacific region, offset by softer performance elsewhere
- Third consecutive quarter of double-digit ex-U.S. spine growth
- U.S. spine will be slower over next couple of quarters due to increasingly price sensitive market, internal product introduction delays, gaps in product offering (such as a cervical plate) – but no slowdown observed in overall spine market

OP-1 Update

- Still evaluating a host of strategic options; process taking longer than anticipated
- Early clinical data demonstrates promising efficacy in the soft tissue market

Acquisition of Ascent Medical

- Reprocessor of single-use medical devices
- Will be reported under MedSurg, not broken out as a separate line item
- Represents a new growth platform in a high-growth market, on the right side of cost containment, value-added medical technology and environmental responsibility
- Long-term opportunity to leverage physician relationships, hospital presence
- Attractive pipeline of 510(k) filings
- Longer-term potential for ex-U.S. expansion

ZIMMER

- \$3,893.0MM, +2%
 - ◆ Hips \$1,228.0MM, -2%
 - ◆ Knees \$1,761.0MM, +2%
 - ◆ Extremities \$136.0MM, +14%
 - ◆ Trauma \$234.8MM, +6%
 - ◆ Spine \$253.6MM, +12%
 - ◆ Orthopaedic Surgical/Other \$277.6MM, flat

General

- Price pressures persisted throughout 2009
- Expects another year of moderate price erosions of -1% to -2%, will offset negative price mix with positive mix from new product contributions
- Expects impact of pricing in Japan to mirror that of prior periods
- Exceeded objective of training >20,000 surgeons/clinicians in 2009; early signs for courses on new products indicate high interest

Recon

- For 4Q knees, volume and mix growth of 6.2% partially offset by negative price of 0.7%
- For 4Q hips, positive volume and mix of 0.4%, less negative price of 0.8%
- Ex-U.S. hips led by M/L Taper Hip with Kinectiv technology and Fitmore stem
- Feedback remains positive on new MMC and Continuum acetabular cups, expecting significant traction for products in second half of 2010
- In developed countries in Europe, primary markets slowed down more profoundly in hips than in knees
- Knee growth led by Asia Pacific and Americas (+10.3% and 6.2%, respectively), but knees lagging somewhat in Europe
- Flex knees at 57% of knee unit sales globally in 4Q, second consecutive year of >50% of annual knee unit sales for this product
- Patient-specific instruments for knee procedures very well-received in early stages of U.S. and ex-U.S. launches
- Trabecular Metal Should Glenoid experienced continued rapid sales growth in 4Q

Trauma and Spine

- Trauma growth strong in Europe in 4Q, driven by launches in IM nails
- Will round out remainder of nail launches in second half of 2010, finishing femoral options and then starting on humeral
- Spine still challenged by Dynesys reimbursement issues
- Nearing the end of Abbott Spine integration effort
- Abbott revenue contribution consistent with past quarters (~\$20MM)
- Pathfinder II and other minimally invasive spine offerings form comprehensive coverage for segment in 2010

Sources: Company conference calls, press releases, JPMorgan Healthcare Conference

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FROM OUR NATION'S CAPITOL

Developments Affecting the Healthcare Industry

As the actions of Washington increasingly affect our livelihood, we will continue to keep an eye on the various hearings, developments, proposed rules and events. Here are some of the more recent happenings. Watch for more in future issues.

FDA Issues Guidance for Device Trials

FDA has issued guidance on the use of Bayesian statistical methods in the design and analysis of medical device clinical trials that could result in less costly and more efficient patient studies.

The Bayesian method applies an algorithm that makes it possible for companies to combine data collected in previous studies with data collected in a current trial. FDA noted that the combined data may provide "sufficient justification for smaller or shorter clinical studies." FDA has cleared a number of medical devices whose approval applications submitted to the FDA included clinical studies that used the statistical methods.

The final guidance, titled *Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials*, describes use of Bayesian methods, design and analysis of medical device clinical trials, the benefits and difficulties with the Bayesian approach, and comparisons with standard statistical methods. The guidance also presents ideas for using Bayesian methods in postmarket studies. See www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071072.htm#7

FDA Budget for FY 2011 to Rise 23%

The Obama administration is proposing to increase FDA funding by 23% in fiscal 2011 as part of the agency's effort to transform the way it regulates products.

The proposed budget of \$4.03BB reflects FDA's intention to address key initiatives including those to:

- ◆ Protect patients to ensure the safety of drugs, devices and vaccines (an extra \$100.8MM)
- ◆ Modernize FDA regulatory science and strengthen the agency's core scientific capacity (an extra \$25MM)

President Obama Calls for Bipartisan Summit on Healthcare

Republicans and Democrats from the House and Senate are invited to participate in a televised,

half-day summit to occur on 2/25/10 to talk about how to pass an overhaul of the U.S. health-care system.

Options previously discussed:

- ◆ The House may vote on the Senate-approved measure
- ◆ The House could consider the Senate bill along with House and Senate votes on a companion package of House amendments, using a Senate parliamentary procedure of budget reconciliation that would only require 51 Senate votes to pass
- ◆ Attempts could be made to develop a scaled-down bill to gain bipartisan support
- ◆ The legislation could be shelved

FDA Public Meeting/Comment Request on Incorporating New Science Into CDRH Regulatory Decisionmaking

FDA convened a public meeting on 2/9/10 to discuss measures for incorporating new science (i.e., novel technologies or novel uses of existing technologies, evolving information and knowledge or new methods to support decision-making) into the FDA Center for Devices and Radiological Health decisionmaking processes. The comment period closes on 2/24/10. See edocket.access.gpo.gov/2009/pdf/E9-30114.pdf and www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm191579.htm.

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