

press release

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Healthsystems™ Provides Insight into How Current Economic and Regulatory Climate is Affecting Workers' Comp Pharma Industry at NAMA Conference

Tampa, FL - Healthsystems LLC (Health**e**systems), a leading provider of medical cost management solutions for the workers' compensation industry, delivered a presentation to a group of workers' compensation industry professionals titled "Drug Utilization, the Economy, and Complex Claims: Focusing on Prescription Trends to Better Manage Claims Outcomes." The presentation, given by Dr. Michael Seise, PharmD, and Todd Piscioti, VP of Sales & Marketing, provides valuable insight into how the current economic and regulatory climate is affecting the U.S. pharmaceutical industry and looks at how past trends can help in predicting prescriber behavior in the workers' compensation environment. The presentation was recently given during the National Association of Medical Advancement (NAMA) Workers' Compensation and Disability Symposium held in Chicago, IL.

"We are very excited that Healthsystems was able to speak about prescription costs, trends and treatments as these topics are important to our conference attendees and the subject matter fits well into the NAMA's goal of providing relevant and new emerging information addressing workers' compensation issues," stated David Staral Jr., President of NAMA.

The overall theme of the presentation illustrates examples of how workers' compensation claims professionals need to be more aware of changes occurring with pharmaceutical products and the impact these changes have on claimant prescription treatment programs, while also understanding the influence drug companies may have on physicians and their overall prescribing patterns. In addition, the presentation reviews how both payers and pharmaceutical companies are operating during this unique period in economic history.

As is the case with many industries, pharmaceutical companies have been modifying some of their business strategies in order to address the significant reduction in consumer and corporate spending while workers' compensation payers are challenged with addressing the higher potential for co-pay dependent group health prescriptions showing up in the workers' compensation benefit arena. According to a recent IMS Health report¹, in 2008 sales growth of prescription drugs in the U.S. slowed for the second straight year and is



expected to contract by 1-2 percent in 2009. This is a stark contrast to an industry that historically has been unaffected during previous recessions and further illustrates the impact the economy is having on consumer drug purchases. The National Association of Insurance Commissioners reports that in 2008 11% of Americans have cut back on their prescription dosages to make medications last longer while health plans have continued to increase their requirements for using generic drugs compared to more expensive brand counterparts.

What does this mean for the workers' compensation market where pharmacy spend comprises less than 4% of the total annual U.S. prescription drug sales, and where the emphasis on expensive, pain-related treatment drugs continues to drive a significant portion of the overall medical spend? It means that an already complex prescription treatment environment is now faced with additional factors that can influence prescription trends and drug utilization. As drug manufacturers navigate through the economic downturn, they continue to rely on many of the historically successful strategies traditionally used to shape physician and consumer prescribing patterns while also incorporating new strategies to address the changes occurring in the market. This requires workers' comp payers to be even more vigilant with reviewing drug treatment regimens, especially on the narrow percentage of complex claims that contribute to the majority of costs. According to a Healthsystems prescription trending analysis, less than 10% of injured workers' receiving prescriptions can drive upwards of 60% of a payer's overall drug expenditures.

In addition to the overall economic conditions, several other factors are contributing to the slower growth of pharmaceutical sales. According to some industry estimates, the U.S. pharmaceutical industry stands to experience a loss in revenue sources upwards of \$200,000,000,000 by the year 2015 due to drug patent cliffs (brand drugs with expiring patents losing market exclusivity). Several drugs prescribed to workers' compensation claimants approaching patent expiration include:

<u>Year</u>	<u>Medication</u>	<u>Drug Manufacturer</u>
2009	Prevacid [®]	Takeda
2010	Kadian [®]	Alpharma
2011	Lipitor [®] ; Seroquel [®]	Pfizer; AstraZeneca
2012	Lexapro [®] ; Lunesta [®]	Forest Labs; Sepracor
2013	Opana ER [®]	Endo
2015	Provigil [®]	Cephalon

In addition, the number of new, FDA approved products has been decreasing with only 24 occurring in 2008. This "innovation deficit" of new products has drug manufacturers searching for new blockbuster product category entries (drugs achieving annual sales of over \$1 billion) to distribute in an already saturated portion of the market. Combining these economic factors with the potential introduction of proposed federal regulations such as: "The Pharmaceutical Market Access & Drug Safety Act" (which addresses drug re-importation) and "The Preserve Access to Affordable Generics Act" (which addresses "pay to delay" tactics used to extend a brand drug's market exclusivity), places the drug manufacturers in a situation where they must devise new strategies to maintain or grow market share.

Over the years, the pharma industry has achieved sales success using direct to consumer marketing campaigns and physician detailing programs. According to a 2008 study by York Universityⁱⁱ researchers, Pharma promotional spending has represented upwards of 18% of many pharma companies' total sales with total industry spend reaching as high as \$57 billion in 2004. This, however, has begun decreasing over the last two years due to factors such as companies waiting longer to advertise new drugs to consumers. Since workers' compensation is a specialty area for drug treatment (mainly addressing the treatment of acute or chronic pain) most of the influence is targeted directly to the physician community versus the consumer and these efforts have helped keep the opioid drug class number one in total prescription costs for workers' compensation claimants. However, there have been many negative consequences resulting from these powerful agents such as the significant increase in the misuse, abuse, accidental overdose and inappropriate prescribing of opioids over the past 10 years. According to a presentation given during a recent IAIABC seminar titled "The Appropriate Use of Narcotics in the Treatment of Occupational Injuriesⁱⁱⁱ," the top eight most abused opioids in the U.S. ordered in terms of prevalence include: OxyContin, Hydrocodone, Other Oxycodone Preparations, Methadone, Morphine, Hydromorphone, Fentanyl and Buprenorphine. Several of these medications are seen in the list of top 10 Workers' Comp Medications by Total Paid as shown below.

2005	Type	2008	Type
Hydrocodone/Acetaminophen	Analgesic	Oxycodone HCL-OxyContin	Analgesic
Gabapentin-Neurontin	CNS	Lidoderm	Topical Anes.
OxyContin	Analgesic	Lyrica/Pregabalin	CNS
Carisoprodol	Muscle relax.	Celebrex	Anti-inflam.
Celebrex	Anti-inflam.	Gabapentin/Neurontin	CNS
Lidoderm	Skin prep.	Hydrocodone/Acetaminophen	Analgesic
Skelaxin	Muscle relax.	Fentanyl	Analgesic
Mobic	Anti-inflam.	Cymbalta	Antidepressant
Oxycodone HCL	Analgesic	Skelaxin	Muscle Relax.
Naproxen	Anti-inflam.	Actiq/Fentora	Analgesic

*Data compiled from Healthsystems 2009 prescription trending analysis

When the top 10 workers' comp drug classes are ranked by total prescription cost, Analgesics-Opioids and Analgesics-Anti-Inflammatories are highly ranked in terms of percent of cost and the top two comprise almost 45% of total annual drug costs (illustrated in the chart below).

Drug Class	Example	2005		2008	
		Rank	% of Cost	Rank	% of Cost
Analgesics-Opioid	Actiq, Fentora, Duragesic, Vicodin, Lortab, Oxycontin	1	34.85%	1	33.69%
Analgesics-Anti-Inflammatory	Celebrex	2	11.13%	3	8.42%
Anticonvulsants	Neurontin, Lyrica	3	10.21%	2	10.52%
Musculoskeletal Therapy Agents	Carisoprodol, Skelaxin	4	9.28%	4	7.45%
Antidepressants	SSRIs, SNRIs	5	7.32%	5	7.13%
Anti-Ulcer Drugs	Prilosec, Nexium, Prevacid	6	4.22%	7	3.70%
Topical Anesthetic	Lidoderm			6	4.17%

What does the road ahead hold for the pharmaceutical industry? Merger and acquisition activity has increased as a strategy for companies to bolster drug pipelines with Pfizer and Wyeth leading the pack with their recent \$68 billion merger. Some research and development strategies have included the creation of new drugs by isolating “superior” isomers of existing drugs whereby the newly created drugs’ benefits may only be marginal, yet enough to achieve FDA approval. “Drug repositioning” or “evergreening” of existing drugs is also a common trend since it helps pharma companies maintain drug exclusivity with already approved drugs while also avoiding the costs and time associated with developing new ones. Physicians are also already familiar with the drug’s effects and these existing drugs are easier to market for new uses.

Certain newly defined medical conditions have also raised questions as to whether the pharmaceutical industry’s approach to disease awareness campaigns are detrimentally increasing self-diagnoses from the general public, whereby people are subsequently requesting specific medications for treatment. This has recently been covered in articles published in the Wall Street Journal^{iv} and the New York Times^v regarding the diagnosis of diseases such as Restless Leg Syndrome (RLS) and Fibromyalgia.

All of these factors, coupled with the current state of the U.S. economy have compounded the level of complexity for workers’ compensation medical treatments whereby the pharmaceutical industry’s historical methods for growing their businesses will continue to have a heavy influence on prescribing patterns in the near future. The silver lining, however, is that many of the pharmaceutical cost drivers noted above can be addressed with the proper strategy. Payers capitalizing on better drug pricing opportunities is important, but being proactive with controlling prescription utilization and achieving the optimal drug mix for injured workers will be even more important.

Health**esystems** is a specialty provider of innovative medical cost management solutions for the workers' compensation industry. The company offers a diverse suite of services including a leading pharmacy benefits and clinical management program as well as a prospective adjudication solution for managing ancillary medical services. Leveraging powerful technology, clinically-based outcomes management expertise and enhanced workflow automation tools, Health**esystems** provides clients with flexible programs that reduce the total cost of medical care while increasing the quality of care for injured workers.

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ⁱ "IMS Health Lowers 2009 Global Pharmaceutical Market Forecast to 2.5 – 3.5 Percent Growth." IMS Health, April 22, 2009, available at <http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=1e61fa8adbec0210VgnVCM100000ed152ca2RCRD&cpsexcurrchannel=1>

ⁱⁱ York University (2008, January 7). "Big Pharma Spends More On Advertising Than Research And Development, Study Finds." *ScienceDaily*. Retrieved June 5, 2009, from <http://www.sciencedaily.com/releases/2008/01/080105140107.htm>

ⁱⁱⁱ "The Appropriate Use of Narcotics in the Treatment of Occupational Injuries" seminar. IAIABC in collaboration with the Florida Association of Workers' Compensation Claim Professionals (WCCP), available at www.iaibc.org/i4a/pages/index.cfm?pageid=3513. February 12, 2009.

^{iv} Jeanne Whalen, "How Glaxo Marketed a Malady to Sell a Drug," Wall Street Journal, available at www.online.wsj.com. October 26, 2006.

^v Alex Berenson, "Drug Approved. Is Disease Real," New York Times, available at www.nytimes.com/2008/01/14/health/14pain.html?_r=1. January 14, 2008