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The ABCs of SCI

Spinal Cord Injury (SCI) is a catastrophic trauma resulting in damage that affects the ability of the brain to send and receive signals to the body's systems below the injured area that control sensory, motor and autonomic functions, thereby causing paralysis. Accordingly, when an SCI happens, some people lose the ability to use their legs and lower body only (paraplegia), while others lose ability from the neck down (quadriplegia).

When a spinal cord injury occurs, the nerves within the bony protection of the spinal canal are often damaged. The most common cause of work-related spinal cord injury is trauma. However, SCI damage can occur from different diseases occurring at birth or even later in life. Injuries can also result from tumors, poisons, electric shock or lack of oxygen. What's not often realized is that the spinal cord does not have to be severed to result in a loss of function. Most people with spinal cord injuries have an intact spinal cord that has been bruised, not cut or detached.

Basic Spinal Cord Anatomy

The spinal cord is made up of thousands of nerves and is responsible for synchronizing movement and sensation within the body. It is the pathway for information connecting the brain and peripheral nervous system, and coordinates all bodily functions. The spinal cord extends from the base of the brain to the middle of the back, where the nerves of the spinal cord join at the lower spine. It is enclosed in and protected by the bony vertebral column.



SCI Lifecycle

It's important to understand that a spinal cord injury is more than a single event. The initial trauma damages or kills nerve cells at the area of impact. After the initial injury, a surge of secondary events occur—including oxygen loss as well as the release of toxic chemicals at the site of the injury—further damaging the spinal cord. The first hours following a spinal cord injury are critical in keeping secondary events at bay. Current practice immediately following an SCI includes administering steroid (methylprednisolone) treatment in the hopes of limiting damage. However, this treatment modality is still being debated and as a result is not yet practiced universally.

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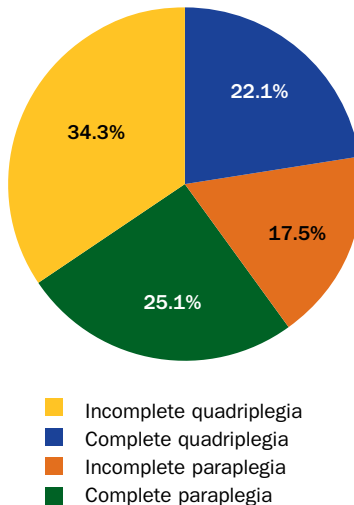
After the injury, swelling of the spinal cord begins to decrease and many injured individuals may show some functional improvement. With incomplete injuries, some function is preserved below the lesion level. An individual may recover some motor or sensory functions up to 18 months following the date of injury. In a complete spinal cord injury, nerve damage obstructs or stops all signals coming from the brain to the body parts, muscles and organs innervated by nerves that are located below the injury level. With ongoing research and enhanced technologies, more and more is being done today to improve the outcomes of this catastrophic injury.

SCI Care and Improvements Over the Years

Until the mid 1940s, individuals sustaining a spinal cord injury usually died from urinary tract infections, pneumonia, and/or skin infections or breakdown due to lack of mobility. Medical research and development conducted over the past 60+ years has changed this bleak outcome. The introduction of antibiotics such as sulfa drugs, new therapeutic interventions, and improved technology has changed the prognosis for many SCI individuals from a death sentence to a normal life expectancy. Individuals with spinal cord injuries are surviving and living long, fruitful lives. **Today there are 247,000 Americans currently living with an SCI, with approximately 11,000 new injuries occurring yearly—and a new SCI occurring every 49 minutes.** The most frequent level of

injury at the time of hospital discharge is illustrated below.

Level of Injuries at Hospital Discharge



Workplace Outcomes

About 40% of injured individuals with paraplegia and 30% with quadriplegia eventually return to work. Factors that affect return to work include magnitude of the injury (incomplete or complete), level of independent mobility, employment history, education, and demographics such as age, gender and race. SCI individuals who return to work in the first year post-injury usually return to the same job for the same employer; those who return to work after the first year post-injury usually go to work for different employers.

Daily Care for an SCI

Because of the complexity of SCI, injured individuals require a wide range of durable medical equipment (DME), supplies, prescriptions and therapies. It is imperative that the injured individual, physicians, healthcare staff, and family are all educated and in agreement on a short- and long-term plan of care. PMSI provides a single-source solution for the needs of catastrophically injured individuals. Through actively managing a national vendor network, PMSI provides a one-call approach for coordinating the medications, medical services, products and equipment for injured individuals—saving busy claims professionals time and lowering costs, while reducing risk and providing world-class care.

PMSI's goal is to provide the right product, at the right time enabling individuals with spinal cord injuries to lead a more productive and active life to the fullest extent possible.

Reference: <http://www.spinalcord.uab.edu/show.asp?durki=19775> <Accessed May 15, 2009>

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features

FDA Advisory Panel Recommends Withdrawal of Propoxyphene Products

A Food and Drug Administration (FDA) advisory panel voted 14 – 12 in early 2009 to recommend a withdrawal of propoxyphene products (Darvon, Darvocet) from the U.S. market, citing clinical studies that show non-superiority over acetaminophen (Tylenol®). Originally approved in 1957 for the treatment of mild to moderate pain, propoxyphene products continue to be one of the most widely prescribed analgesic agents available; a reported 20 million prescriptions were written for these agents in 2007. Clinical studies comparing the safety and efficacy of acetaminophen versus combination propoxyphene/acetaminophen (Darvocet) have demonstrated no clinical advantage over acetaminophen alone, implying that propoxyphene only adds potentially life-threatening side effects while contributing no additive analgesic benefits.

While the manufacturers of Darvon argue that physicians need a varied arsenal of analgesics to effectively treat patients, others strongly disagree. “With a drug that has almost no evidence of benefit, any risk is unacceptable,” states Sidney Wolfe, MD, a member of Public Citizen, the consumer advocacy organization that recommended the withdrawal of Darvon to the FDA. The FDA is not bound to follow the panel’s recommendations; however, the agency typically heeds this sort of advice. Although the potential withdrawal of Darvon from the U.S. market would limit analgesic choices for patients, a myriad of other alternatives (i.e., hydrocodone, oxycodone, hydromorphone, tramadol, etc.) would still remain available.

It is anticipated that the potential removal of propoxyphene products will have no significant impact on effective pain management. If approved, it is expected that a withdrawal would be gradual in nature, as pharmacies would be allowed to continue dispensing propoxyphene products until supplies are completely liquidated.

Reference: *FDA Advisers: Ban Painkiller Darvon*. CBS News Online. January 30, 2009. http://www.cbsnews.com/stories/2009/01/30/health/main4764797.shtml?source=RSSattr=HOME_4764797 <Accessed January 30, 2009>

Meeting agenda: FDA, Center for Drug Evaluation and Research. <http://www.fda.gov/ohrms/dockets/ac/09/briefing/2009-4411b1-01-FDA.pdf> <Accessed February 19, 2009>

FDA to Meet with Drug Companies About REMS for Certain Opioid Drugs

The Food and Drug Administration (FDA) conducted a meeting in early March 2009 with companies that manufacture potent opioid analgesics to discuss plans to develop a Risk Evaluation and Mitigation Strategy (REMS) for certain opioids. Opioid analgesics are widely prescribed for moderate to severe pain originating from cancer and non-cancer etiologies. However, risks associated with improper use of opioid analgesics can have far-reaching, harmful societal effects that may include the loss of human lives, added economic burden, abuse, and accidental overdose of these medications. Last quarter’s edition of *PMSInfo* newsletter featured a study that characterized patterns of abuse among unintentional pharmaceutical overdose fatalities (one of the risks involved with the use of these medications), which illustrated that opioid analgesics were taken by 93.2% of decedents.

According to the FDA, REMS is a strategy to manage a known or potential serious risk associated with an approved/licensed drug or biological product. Components of a REMS program may include a medication guide, patient package insert, communication plan, elements to assure safe use, an implementation system, and it must include a timetable for assessment of the REMS. Requiring REMS for certain potent opioid analgesics will hopefully further highlight the serious risks that are associated with opioid agents, encourage prescribers to embrace opioid treatment guidelines, and limit the use of opioids that are associated with a high frequency of abuse. PMSI has implemented several programs within its patient population to assist in curtailing inappropriate utilization of opioids. Clinical initiatives such as PMSI’s prior authorization program (for short- and long-acting opioids) are designed to reduce inappropriate prescribing (dose or patient selection) and authorization of certain opioids in the injured worker population.

Reference: FDA, Center for Drug Evaluation and Research. <http://www.fda.gov/cder/drug/infopage/opioids/default.htm> <Accessed April 15, 2009>

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Obama Administration Lifts Ban on Stem Cell Research

Following an eight-year ban prohibiting the use of federal funds for the study of stem cell research, the Obama administration announced in early 2009 that stem cell research would be allowed to commence. Stem cells are a precursor class of cells that possess the ability to transform into any specialized tissue in the body. Serious conditions, such as birth defects and cancer, can be attributed to errors that occur in this stem cell development phase. Attaining a better understanding of normal cell development could potentially lead to a reduction in the occurrence of various detrimental medical conditions. Scientists have been experimenting with human embryonic stem cells (hESC) since the late '90s, when a group led by Dr. James Thomson at the University of Wisconsin developed a technique to isolate and grow the cells. Unfortunately, scientists have had to depend on the use of federal funds to subsidize their research, which was a limiting factor in the advancement of this branch of science since the beginning of the Bush administration.

It's important to note that although hESC are thought to offer potential cures and therapies for many devastating diseases, research using them is still in its early stages. Today, the process of utilizing donated tissues and organs is common in the treatment of diseased or destroyed body systems. Unfortunately, the multitude of patients in need of a transplant exceeds the number of organs available for transplantation. Stem cells offer a possible renewable source of replacement cells and tissues to treat a number of diseases, including Parkinson's disease, spinal cord injury, and diabetes. It will be interesting to watch and report on how hESC research impacts the devastating effects on long-term healthcare and associated costs following spinal cord injuries, traumatic brain injuries and even burns—all very high-cost injuries for insurance companies.

References: *Stem Cells and Diseases*. Stem Cell Information. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2009. <http://stemcells.nih.gov/info/health> <Accessed April 13, 2009>

Obama Reverses Bush Policy on Stem Cell Research. *The Washington Post*. March 10, 2009. <http://www.washingtonpost.com/wp-dyn/content/article/2009/03/09/AR2009030901194.html> <Accessed April 16, 2009>

Consumer Reports Indicates Most Americans Suffer from Back Pain

A recent study conducted by *Consumer Reports* reported that 80% of adults have complained of back pain at some point in their lives. Figures indicate that more than half of these patients suffer from debilitating pain, limiting daily routines for at least a week's time. The study indicates that those suffering from back pain reported the use of five to six different treatment regimens to ease their pain. Recently, CBS correspondent Dr. Jennifer Ashton noted that back pain was listed as the "most common ailment in the country." Dr. Ashton went on to comment that most people found "hands-on therapy" worked best in relieving symptoms and acknowledged that patients are "staying away from things like medication, prescription drugs and surgery." She also stated that patients were pursuing "acupuncture, physical therapy and chiropractic treatment." Yoga was also mentioned as an alternative.

Many physicians believe the best treatment for back problems is to prevent them in the first place—noting that stretching, maintaining correct posture and sleeping on a good mattress can help prevent back pain from occurring. Dr. Ashton warned against a "quick fix," commenting, "a lot of times that's prescription narcotics, which is actually probably the worst thing for you." When little relief occurs, surgery may be considered, but this option should be used as a last resort. Dr. Ashton indicated that if a herniated disc was present with neurological symptoms, surgery might be effective. In the past, surgery was sometimes the first treatment to take place, and now it is one of the last considered.

Back injury in workers' compensation remains one of the leading causes of lost days, escalating indemnity and medical costs, and may result in failed back syndrome, often catastrophic in nature, due to increased reserves. Safety programs and prevention of injuries are the first line of defense in deterring back pain symptoms.

References: *Relief for your aching back: What worked for our readers*. *Consumer Reports*. <http://www.consumerreports.org/health/medical-conditions-treatments/back-pain/overview/back-pain.htm> <Accessed April 17, 2009>

Jennifer Ashton, MD. *Best Ways to Prevent Back Pain*. CBS News Online. <http://www.cbsnews.com/stories/2009/04/08/earlyshow/health/main4928851.shtml> <Accessed April 17, 2009>

New Introduction

Breathing Pacemakers

Released: July 2008

Many people who have lost the ability to breathe on their own either by injury or disease are dependent on machinery to breathe for them for the rest of their lives. Now there is an alternative: An implantable diaphragmatic/phrenic nerve stimulator similar to a pacemaker—a breathing pace-maker. Injured individuals with high spinal cord or brainstem injuries are typical candidates for the diaphragmatic/phrenic nerve stimulator. This breathing system is more natural and affords a better quality of life.

New Drug Approvals

Ryzolt™ (tramadol)

Approved: December 30, 2008

Joining Ultram® ER as one of two branded versions of extended-release tramadol, Ryzolt became available in the United States in May 2009. Similar to Ultram ER, Ryzolt contains tramadol, a partial opioid analgesic used in the treatment of moderate to moderately severe pain. Due to the combination immediate-release and extended-release properties of this agent, it is not yet known what impact the introduction of Ryzolt will have on current pain therapy.

Savella™ (milnacipran)

Approved: January 14, 2009

Milnacipran joins Cymbalta® and Lyrica® as one of three FDA-approved medications for the treatment of fibromyalgia. Owing to its serotonin-norepinephrine reuptake inhibitor mechanism of action, milnacipran has also been used in an off-label fashion for the treatment of depression. It is anticipated that milnacipran will become available sometime in mid to late 2009.

Kapidex™ (Dexlansoprazole)

Approved: January 30, 2009

Kapidex (dexlansoprazole) will become the next agent to join the proton-pump inhibitor class of gastroprotective agents. Takeda Pharmaceuticals' other proton pump inhibitor, Prevacid® (lansoprazole) is expected to lose its rights for marketing exclusivity in late 2009. Due to the similarity of this agent to currently available agents, it is uncertain if the introduction of Kapidex will provide any significant clinical advantage.

New Formulation

Zolpimist™ (zolpidem)

Approved: December 19, 2008

The once tablet-only sedative sleep agent, zolpidem, was recently approved by the FDA in an oral spray dosage form, under the name of Zolpimist. Similar to Ambien®, this new formulation contains either 5 mg or 10 mg of regular-release zolpidem and is only approved for the short-term treatment of insomnia. Due to the similarities of this agent to generically available zolpidem, it is expected that this drug will likely not provide any new clinical benefit for the treatment of insomnia.

New Generic Launch

Topamax® (topiramate)

Launched: March 27, 2009

Topamax tablets are now available as the generic equivalent, topiramate. Topiramate is an anticonvulsant agent used in a number of epileptic disorders; Topiramate is also used in an off-label manner for the treatment of neuropathic pain. Teva Pharmaceutical Industries, which received approval to market the newly appointed generic, will produce 25 mg, 50 mg, 100 mg, and 200 mg tablets.

FDA MedWatch Reports

Highlighting Important Safety Issues from the FDA

Medical Device Recall—Hill-Rom 70 Semi-Electric Bed (Class 2 Recall)

Posted: January 16, 2009

Date Recall Initiated: November 11, 2008

Recall Number Z-0506-2009

Product

Hill-Rom 70 Semi-Electric Bed Model HS-968. The bed is a general purpose bed for use with low to medium acuity patients in the home-care environment.

Code Information Serial numbers HC100001 through HC101261.

Recalling firm/manufacturer

Hill-Rom, Inc.
125 E. Pearl St.
Batesville, Indiana 47006

Reason for recall

Failure, mechanical: If the bed mechanism is cranked downward when the bed is already in its lowest position, the springs may cause the bed to rise suddenly if the bed is empty, more slowly if occupied by a patient, or when the patient exits the bed. For further information, please contact Hill-Rom, Inc. at 800.445.3720.

For additional information, contact:

Steven S. Hollingsworth, 812.934.6727

Action

Consignees were notified of the problem by letter dated 11/11/08 and instructed to position the bed at least 3 inches above the lowest bed position in order to prevent the problem, and then to only use the pendant electronic controls to raise and lower the head and foot sections of the bed, until Hill-Rom can repair the bed. The letter was entitled "Urgent Medical Device Correction."

Quantity in commerce: 567

Distribution: Nationwide

Reference: *Hill-Rom 70 Semi-Electric Bed Recall. FDA Recall.* November 11, 2008. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?ID=74910>

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Transdermal Patches with Metallic Backings

Posted: March 5, 2009 — FDA notified healthcare professionals and patients that certain transdermal patches (medicated patches applied to the skin), containing aluminum or other metals in the backing of the patches, can overheat during an MRI scan and cause skin burns in the immediate area of the patch. FDA is in the process of reviewing the labeling and composition of all medicated patches to ensure that those made with materials containing metal provide a warning about the risk of burns to patients who wear the patches during an MRI scan. Until this review is complete, FDA recommends that healthcare professionals referring patients to have an MRI scan identify those patients who are wearing a patch before the patients have the MRI scan. The healthcare professional should advise these patients about the procedures for removing and disposing of the patch before the MRI scan, and replacing the patch after the MRI scan. MRI facilities should follow published safe-practice recommendations concerning individuals who are wearing patches.

Reference: FDA MedWatch Report. <http://www.fda.gov/medwatch/safety/2009/safety09.htm> <Accessed March 11, 2009>

Various Opioid Analgesics Removed from U.S. Market

Posted: March 31, 2009 — The FDA recently sent warning letters directing various companies to stop making and distributing specific narcotic products in certain dosage forms that lacked required FDA approval. Affected products include unapproved high-concentrate oral solutions containing morphine sulfate and unapproved immediate-release tablets containing morphine sulfate, hydromorphone, or oxycodone. While the FDA works to ensure that all marketed unapproved drug products obtain approval or are removed from the market, healthcare practitioners and consumers can use the National Drug Code (NDC) Directory to determine whether a drug is FDA approved. The NDC Directory is limited to prescription drugs and insulin products. Search results from the NDC directory include a column marked “Application Number.” FDA-approved products will have an associated NDA (new drug application) or ANDA (abbreviated new drug application) number in this column.

Consumers should be aware that they will continue to have access to FDA-approved narcotic drugs. This action will have the most impact on consumers who use high-



concentrate unapproved morphine sulfate oral solutions and unapproved immediate-release tablets containing morphine sulfate, hydromorphone, or oxycodone. There are, however, several firms that market products containing the same active ingredients that have FDA-approved applications. There are also other FDA-approved drugs, including different narcotics, which can be used to relieve pain. Consumers should consult a healthcare professional for detailed guidance on their treatment options.

Reference: FDA, Centers for Drug Evaluation and Research. http://www.fda.gov/cder/drug/unapproved_drugs/narcoticsQA.htm <Accessed April 3, 2009>



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Founded in 1976, today PMSI is one of the nation's largest providers of specialty managed care services and products for workers' compensation. PMSI provides a best-in-class integrated portfolio of clinically based services in Pharmacy, Medical Services and Equipment, and Settlement Solutions that promotes quality care for injured workers while helping clients contain costs and control utilization.

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