



# MCRA OVERLOOKING THE HILL

August 2009

## INTRODUCTION

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### U.S. Healthcare Finance Remains a Major Focus of Federal Regulators

US healthcare finance reform legislation continues to dominate discussion. From Capitol Hill to town hall meetings, citizens are engaged in debate as to whether health care reform is required, and what reforms are necessary. House Democrats propose a government-run insurance program to compete with private industry, along with compulsory coverage by employers with greater than 25 employees, and other changes which are being challenged now by Republicans and other stakeholders. Most notably, the America's Affordable Health Choices Act (H.R. 3200) passed the House Energy & Commerce Committee by a vote of 31 to 28. A preliminary analysis completed by the United States Congressional Budget Office estimates the proposed bill would increase the Federal deficit by approximately \$239 billion over the 2010 – 2019 period. The CBO calculates offsets by net savings of \$50 billion, additional revenues of \$86 billion, resulting in a net increase in deficit spending of approximately \$65 billion by 2019.

Prior to its recess, the Senate Health, Education, Labor & Pensions Committee approved its version of health care reform by a vote of 13 to 10 (Quality, Affordable Health Coverage for All Americans). The US Senate Finance Committee, which shares jurisdiction over health reform legislation, was unable to act upon a bill and must build greater consensus within political ranks to produce a compromise bill. Major considerations within the three most prominent bills concerning U.S. health care reform legislation include: compulsory coverage for individuals, subsidized by the government below defined income thresholds, employer-mandated coverage, introduction of a public health plan option, expansion of purchasing cooperatives and other provisions. Thus, health care reform legislation remains a major focus of discussion within the United States, with no clear resolution in expected in the immediate future.

While the nation's focus remains on major health care finance reform, regulators continue their focus on topics including comparative effectiveness, transparency and medical device safety legislation. Senators Baucus and Conrad introduced additional legislation on June 9 to enable comparative outcomes research by amending 42 U.S.C. 1301 et seq and establish a new, not-for-

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profit, organization to known as the Patient-Centered Outcomes Research Institute.

On August 4, 2009, the U.S. Senate Committee on Health, Education, Labor & Pension (HELP) conducted hearings on S.540 entitled Medical Device Safety Act of 2009. This bill seeks to retroactively reverse the U.S. Supreme Court ruling in *Riegel v. Medtronic, Inc.*<sup>2</sup> Additional bills may be found at the end of this newsletter, or through Senate and House web sites.

In other news, Medicare published its final rule affecting inpatient hospital services, which would appear to favor orthopedic technologies. Incremental changes to the Medicare's outpatient draft rule continue, and within this edition of *Overlooking the Hill*, Reimbursement Director Tim Hunter examines rule changes and their effects on biologic technologies. Consultants Jeff Zigler and Adam Herder evaluate FDA's reclassification of twenty-five Class III medical technologies, while Patent Director Urmi Chattopadhyay and Analyst Andy Riutta continue their discussion about patent management and share their PTO experiences in how to obtain and maintain valuable exclusionary rights.

Medical technology companies must remain vigilant in their review of administrative and regulatory changes which may affect future innovations. Playing an active role in the regulatory process, sponsorship of quality clinical and economic data, and communication of its value message will continue to be required to ensure timely access to technology innovations. MCRA consultants will continue to monitor legislative activities and evaluate how regulatory trends may affect strategic planning of its medical device and biologic customers. ■

## INSIDE THIS ISSUE

FDA's Reclassification of Major Device Types: Rationale and the Impact on Orthopedic Sectors.....	2
Medicare FY 2010 IPPS Final Rule: Impact Analysis for Orthopedics.....	4
Medicare Consideration of Rule Change for Implantable Biologicals in the Hospital Outpatient Setting Should Benefit Competing Medical Devices.....	5
The Value of Invention Documentation.....	7
Legislative Watch.....	8

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<sup>2</sup> For an audio / video replay of this hearing, please visit [http://help.senate.gov/Hearings/2009\\_08\\_04/2009\\_08\\_04.html](http://help.senate.gov/Hearings/2009_08_04/2009_08_04.html) (202) 552-5800.



# MCRA

## OVERLOOKING THE HILL

August 2009

### FDA's Reclassification of Major Device Types: Rationale and the Impact on Orthopedic Sectors

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Since its introduction into the Federal Register on April 9, MCRA consultants have been advising clients and addressing the impact of an FDA Order requiring manufacturers of 25 types of Class III medical devices, including some in major orthopedic sectors, to submit “a summary of, and a citation to, any information known or otherwise available to them respecting such devices, including adverse safety or effectiveness information concerning the devices...”<sup>2</sup> This article describes the background and rationale behind these required submissions, due in to the Agency by August 7, and explores the potential impact on medical device manufacturers that they may have.

The FDA's Order follows a January GAO report, which assessed the status of the FDA's review process for certain ‘preamendments’ medical devices considered ‘high-risk’ based on their Class III designation.<sup>3</sup> The 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act (FDCA)<sup>4</sup> provide regulations for medical devices, including their classification and reclassification. Under the Amendments, three classes of medical devices are defined depending upon their risk, and the degree of regulatory control needed to provide reasonable assurance of their safety and effectiveness. Devices that present the lowest risk, Class I, are subject to General Controls only, which include manufacturing establishment registration, Quality System regulation, provisions regarding adulteration and misbranding, record keeping, and reporting

of adverse events. As they generally pose higher risks than Class I devices, Class II devices are subject to General Controls and a variety of Special Controls that FDA may implement from time to time. Examples of Special Controls include guidance documents, performance standards and labeling. When General and Special Controls do not provide the FDA assurance that is sufficient to ensure safety and effectiveness of a device, FDA classifies the device as Class III. Class III devices are subject to premarket approval (PMA).

The January GAO report noted deficiencies in the FDA's clearance of certain ‘preamendments’ devices, as well as those post-‘amendments’ products claiming substantial equivalence to them. These devices, although classified as Class III, were never formally reclassified or reviewed through the PMA process. As it is currently written, the Amendments allow for the FDA's review and clearance of these devices under the 510(k) premarket notification process. This process will remain unchanged unless the FDA amends its regulations to account for the devices' review and approval, and possibly their reclassification.

Therefore, the GAO recommended that FDA “expeditiously take steps to issue regulations for each Class III device type currently allowed to enter the market through the 510(k) process.”<sup>5</sup> Based on the adverse event information, proposed Special Controls, as well as other efficacy data submitted by the applicant-manufacturer(s), the FDA will determine whether the device should continued be classified to Class III (whereby the submission of a PMA application would be required), or remain classified as Class II. Failure to comply with the FDA Order could result in charges of misbranding and possible seizure, injunction, civil penalties, and criminal

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<sup>2</sup> See 74 Fed. Reg. 16214 (April 9, 2009).

<sup>3</sup> A ‘preamendments’ device is one that was in commercial distribution in the United States before May 28, 1976, the day the Medical Device Amendments became law. ‘Preamendments’ devices are classified after FDA has received the recommendation from FDA's advisory committee, published the panel's recommendation for comment with a proposed regulation classifying the device and published a final regulation. Preamendments Class III devices may be marketed by means of a cleared premarket notification or 510(k) without submission of a premarket approval application until FDA issues a final regulation requiring premarket approval. Unclassified devices are those that were not classified at the time of the Amendments' promulgation, and which are regulated as unclassified devices via premarket notification.

<sup>4</sup> Ref Medical Device Amendments to FDCA, P.L. 94-295 (May 28, 1976).

<sup>5</sup> GAO Report, “Medical Devices—FDA Should Take Steps to Ensure that High Risk Device Types are Approved through the Most Stringent Premarket Review Process” (GAO-09-190) (January 2009).



# MCRA

## OVERLOOKING THE HILL

August 2009

prosecution.<sup>6</sup> Information in support of the reclassification of the device must consist of adequate, valid scientific evidence showing that General Controls, along with Special Controls, will provide a reasonable assurance of the safety and effectiveness of the device.

Specific sectors of the orthopedics market that are affected by this Order include cemented and uncemented metal-on-metal artificial hips, as well as pedicle screw-based spinal systems.<sup>7</sup> Therefore, this Order affects hundreds of orthopedic devices, cleared through the Premarket Notification 510(k) route. According to Daniel G. Schultz, MD, former director of the FDA's Center for Devices and Radiological Health, "We are taking the necessary steps to complete this very complex process while continuing to protect public health by thoroughly reviewing and evaluating all medical device submissions presented to the agency. New premarket notification submissions for devices of these 25 types will continue to receive an appropriate level of scrutiny to ensure safety and effectiveness."<sup>8</sup>

Unlike metal-on-metal artificial hip manufacturers, as well as the other 23 device types identified within the FDA Order, pedicle screw manufacturers face a unique situation in submitting information. Only those pedicle screw systems that are indicated for DDD and low-grade spondylolisthesis are required to provide information pertaining to the device's safety and effectiveness. In most cases, a pedicle screw system was cleared for use via the 510(k) process, whether containing Class II or Class III indications. Ironically, the majority of the data that supports the use of pedicle screw systems as an adjunct to fusion in treating DDD has been collected in recent years as the control arms of artificial disc replacements' (Class III products) Investigational Device Exemption (IDE) clinical trials.

On May 3, 2004 the FDA issued a document entitled Guidance for Industry and FDA Staff: Spinal System 510(k)s, which updated

premarket notification information on spinal systems.<sup>9</sup> The document specifically addressed the newly-defined Class III 'pre-amendments' pedicle screw systems (which would require only 510(k) clearance), and described the Special Controls that should be performed to determine the safety and efficacy of these devices. Special Controls are specific to Class II, not Class III, medical devices. If determined to be Class III following this FDA Order, a PMA will be required of these devices for manufacturers to continue marketing them, but the logistical concerns of such a reclassification have yet to be addressed.

The FDA has yet to provide a response date regarding the outcome of the class III preamendments device. Furthermore, the Agency will not publish one Federal Register notice encompassing all 25 affected device types, but instead publish a notice for each individual device type, announcing the final decision within the notice. It is estimated that it will take, at minimum, one year for the FDA to complete their review of the data before convening an Advisory Panel. If it is determined that the information provided by industry for a given device type is insufficient to demonstrate safety and effectiveness or insufficient in establishing the appropriate Special Controls, the FDA will require (call for) PMA submissions from manufacturers for each marketed device. However, if the FDA has determined the overall body of evidence provided by manufacturers warrants the classification of a device type from class III preamendments to class II, no further action will be required of manufacturers. Currently, manufacturers may market their devices until a classification decision by the FDA has been reached.

MCRA analysts consider it unlikely that the FDA will require PMA submissions for pedicle screw-based spinal systems, based on the FDA's placement of Special Controls upon them in 2004 (a Class II-only distinction). MCRA will continue to monitor and report upon FDA statements and guidance documents, which may offer insight for those manufacturers affected. ■

<sup>6</sup> Source: <http://www.klgates.com/newsstand/Detail.aspx?publication=5558>.

<sup>7</sup> See 21 CFR 888.3320 et seq; 21 CFR 888.3070(b)(2); 21 CFR 870.3680(b)

<sup>8</sup> Source: <http://www.news-medical.net/news/2009/04/08/48135.aspx>.

<sup>7</sup> Source: <http://www.dotmed.com/news/story/8978> (accessed 5/7/2009)

<sup>9</sup> Source: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072459.htm>.



# MCRA

## OVERLOOKING THE HILL

August 2009

### Medicare FY 2010 IPPS Final Rule: Impact Analysis for Orthopedics

*Tim Hunter, Director of Reimbursement<sup>1</sup>*  
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CMS released the Medicare Fiscal Year (FY) 2010 Hospital Inpatient Final Rule on August 1, 2009.<sup>2</sup> While the outlook for orthopedic procedures is good, overall payments to hospitals will not increase significantly for FY 2010. Manufacturers of orthopedic devices must remain vigilant as hospitals may be experiencing reduced payments for other procedures routinely performed in the inpatient setting and looking for ways to make up the lost revenue.

#### Impact for Orthopedics

Generally, payments for orthopedic procedures have increased significantly in the past two annual updates. While not all orthopedic-focused MS-DRGs have fared well, the average FY 2010 increase among 47 MS-DRG analyzed by MCRA is approximately 13%; the average two-year increase over FY 2008 payment amounts is approximately 19%.

Impact of FY 2010 Final Rule on 47 Orthopedic MS-DRGs Assessed by MCRA					
2010 vs. 2009			2010 vs. 2008		
Low	High	Average	Low	High	Average
0%	121%	13%	-31%	54%	19%

Within orthopedics, the largest increases from FY 2008 to FY 2010 generally have been applied to cases with major comorbidities and complications, but cases falling into all severity ranges have experienced significant payment increases, with a few exceptions. The table on the right includes 12 commonly used MS-DRGs for orthopedic procedures. Payments rates increased significantly for four of the five MS-DRG sets listed. Two-year increases range from -3% to 46%, many with at least 20% payment rate increases.

Impact of FY 2010 Medicare IPPS Final Rule for Selected Orthopedic MS-DRGs			
MS-DRG	Description	FY-2010 % Change From FY-2009	FY-2008 v FY-2010 % Variance
459	Spinal fusion except cervical with MCC	14%	46%
460	Spinal fusion except cervical without MCC	15%	23%
469	Major joint replacement or reattachment of lower extremity with MCC	12%	44%
470	Major joint replacement or reattachment of lower extremity without MCC	13%	20%
490	Back and neck procedures except spinal fusion with CC/MCC or disc device	14%	37%
491	Back and neck procedures except spinal fusion without CC/MCC	12%	9%
495	Local excision and removal external fixation devices except hip and femur with MCC	0%	29%
496	Local excision and removal external fixation devices except hip and femur with CC	1%	6%
497	Local excision and removal external fixation devices except hip and femur without CC/MCC	2%	-3%
503	Foot procedures with MCC	5%	44%
504	Foot procedures with CC	13%	24%
505	Foot procedures without CC/MCC	15%	3%

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<sup>2</sup> Source: [http://www.federalregister.gov/OFRUpload/OFRData/2009-18663\\_PI.pdf](http://www.federalregister.gov/OFRUpload/OFRData/2009-18663_PI.pdf) (Accessed August 6, 2009).



# MCRA

## OVERLOOKING THE HILL

August 2009

### Payment Updates

CMS implemented its proposed annual update of 2.1%, despite recommendations from the Medicare Payment Advisory Commission's (MedPAC) that the update should be higher. However, hospitals received some good news regarding the expected documentation and coding adjustment. In the June 2009 edition of *Overlooking the Hill*, Jeff Zigler noted that a -1.9% documentation and coding adjustment proposed by CMS for FY 2010 would provide a blow to hospital inpatient payment rates. As the American Hospital Association noted in its public comment, this proposed negative adjustment would equate to approximately \$1 billion less in payments to hospitals for FY 2010. After considering public comments, CMS ultimately decided to delay implementation of the payment decrease, subject to a more complete analysis of FY 2009 claims data.

While this development certainly is good news for hospitals in 2010, it creates a potentially larger problem in future years. Delaying the proposed decrease does not make it go away. Should CMS validate its previous evaluation and analysis, these cuts will take place in future years. Unless CMS elects to spread the adjustment over multiple years, the result of this delay could be an even larger negative adjustment in FY-2010.

### Quality Reporting & Payments

CMS estimates that 96 hospitals may not receive full payments in FY 2010 due to non-compliance with the quality reporting requirements, representing far less than 1% of all hospitals for which the requirement exists. However, the more important statistic may not be available until the FY 2011 rulemaking process. In FY 2010, CMS will begin validating the information reported by hospitals using a chart audit process. Those hospitals with reporting reliability under 80% may be subject to the statutory payment reduction in FY 2011. The process changes again in FY 2012, perhaps making it more difficult for hospitals to satisfy the validation requirement.

While short-term signs point to positive positioning for orthopedic procedures within the Medicare IPPS setting, hospitals likely will be looking for efficiencies in all areas in order to make up for payment shortfalls elsewhere. Medical device and biologic stakeholders are encouraged to use claims data, quality analysis and publications to support the value message of their technology. ■

### Medicare Consideration of Rule Change for Implantable Biologicals in the Hospital Outpatient Setting Should Benefit Competing Medical Devices

*Tim Hunter, Director of Reimbursement<sup>1</sup>*

CMS released the 2010 Medicare Hospital Outpatient Prospective Payment System (OPPS) proposed rule on July 15, 2009.<sup>2</sup> Among the provisions proposed by CMS is one to further classify implantable biologicals as devices for the purposes of applying transitional pass-through status and payment. To date, very little has been written about this CMS policy, but the provisions, both implemented and proposed, can shift the competitive landscape for competing biological and medical device products that are implanted during outpatient surgical procedures.

Based upon the discussions in the 2009 OPPS rules and 2010 OPPS proposed rule, CMS loosely categorizes an implantable biological as one that:

- Is integral to the surgical procedure
- Is implanted through a surgical incision or natural orifice
- Specifically functions as a surgically implanted device<sup>3</sup>
- May or may not replace an implantable medical device

For example, CMS determined in 2009 that the TissueMend™ Soft Tissue Repair Matrix fit the definition of an implantable biological because it is indicated exclusively for use in open and arthroscopic

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<sup>2</sup> CMS-1414-P, Medicare Hospital Outpatient Prospective Payment System Proposed Rule. July 15, 2009.

<sup>3</sup> For non-pass-through biologicals that may sometimes be used as implantable devices, CMS has indicated that it will continue the policy of instructing hospitals not to bill separately only for those uses.



# MCRA

## OVERLOOKING THE HILL

August 2009

ic surgical procedures as a scaffold to aid in soft tissue healing.

The wording in the 2009 final rule and 2010 proposed rule indicate that the final and proposed policies described below are applicable to biologicals regardless of whether the product was approved by the FDA as a true biological or approved or cleared through the medical device review processes.

### Established CMS Policy

Beginning for dates of service on or after January 1, 2009<sup>4</sup>, CMS instituted a policy by which these implantable biologicals are considered to be implantable devices for the purposes of determining the appropriateness of separate payment in the hospital outpatient setting. The rule extends 2007 CMS guidance instructions regarding billing for products when they are used as implantable devices.<sup>5</sup> After the pass-through payment period, implantable biologicals are bundled into the Ambulatory Payment Classification (APC) associated with the primary surgical procedure for payment purposes.

### CMS Proposed Policy

Beginning on January 1, 2010, CMS proposes to further integrate implantable biologicals into the transitional pass-through process for medical devices by changing the application and reimbursement mechanisms during the pass-through period to conform to those for medical devices. Specifically, implantable biologicals would no longer be eligible for reimbursement based upon the methodology for drugs and biologicals during the pass-through period, currently based upon the product's Average Sales Price (ASP). Under the proposal, these products would be paid separately during the pass-through period at a rate equal to the technology cost minus any offset amount that CMS determines to already be accounted for in the surgical procedure itself, including competing medical device technologies that no longer are eligible for separate pass-through payment.

### Impact for Implantable Biologicals & Medical Device Competitors

These changes can directly impact the competitive landscape for technology markets in which implantable biologicals and medical

devices compete directly. Currently, facilities are eligible to receive separate payment for an implantable biological based upon the product's average sales price, similar to drugs and biologicals, but only limited payment for a competing medical device during the same 2-3-year period of pass-through eligibility. Under the proposal put forth by CMS, both products will be treated identically for the purposes of payment during the pass-through period.

Based upon CMS's descriptions in the 2009 and 2010 rules, these policies are applicable to implantable biologicals regardless of FDA designation. In the example of TissueMend™ above, CMS bundled the cost of the product into the applicable APC(s). If CMS finalizes this proposal for 2010, the eventual pass-through payment for any new biological that replaces TissueMend™ in a surgical procedure would be reduced by some amount as calculated by CMS. This offset amount will be based on the costs associated with TissueMend™ and any other applicable implantable product already contemplated within the surgical procedure. This offset calculation currently only occurs for implantable medical devices.

### Potential Impact for Designated Implantable Biologicals

- Potential for lower level of separate payment under medical device rules
- Potential for minimal additional payment during pass-through period if existing technologies already are bundled into the relevant APC(s)
- More onerous new technology pass-through application, requiring technology manufacturer to meet additional criteria for pass-through status and payment

**Table 1: Impact of CMS Rule Changes for Designated Implantable Biologicals**

	2009	2010 Proposed
<b>Separate Payment</b>	Limited to 2-3 Years	Limited to 2-3 Years
<b>Payment Methodology</b>	ASP-Based (Drugs/ Biologicals)	Subject to APC Off-Set (Medical Devices)
<b>Payment Rate Impacted by Previous Competing Technologies?</b>	No	Yes
<b>CMS New Technology Pass-Through Application</b>	Drugs and Biologicals	<b>Medical Device Application</b>

<sup>4</sup> CMS-1404-FC, Medicare Hospital Outpatient Prospective Payment System Final Rule, November 18, 2008.

<sup>5</sup> CMS Change Request 5718, September 14, 2007.



# MCRA

## OVERLOOKING THE HILL

August 2009

### Potential Impact for Competing Medical Devices

- Treats competing implantable biologicals like medical devices
- Eliminates competitive advantages for implantable biologicals in securing pass-through status and payment

The proposed 2010 change regarding payment for implantable biologicals during the pass-through payment period will further equalized Medicare payment policies for implantable biologicals and implantable medical devices. The change will favor manufacturers of certain implantable devices by eliminating an opportunity for hospitals to potentially receive much higher payments when using a new biological instead of a new or older medical device.

**CMS will be accepting public comments on this and other provisions of the 2010 Medicare Hospital Outpatient Prospective Payment System proposed rule through August 31, 2009. Please contact MCRA at [thunter@mcra.com](mailto:thunter@mcra.com) for more information regarding the comment submission process or if you need assistance with comment development and submission. ■**

### The Value of Invention Documentation

*Urmi Chattopadhyay, Director*  
*Andy Riutta, Patent Analyst<sup>1</sup>*

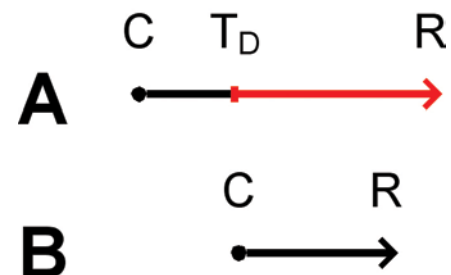
In the medical technology sector, patent landscapes are crowded. Competing organizations race to file patent applications in rapidly developing technologies in the hopes of obtaining valuable exclusionary rights. While the first applicant to file has the prima facie right to a patent, the U.S. system grants patent rights to the first to invent. Accordingly, it is important that medical technology organizations institute documentation systems to track and record pre-filing activities in establishing the dates their products or technologies were invented. During patent prosecution and interference proceedings, where entitlement based on first inventorship is challenged, these documentation systems can be called upon.

**Because the U.S. has a first-to-invent system, medical technology organizations should establish documentation guidelines to establish the dates their products or technologies were invented.**

In the U.S., the date of invention can go back to the date the idea of the invention was first conceived. To conceive an invention is to mentally develop an idea to the point where it could be created or implemented by a person skilled in the field, with no additional inventive activity required. To benefit from the date of conception, inventors must be able to show that they have employed reasonable diligence in reducing the invention to practice, which can be done in two ways: actually, by producing a prototype or practicing the invention, or constructively, by filing a patent application. For further information, please refer to 37 CFR 1.131 and 37 CFR 41(E).

The following figure illustrates one example of two parties competing for first inventorship. Party A was the first to conceive of an invention (C), but Party B was the first to reduce it to practice (R). If Party A can show it employed reasonable diligence in the critical time period indicated in red, it will be considered the first to invent.

### Example Timeline



Reasonable diligence means that, beginning at time  $T_D$ , Party A steadily employed all practical effort to reduce the invention to practice. Diligence can be established based on documentation,

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# MCRA

## OVERLOOKING THE HILL

August 2009

such as lab notebooks or invention disclosure statements. Good documentation is important, because undocumented inactivity as brief as two days has been enough to destroy a case for reasonable diligence in court.<sup>2</sup>

Because the U.S. has a first-to-invent system, medical technology organizations should establish documentation guidelines that ensure all scientists and engineers engaged in inventive activity follow best-practice policies for keeping lab notebooks, completing invention disclosure statements, and archiving records. Thereby, a clear timeline of activity from conception to reduction to practice of the invention is accounted for and on record. This documentation can be used as evidence of first inventorship in interference proceedings. It can also be used as evidence in declarations or affidavits during prosecution to predate a reference cited in a prior art rejection.

It should be noted that the Patent Reform Act of 2009 (S. 515/S. 610/H.R. 1260) could change the U.S. system to first to file, bringing the U.S. in line with the majority of patent offices across the world. However, until such legislation passes, the current system remains first-to-invent. Accordingly, there is value in establishing proper documentation systems.

### MCRA Services

To maximize the value of your intellectual property, you should monitor the patent filings of your competitors in addition to establishing a quality documentation system. This combination is an effective offensive and defensive strategy for obtaining the patent protection to which you are entitled and preventing others from patenting your invention. MCRA provides competitive patent landscape searches and analyses that will allow you to take advantage of your intellectual property. For more information on our services, please visit [http://www.mcra.com/services\\_ip.html](http://www.mcra.com/services_ip.html) ■

### Legislative Watch

The following are US Federal pending legislation and represent but a few bills introduced by the House (H.R.) and Senate (S) that may interest to technology companies:

Bill	Title	Major Subject	Sponsor	Status
H.R. 873	Stem Cell Research Enhancement Act of 2009	Stem Cell Research	Rep. D. DeGette (D-CO)	Referred to Energy & Commerce Committee
H.R. 1346	Medical Device Safety Act of 2009	Allow for Product Liability Lawsuits in State Court	Rep. F. Pallone (D-NJ)	Referred to Energy & Commerce Committee; Hearing Held
H.R. 1427	Promoting Innovation and Access to Life-Saving Medicine Act	Creating Biosimilar Pathways	Rep. H. Waxman (D-CA)	Referred to Energy & Commerce and Judiciary Committees
H.R. 1548	Pathway to Biosimilars Act	Creating Biosimilar Pathways	Rep. A. Eshoo (D-CA)	Referred to Energy & Commerce and Judiciary Committees
H.R. 1706	Protecting Consumer Access to Generic Drugs Act of 2009	Generic Drug Access	Rep. B. Rush (D-IL)	House Subcommittee Referred Mark-Up Bill to House Energy Committee; In Review by House Judiciary Committee
S. 45	Medical Care Access Protection Act of 2009	Liability Reform	Sen. J. Ensign (R-NV)	Referred to Health, Education, Labor & Pension Committee
S. 301	Physician Payments Sunshine Act of 2009	Physician Payment Disclosures	Sen. C. Grassley (R-IA)	Referred to Senate Finance Committee
S. 444	National Health Information Technology and Privacy Advancement Act of 2009	Information Technology	Sen. S. Whitehouse (D-RI)	Referred to Health, Education, Labor & Pension Committee
S. 540	Medical Device Safety Act of 2009	Allow Product Liability Lawsuits in State Court	Sen. E. Kennedy (D-MA)	Referred to Health, Education, Labor & Pension Committee

<sup>2</sup> In re Mulder, 716 F.2d 1542, 1545, 219 USPQ 189, 193 (Fed. Cir. 1983)