



Chronic Pain: Debilitating Patients, Insurance Companies, and Our Economy



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“Pain from common conditions such as headaches and backaches costs U.S. employers about \$80 billion a year in lost productivity. The bulk of the loss, about \$64 billion, is largely invisible to employers because it occurs when workers are on the job but in too much pain to perform up to job standards, not when they take sick days.”

~American College of Occupational and Environmental Medicine (ACOEM). Occupational Medicine Practice Guidelines, second edition. Pg. 105-106

There clearly is no debate regarding the tremendous toll that chronic pain takes on our work force, economy, healthcare system and population in general. With more than 100 million Americans suffering from chronic pain and \$600 billion dollars being spent annually in medical costs and lost productivity, the argument is not the existence of the problem, but rather the remedy. Patients, practitioners, employers, and Payer are being bombarded by costs (physical, emotional and financial) and to date, effective solutions have eluded us.

“Prolonged use of narcotic medications may cause both physiologic and psychological addiction and may reduce the body’s supply of endorphins, causing depression and delayed recovery ... Pain medications are typically not useful in the subacute and chronic phases and have been shown to be the most important factor impeding recovery of function...”

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Pain management traditionally defaults to prescription medications ranging from acetaminophen to NSAIDS (Motrin) to COX-2 inhibitors (Celebrex) and on to opiates of varying degrees such as codeine, Vicodin, morphine and OxyContin. These are often combined with treatments such as epidural nerve injections, antidepressants, sedatives and other concurrent medications leading to a wide array of potential side effects which are then followed by additional strain on the healthcare system, the economy, the families involved, and you, the Payer.

Breaking the Drug Cycle

These heavy-duty painkillers may not be all they are cracked up to be. In 2008, the California Workers’ Compensation Institute issued a study that questioned how such opioid drugs are used to treat chronic back pain among California workers injured on the job. In the study of 166,336 workers with back injuries, the association found one in four received prescriptions for opioid painkillers and those workers averaged more than five prescriptions for the drugs during treatment. More drugs prescribed meant more time off from work and longer temporary-disability payments.

Without careful utilization management and a treatment approach that focuses on patient education and engagement, opioid abuse can negatively impact an employee’s ability to return to work. In fact, prescription narcotics caused nearly 16,000 deaths in 2009, according to the Centers for Disease Control and Prevention. Furthermore, work-



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ers' compensation Payers spent roughly \$1.4 billion that year on narcotics. Employers are facing increased medical and indemnity costs, death benefit exposure and unlimited liability and reputational risk.

Propelled by an increase in prescription narcotic overdoses, drug deaths now outnumber traffic fatalities in the United States. Public health experts have used the comparison to draw attention to the nation's growing prescription drug problem, which they characterize as an epidemic.

Today, prescription drugs account for roughly 20 percent of workers' compensation medical costs. Contributors to the rising costs include drug over-utilization, fraud, physician dispensing, costs associated with compound medications, an epidemic of opioid use and abuse, and inconsistent national oversight of providers resulting in duplicate therapies. The recent acceleration in the rate at which prescription narcotics are used in the United States has become a significant public health emergency. A recent report by the National Center for Addiction and Substance Abuse found that 15.1 million Americans, more than six percent of the adult population, admit to abusing prescription drugs – more than all other forms of drug abuse combined.

A 2011 report by the Center for Disease Control and Prevention noted that in 2007, drug-induced deaths had become more common than alcohol-induced or firearm-related deaths in the United States, and the increase was associated with "prescription opioid painkillers and psychotherapeutic drugs being prescribed more widely by physicians," and that these drugs had "supplanted illicit drugs as the leading cause of drug-related deaths."

Medications are not cheap and side effects can be severe. The direct cost of medications can average \$300-\$600 per month. Equal to that, however, is the cost of treating the complications related to the medication, which exceeds \$2 billion per year from NSAIDS alone (Griffin, 2008).

Side effects of NSAIDs can include renal dysfunction and raised arterial blood pressure. Other studies have shown that when NSAIDs are used for more than a few weeks, they can retard or impair bone, muscle and connective tissue healing and perhaps cause hypertension.

There are endless studies and statistics regarding cost factors involved with the chronic pain epidemic in the U.S. As a Payer, you are well aware of these direct and future costs associated with extended periods of prescription drug use. In order to break this cycle, practitioners, patients and third party payers must all assume an active role in seeking alternative forms of pain relief that do not carry the side effects nor detriments of long term medicinal management of chronic pain.



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Drug Free Treatments Come With Inherent Costs and Limitations

Historically, non-drug related interventions have included:

- Physical Therapy
- Surgery
- Other pain relief modalities such as TENS

The efficiency of these treatments will not be debated in this paper, as they all have their merits and protocols for successful use. Instead, the cost effectiveness and limitations of each treatment regimen should be considered.

Physical Therapy

While Physical Therapy is proven to provide significant improvements in patient strength, range of motion, and education (which may prevent re-injury), it falls short in the area of day-to-day pain management. With patients typically receiving therapy treatments for 60-90 minutes T.I.W., they are left with approximately 163 non-therapy hours each week when pain, spasm and swelling cannot be easily managed. As a result, physical therapy treatments are most often used in conjunction with prescription drugs and, even in the event of successful therapy outcomes, the cost and side effects of medications are still a reality. Overall, for the payer, costs for physical therapy in addition to the costs of medications can exceed thousands of dollars per month. When physical therapy is eventually discontinued, the medical management typically continues, as does the cost and likelihood of future side effects.

Surgery

Without question, surgery has its benefits, but these benefits come at high cost and often the extreme risk of complications, varied results and continued drug use post-op. A non-surgical, low-cost alternative to surgery with little to no risk of side effects should be explored whenever possible. Failure to do so results in undue stress to patients, employers, third party payers and the healthcare system in general.

TENS

TENS is a non-invasive form of electrotherapy indicated by the FDA for the treatment of pain. While it is drug-free and has no side effects, it primarily serves as a mechanism to interfere with pain receptors and prevent pain messages from reaching the brain. Its effectiveness typically decreases in cases of intense pain and offers no benefit when it is not being worn. Additionally, it has no effect on circulation, inflammation, spasm,

atrophy, range of motion, or any other clinical issue accompanied by pain. As a result, a patient being successfully treated with TENS will often require additional interventions (drugs, therapy, etc.) for underlying conditions causing the pain.

Although TENS is relatively inexpensive and easy to use, its contribution to overall recovery is limited. Even under the best of circumstances, there will always be a significant portion of time when the patient is unable to wear the device and will most often resort to medications for pain management during these periods. With no rehabilitation benefit, TENS will have little to no bearing on a patient's return to full health.



H-Wave creates physiologic changes while providing measurable and objective benefits.

A Case for H-Wave

It is imperative to understand that the effectiveness of H-Wave is not on trial. In fact, H-Wave is supported by a significant amount of evidence-based medicine and has more FDA clearances than any other form of electrical stimulation. There is extensive published research validating efficacy (See Appendix A), and the credibility among clinicians and high profile users such as professional athletes is unparalleled in the field of e-stim.

H-Wave creates *physiologic changes* while providing *measurable* and *objective* benefits. Consistent use of H-Wave is proven to result in significant vasodilation, increased blood flow and angiogenesis (formation of new blood vessels). These are the foundation of recovery as opposed to the masking of symptoms associated with drug use.

Research additionally shows measureable and objective results such as increased range of motion, improved activities of daily living (ADLs) and decreased prescription drug use.

Bottom line for the payer: Faster recovery, reduced disability, accelerated return to work

H-Wave offers a unique set of benefits which are unparalleled in physical rehabilitation as it has been shown to be effective modality for treating:

- Chronic Pain
- Acute Pain
- Post-Operative Pain
- Soft Tissue Injury/Inflammation
- Muscle Spasm
- Decreased Range of Motion
- Muscle Atrophy
- Compromised Circulation

With no known side effects, H-Wave is one of the few treatment options that is low-cost, provides for pain relief, facilitates recovery and can be controlled by the patient. Unlike TENS, H-Wave utilizes technology that provides rehabilitative, cumulative and objective benefits. H-Wave is also a drug free option for patients presenting with various comorbidities that prevent them from taking pain meds and anti-inflammatory meds, which can delay physical therapy progression and a return to work.

The H-Wave's success is reflected in several studies. According to one such study,

*“6,774 subjects who had a previous physician-documented diagnosis of chronic soft-tissue inflammation injury or neuropathic pain in an upper or lower extremity or the spine that was unresponsive to conventional therapy, such as physical therapy, medications, TENS and other analgesic electrical stimulator modalities. After treatment with the H-Wave: 65% of study participants reported a **reduced or eliminated need for pain medication**, 79% reported **improved functional capacity or activity**, and 78% reported a **25% or greater reduction of pain.**”*

~ The H-Wave Small Muscle Fiber Stimulator, a Nonpharmacologic Alternative for the Treatment of Chronic Soft-Tissue Injury and Neuropathic Pain: An Extended Population Observational Study. Advances in Therapy, Sep/Oct 2006. Vol:23 No: 5. p 739-749.

H-Wave also has **four distinct clearances with 15 indications for use from the FDA** including but not limited to pain control, maintaining or increasing range of motion, increasing circulation, relaxation of muscle spasm and anesthesia during dental procedures.

FDA Indications For Use	H-Wave	TENS
Chronic intractable pain	YES	YES
Post-operative and traumatic pain	YES	YES
Relaxation of muscle spasm	YES	NO
Maintaining or increasing range-of-motion	YES	NO
Increased local blood circulation	YES	NO
Prevention or retardation of disuse atrophy	YES	NO
Muscle re-education	YES	NO
Immediate post-operative stimulation of calf muscles to prevent venous thrombosis	YES	NO
Muscle spasm associated with TMJ	YES	NO
Muscle re-education, as in regaining control in TMJ	YES	NO
Anesthesia in General Dentistry	YES	NO
Amalgams	YES	NO
Composites	YES	NO
Crown Preparations	YES	NO
Periodontal Scaling and Root Planning	YES	NO



Additional Benefits of H-Wave

- Unlike medications, there are zero side effects.
- Unlike medications, H-Wave creates no work restrictions and does not cause demotivating factors such as depression or a drop in energy or endorphin levels.
- Where medication, physical therapy and surgery may have long-term cost implications, the use of H-Wave is a fixed cost: 100% of any rental cost is applied to the

purchase price. After 10 months, the only cost is periodic replacement of electrode pads, and there are even fixed cost programs for that as well.

- Unlike TENS, due to the increased circulation attribute of H-Wave, patients continue to receive a physiological benefit even when the unit is not in use.
- Unlike physical therapy, the H-Wave is available to the patient 24 hours per day, 7 days per week.

H-Wave in Use Now

Today, H-Wave works with thousands of physicians across the country, has active agreements with the two largest national out-patient therapy companies in the United States, and is a drug free modality of choice for the some of the most elite workers in the country. Players from over 50 professional athletic teams use H-Wave on their injured players, including...

Anaheim Ducks	Dallas Stars	Los Angeles Angels of Anaheim	New York Rangers	San Francisco 49'ERS
Arizona Diamondbacks	Denver Broncos	Los Angeles Kings	New York Yankees	San Jose Sharks
Baltimore Orioles	Detroit Pistons	Los Angeles Lakers	Oakland Athletics	St. Louis Cardinals
Baltimore Ravens	Detroit Tigers	Miami Marlins	Orlando Magic	Stony Brook University
BUFFALO BILLS	Florida Panthers	Milwaukee Brewers	Philadelphia 76ERS	Tampa Bay Buccaneers
Buffalo Sabres	Golden State Warriors	Milwaukee Bucks	Philadelphia Phillies	Tampa Bay Lightning
Carolina Panthers	Green Bay Packers	Minnesota Timberwolves	Phoenix Coyotes	Toronto Blue Jays
Chicago Bulls	Houston Rockets	New Jersey Nets	Portland Trail Blazers	University of Miami – Football
Chicago White Sox	Houston Texans	New York Islanders	Rice University	Washburn University
Colorado Rockies	Indianapolis Colts		Sacramento Kings	Washington Redskins
Dallas Mavericks	Kansas City Royals		San Diego Padres	



Conclusion

To review, H-Wave is NOT a modality on trial. For decades, its therapeutic indications and effectiveness have been witnessed and proven. It has been used successfully by top clinicians, world-class athletes, and our nation's largest providers of physical rehabilitation. Results have been documented over years of use and side-effects have been shown to be non-existent. From the perspective of a third-party payor, H-Wave is an extremely **low- and fixed-cost** treatment option.

When a Payer approves and covers the use of pain medications, a potential Pandora's Box is opened that could lead to extreme future costs for that provider (not to mention unlimited complications for the patient). But thanks to the approval of H-Wave as a treatment regimen, that same Payer is afforded the ability to better manage the risk (due to the fixed cost) and potentially avoid the future expense and exposure that results from prolonged prescription drug use.

In short, the risk/reward with H-Wave is heavily weighted in favor of the Payer and therefore should be a viable and approved treatment option for pain, musculo-skeletal injury, compromised circulation and range of motion loss.

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Appendix: A Summary of Research on H-Wave

Blinded/Controlled Outcome Studies

Repetitive H-Wave® Device Stimulation and Program Induces Significant Increases in the Range of Motion of Post-operative Rotator Cuff Reconstruction in a Double-blinded Randomized Placebo Controlled Human Study. *BMC Musculoskeletal Disorders*. 2009 Oct 29;10(1):132 [PMID:19874593, Indexed for MEDLINE]

Diabetic Peripheral Neuropathy: Amelioration of Pain with Transcutaneous Electrostimulation. *Diabetes Care*. 1997;20(11):1702-1705 [PMID:9353612, Indexed for MEDLINE]

Diabetic Peripheral Neuropathy: Effectiveness of Electrotherapy and Amitriptyline for Symptomatic Relief. *Diabetes Care*. 1998;21(8):1322-1325 [PMID:9702441, Indexed for MEDLINE]

Blinded/Controlled Mechanism of Action Studies

H-Wave® Effects on Blood Flow and Angiogenesis in Longitudinal Studies in Rats. *Journal of Surgical Orthopaedic Advances*. V20, N4, Winter 2011, P255-259 [PMID:22381420, Indexed for MEDLINE]

H-Wave® Induces Arteriolar Vasodilation in Rat Striated Muscle via Nitric Oxide-Mediated Mechanisms. *Journal of Orthopaedic Research*. Sept 2009. DOI 10.1002/jor.20851. P. 1248-1251 [PMID:19204915, Indexed for MEDLINE]

Preliminary Mechanism of Action Studies

Innate Properties of H-Wave® device, a Small Fiber Stimulator Provides the Basis for a Paradigm Shift of Electrotherapeutic Treatment of Pain with Increased Functional Restoration Associated with Human Neuropathies by Affecting Tissue Circulation: A Hypothesis. *J. Med Hypothesis*. Volume 64, Issue 5, 2005, Pages 1066-1067 [PMID:15780518, Indexed for MEDLINE]

Innate Properties of H-Wave® Device, a Small Fiber Stimulator Provides the Basis for a Paradigm Shift of Electrotherapeutic Treatment of Pain with Increased Functional Restoration Associated with Human Neuropathies: A Hypothesis. *Townsend Letter*. 258, 101-104, Jan 2005

Meta-Analysis and Reviews

The H-Wave® Device Is an Effective and Safe Non-Pharmacological Analgesic for Chronic Pain: a Meta-Analysis. *Advances in Therapy*. July 2008. Vol:25 No:7 [PMID:18636234, Indexed for MEDLINE]

The H-Wave® Device Induces NO-Dependent Augmented Microcirculation and Angiogenesis, Providing Both Analgesia and Tissue Healing in Sports Injuries. *The physician and sportsmedicine*. Dec 2008. Vol:36 No:1. P. 103-114 [PMID:20048478]

Cohort Studies

The H-Wave® Small Muscle Fiber Stimulator, a Nonpharmacologic Alternative for the Treatment of Chronic Soft-Tissue Injury and Neuropathic Pain: An Extended Population Observational Study. *Advances in Therapy*. Sep/Oct 2006. Vol:23 No:5. P. 739-749 [PMID:17142209, Indexed for MEDLINE]

H-Wave®, a Nonpharmacologic Alternative for the Treatment of Patients with Chronic Soft Tissue Inflammation and Neuropathic Pain: A Preliminary Statistical Outcome Study. *Advances in Therapy*. May/June 2006. V23 N3. P. 446-455 [PMID:16912027, Indexed for MEDLINE]

Beneficial Effects of Electrical Stimulation on Neuropathic Symptoms in Diabetes Patients. *J Foot Ankle Surgery*. 1998;37(3):191-194 [PMID:9638542, Indexed for MEDLINE]

Case Studies/Series/Abstracts

Resolution of a Double Crush Syndrome. *J Manipulative Physiol Therapy* 1994;17(6):395-397 [PMID:7964200, Indexed for MEDLINE]

Healing Enhancement of Chronic Venous Stasis Ulcers Utilizing H-Wave® Device Therapy: A Case Series. *Cases Journal*. BioMed Central. 2010, 3:54 [PMID:20181141]

Electrical Stimulation Reduces Symptoms Of Thermal Hypersensitivity From Injury Of Sciatic Partial Ligation In Rats. *Anesthesia & Analgesia* 1998;86;S1-S5