



# MCRA OVERLOOKING THE HILL

April 2009

## INTRODUCTION

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Health care continues to be a major focus of politicians within the United States. Pending legislation now includes regulations spanning from universal access, transparency, liability reform to safety and surveillance. In this issue of *Overlooking the Hill*, MCRA consultants briefly review the FDA's Sentinel Initiative as well as AHRQs certification of Patient Safety Organization and foreseeable reporting challenges. Disclosure and reporting requirements are reviewed with this year's version of the Sunshine Act, while Director of Reimbursement Tim Hunter examines competing bills regarding biosimilars and their potential impact on other medical technologies.



With the impending appointment of Kathleen Sebelius as Secretary of Health & Human Services, we should then see other key appointments within the Department. An outline of Governor Sebelius' health care vision may be found through hyperlinks listed below. We have also included a list of interesting bills which you may wish to track. Given the strong interest in US health care reform, MCRA is encouraging all of its domestic and international clients to pay close attention to regulatory activities, and when appropriate, actively engage in discussion with stakeholders to ensure innovation and patient access are not discouraged through regulatory activities. ■

Articles within this newsletter are provided by MCRA for informational purposes only. Information should not be relied upon, but rather stimulate further review and research. For questions or comments, please contact MCRA Vice President of Reimbursement Charles Schneider at [CSchneider@MCRA.com](mailto:CSchneider@MCRA.com) or by calling (202) 552-5800.

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## FDA Seeking Early Warning System for Medical Technologies: Sentinel Initiative Overview

*Prepared By: Glenn Stiegman, Vice President of Regulatory Affairs<sup>1</sup> & Michelle McDonough, Regulatory Associate*



In May 2008, the FDA instituted the Sentinel Initiative to begin planning and strategizing for an electronic, distributed network database which will have the capability to monitor the safety of medical devices and drugs throughout their entire life cycle.<sup>2</sup> The recently passed Food and

Drug Administration Amendments Act of 2007 (FDAAA) mandated the development of such a system.<sup>3</sup> In summary, the FDA and its system partners will establish databases for medical technology monitoring during commercial use of certain devices. Medical device and technology companies should carefully monitor system development, ensure quality reporting and use of their technologies through training and continuing education programs from product users.

FDA staff claim the Sentinel Initiative will not result in additional regulatory burdens on the device industry. The developing plan is to build on existing systems and databases. Nevertheless, development of systems and databases has been slow, despite legislative passage in September 2007. In December 2008, the FDA began holding meetings to discuss implementation of the Sentinel Initiative and gain input from several leading industry individuals and task groups. Identifying and gaining access to public and private databases (with many pilot studies already in place), creating interface tools and national standards, putting in place protection for patient information and determining how to best identify harmful adverse events is next on the Agency's agenda.

Within the next six months, the FDA plans to draft a structure for

### Sentinel Initiative in Brief

- The Sentinel System will allow the FDA and System Partners to monitor medical product safety through database queries that can be sent out to all affiliated users.
- FDA staff hopes to utilize the records from private databases (i.e. insurance payers, hospitals, and suppliers), public databases (i.e. FDA, NIH, CDC) and academic databases.
- The FDA will use this data in addition to their current safety assessing efforts which include health professional, manufacturer and/or patient submitted reports, case reports in the literature, and post approval study results.
- Once developed, queries are expected to identify significant adverse events, specific patient populations, durations of follow-up, as well as, be used to facilitate further research.

Version 1.0 of the Sentinel System. From here, the FDA's goal is to have access to 25 million patient datasets by July 1, 2010 and 100 million patient datasets by July 1, 2012. The unified system will give the FDA and partners an increased capacity to identify issues of safety concerning medical products and drugs as well as recognize these concerns earlier in the device's life cycle. FDA personnel will have access to review available data and make findings available to both healthcare professionals and patients. The Sentinel Initiative is expected to be a long-term FDA project, and it can certainly be expected that changes will be made and many details will need to be worked out, but the Initiative appears to signal an expanded role in the Agency's mission to "protect and promote" the health of patients. ■

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<sup>2</sup> For additional information, see <http://www.fda.gov/oc/initiatives/advance/sentinel/>.

<sup>3</sup> On September 27, 2007, former President George W. Bush signed into law H.R. 3580 to enact the FDAAA into Public Law 110-85.



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### Patient Safety Organizations: Issues with Voluntary Reporting

Jeff Zigler, JD, Senior Associate<sup>1</sup>

Congress created Patient Safety Organizations (PSOs) to collect and analyze patient safety data, with the ultimate goal of increasing patient safety based on aggregating and analyzing hospital risk data on a national level. In the February 2009 issue of *MCRA Overlooking the Hill*, we explored the intent behind the creation of PSOs, as well as the Agency for Healthcare Research and Quality's (AHRQ) administration of the project. The expected health outcomes data from Patient Safety Organizations (PSOs) promises to be valuable to the medical community. The business opportunities for those qualifying as PSOs, marketing to hospitals seeking to improve health outcomes, also seem promising. But once private organizations in the healthcare industry become accredited and listed as PSOs, what will compel them to report their findings on patient health safety to the national data pool? Not only must members of industry determine their own business reasons before seeking accreditation as a PSO, but AHRQ must work with industry to develop rationales for compelling the voluntary submission of this important safety data.

Much has been touted about the privilege afforded patient safety work product developed during the PSO program. Namely, a privilege extends to the data much like attorney-client communications, and it cannot be discovered during legal proceedings, with certain exceptions.<sup>2</sup> Although the privilege may provide some level of comfort in gathering health information associated with the PSO program, there still remains the issue of compelling the active reporting of that privileged data to the national pool. Neither the first-line healthcare providers (nor their staff) collecting the data, or the PSOs themselves are required to report to the National

The expected health outcomes data promises to be valuable and business opportunities for PSOs seem promising, but what will compel them to report their findings on patient health safety?

Patient Safety Databases (NPSDs) tasked with aggregating such data. According to AHRQ, "Every element [of the PSO program] is voluntary—not mandatory. Once information is sent to the PSO, it is voluntary for the PSO to then send it to the NPSD. It is not required for providers or PSOs to send information..."

This raises questions as to the effectiveness the PSO program will have on the medical community, as voluntary reporting systems have historically failed in the medical field. Since the 1950's, drugs and devices have undergone some type of voluntary reporting. The practice began with the AMA's efforts to register cases of drug-induced blood dyscrasias, particularly the antibiotic chloramphenicol's rare side effect of aplastic anemia.<sup>3</sup> The FDA soon established its own reporting system, and by 1961 both the AMA and the FDA collectively studied all adverse reactions to drugs each year.<sup>4</sup> The AMA Registry concentrated on reports from physicians and smaller hospitals (much like the data sought by the PSO program today), while the FDA focused on collecting information from larger hospitals, universities, and the federal government. In 1962, the Food and Drug Act was amended to require drug manufacturers to report adverse drug reactions to the FDA. The dual reporting system continued until 1970, when the AMA dissolved its Registry, due in large part to the underreporting observed.

The PSO program is no doubt important to aggregating the country's patient safety information. But history has taught us that underreporting can have deleterious effects on even the most well-intentioned of information collection programs. Ultimately, the aggregation of patient safety data collected by PSOs relies on the full and willing participation of all those involved with the program, and AHRQ must make every effort not only to ensure quality of safety data gathered, but also to engender an environment where PSOs (and their individual members) are somehow incentivized to report. ■

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<sup>2</sup> P.L. 109-41. However, the Act permits disclosure: 1) for use in a criminal proceeding after a court determines that such work product contains evidence of a criminal act and is material to the proceeding and not reasonably available from any other source; 2) to the extent required to seek redress for violations through a civil action; and 3) if authorized by each provider identified in such work product.

<sup>3</sup> Lee B, Turner WM. Food and Drug Administration's adverse drug reaction monitoring program. *Am J Hosp Pharm.* 1978;35:929-932. Scott HD, Thatcher-Renshaw A, Rosenbaum SE, Waters, Jr. WJ, Green M, Andrews LG, Faich GA. Physician reporting of adverse drug reactions: Results of the Rhode Island adverse drug reaction reporting project. *JAMA.* 1990;263: 1785-1788.

<sup>4</sup> *Id*



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### Physician Payment Sunshine Act of 2009

**Robert Hoehn, JD, Compliance Director<sup>1</sup>**

On January 22nd, 2009, Senators Charles Grassley (R-IA) and Herb Kohl (D-WI) introduced the Physician Payment Sunshine Act of 2009.<sup>2</sup> This legislation will require drug, device and biologics manufacturers to disclose payments made to physicians with an aggregate value of \$100 or more. This amended bill is similar to the original Bill, the Physicians Payment Sunshine Act of 2007, but incorporates many of the recommendations made by the Medicare Payment Advisory Commission (MedPAC).

Within the 2008 version of the Physician Payment Sunshine Act, 20 organizations endorsed the proposal.<sup>3</sup> Since that time, there have been significant changes to the legislation so that it now bears only a slight resemblance to what was originally endorsed. One area of particular importance is that of preemption. The original legislation was intended to preempt state laws which would ease the burden on manufactures by forcing them to comply with one set of rules. The new legislation provides for only partial preemption which still allows states to enact even stricter laws. This lack of preemption could theoretically result in drug and device manufacturers being forced to comply with regulations of 50 different states, as well as federal regulations. Clearly, this is not what was originally endorsed. The cost of compliance will be astronomical and will ultimately be passed along to the consumer.

The new Bill seeks to amend Title XI of the Social Security Act, and requires disclosure of all payments made to physicians relating to products that are paid for under Medicare, Medicaid, or SCHIP. Payments requiring disclosure include consulting fees, gifts, charitable contributions and compensation for research or for continuing medical education faculty. Payments excluded from disclosure include product samples for patient use, educational materials,

discounts and in-kind items used for the provision of charity care. In addition, manufacturers will be required to disclose physician ownership or investment interest. This will include the dollar amount invested by each physician, the value and terms of the ownership or investment interest, and any payment or other transfer of value provided to a physician holding an ownership or investment interest. Ownership in a publicly traded security or mutual fund will be exempt from this disclosure.

Ultimately, these disclosures will be made available to the public including the name and business address of the recipient, the value of the payment, the dates of payment, a description of the payment (i.e. cash, in-kind services, stock, return on investment), the nature of the payment (i.e. consulting, honoraria, gifts, food, etc) and the drug, device or biologic to which the payment relates. ■

### Congressional Action on Biosimilars Impacts Makers of Biologics and Medical Devices Alike

**Tim Hunter, Director of Reimbursement<sup>4</sup>**

Once again, Members of Congress have introduced legislation to create a regulatory pathway for biosimilars (also known as follow-on biologics). Any congressional action that creates a pathway to market for biosimilars has the ability to greatly impact coverage and reimbursement for not only the biologics industry but also any competing technologies, such as medical devices.

Currently, the FDA does not review biosimilars for commercial use in the United States, not does it have a pathway for doing. In the past, the FDA has indicated that it has not determined what scientific data are needed to demonstrate that the follow-on biologic can be safely substituted for the original innovator product.<sup>5</sup> The following bills have been introduced in both chambers and would greatly impact the current landscape:

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<sup>2</sup> S.301: Physician Payment Sunshine Act of 2009

<sup>3</sup> <http://finance.senate.gov/press/Gpress/2008/prg071608a.pdf>

<sup>4</sup> Mr. Hunter is a leading reimbursement expert on biologics, stem cell application and other medical technologies. For questions regarding this article, please contact Mr. Hunter at thunter@mcra.com or by calling (202) 552-5800.

<sup>5</sup> U.S. Food and Drug Administration, "U.S. FDA Considerations: Discussion by the National Regulatory Authorities with World Health Organization (WHO) On Possible International Non-proprietary Name (INN) Policies for Biosimilars", September 1, 2006.



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H.R. 1427, *The Promoting Innovation and Access to Life-Saving Medicine Act* was introduced on March 11, 2009 by Rep. Henry Waxman (D-CA), Rep. Frank Pallone (D-NJ), Rep. Nathan Deal (R-GA), and Rep. Jo Ann Emerson (R-MO). The companion bill in the Senate, S.R. 736, was introduced by Sen. Charles Schumer (D-NY), Sen. Sherrod Brown (D-OH), Sen. Susan Collins (R-ME), and Sen. Mel Martinez (R-FL).

H.R. 1548, the *Pathway to Biosimilars Act*, was introduced in the House on March 17, 2009 by Rep. Anna Eshoo (D-CA), Rep. Jay Inslee (D-WA), and Rep. Joe Barton (R-TX). This bill represents a combined effort by Rep. Eshoo and Rep. Inslee, who separately introduced legislation last year.

The bills before Congress differ in a number of ways, with two of the most important regarding how biosimilars should be reviewed and approved by the FDA and what protections will exist for the innovator biologic. For example, do biosimilars require clinical studies demonstrating both safety and efficacy? Will manufacturers of innovative biologics be required to release additional information regarding product development and processes to facilitate the development of alternative products? The Biotechnology Industry Organization (BIO), the leading trade association representing the effected industry, has supported H.R. 1548 as providing “patients with the right balance between innovation and competition.”<sup>6</sup>

If legislation is passed and signed into law, it will be up to the FDA to develop regulations outlining the review and approval processes, including the specific evidence required for approval. Interested stakeholders will almost assuredly have one or more opportunities for public comment during the rulemaking process. However, the FDA only has the authority to address stakeholder concerns that are within the parameters defined by a particular law — input challenging aspects of the law would not be germane to the discussion.

### What Are Biosimilars?

Biosimilars, or follow-on biologics, are close versions of currently available proprietary biologics. While similar to generic versions of prescription drugs, biosimilars are not exact replicas of the proprietary biologic. The inability to exactly replicate biologics raises questions regarding the appropriate pathway for FDA approval.

### The Outcome Will Impact both Biologic and Medical Device Competitors

The establishment of a FDA review process for biosimilars will most notably impact the innovator biologic technologies themselves.

The extent of the impact on coverage and payment will in large part be dependent upon the specifics of the law and implementation by the FDA. For example, the creation of a regulatory framework that requires minimal clinical evidence would allow a biosimilar manufacturer to bring a product to market faster and with less capital investment, which likely will result in a lower product cost.

While the impact on biologics of an eventual FDA regulatory pathway is often discussed, the impact on medical devices often is overshadowed. As the biologics industry continues to grow, it will continue to expand into markets that previously were dominated by medical device technologies. In orthopedics and cardiology, for example, biologic entrants are redefining the treatment paradigm, either alone or in conjunction with medical devices. A biosimilar introduced in this market will affect all competing products, regardless of design or mechanism of action.

Right now, it is unclear how lawmakers will balance patient safety and potential cost savings to the health care system, but the cost saving component likely will be present in some format. After all, the current consensus among lawmakers seems to be “to bring new competition, choices, and lower prices”<sup>7</sup> to the industry. ■

### Legislative Watch

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

<sup>6</sup> Biotechnology Industry Organization Press Release, “New Bipartisan, Consensus Bill Points to Right Path to Biosimilars”, March 17, 2009.

<sup>7</sup> Press Release from Rep. Anna Eshoo, “Reps. Eshoo, Inslee, and Barton Introduce Pathway for Biosimilars Act”, March 17, 2009. See also Press Release from Rep. Henry Waxman, “Bipartisan Group of Members Introduces ‘Promoting Innovation and Access to Life-Saving Medicines Act’”, March 11, 2009.



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Bill	Title	Sponsor	Major Subject
H.R. 15	National Health Insurance Act	Rep. J. Dingell (D-MI)	Universal Health Care
S. 45	Medical Care Access Protection Act of 2009	Sen. J. Ensign (R-NV)	Liability Reform
H.R. 193	AmeriCare Health Care Act of 2009	Rep. P. Stark (D-CA)	Universal Health Care
S. 301	Physician Payments Sunshine Act of 2009	Sen. C. Grassley (R-IA)	Physician Payment Disclosures
S. 444	National Health Information Technology and Privacy Advancement Act of 2009	Sen. S. Whitehouse (D-RI)	Information Technology
S. 540	Medical Device Safety Act of 2009	Sen. E. Kennedy (D-MA)	Allow Product Liability Lawsuits in State Court
H.R. 676	United States National Health Care Act	Rep. J. Conyers (D-MI)	Universal Health Care
H.R. 873	Stem Cell Research Enhancement Act of 2009	Rep. D. DeGette (D-CO)	Stem Cell Research
H.R. 1346	Medical Device Safety Act of 2009	Rep. F. Pallone (D-NJ)	Allow for Product Liability Lawsuits in State Court
H.R. 1427	Promoting Innovation and Access to Life-Saving Medicine Act	Rep. H. Waxman (D-CA)	Creating Biosimilar Pathways
H.R. 1548	Pathway to Biosimilars Act	Rep. A. Eshoo (D-CA)	Creating Biosimilar Pathways
H.R. 1706	Protecting Consumer Access to Generic Drugs Act of 2009	Rep. B. Rush (D-IL)	Generic Drug Access

\* To review legislation above, or other legislation of interest, please see [www.Thomas.gov](http://www.Thomas.gov) or [www.GovTrack.us](http://www.GovTrack.us).

### Keeping You Up to Date

- ICD-10-PCS audio conference available from CMS on-line at [http://www.cms.hhs.gov/ICD10/07\\_Sponsored\\_Calls.asp](http://www.cms.hhs.gov/ICD10/07_Sponsored_Calls.asp)
- Senate Finance Committee DHHS Secretary nomination testimony at <http://finance.senate.gov/sitepages/hearing040209.htm>.
- Medicare's Inpatient Prospective Payment system updates at <http://www.cms.hhs.gov/acuteinpatientpps>
- Medicare's Hospital Outpatient Prospective Payment system updates at <http://www.cms.hhs.gov/hospitaloutpatientPPS>
- Massachusetts Drug and Medical Device Marketing Code of Conduct summary presentation from MA Department of Public Health Deputy General Counsel Melissa Lopes and reporting updates may be found at [www.mass.gov](http://www.mass.gov)