The Treatment of Chronic Pain in Veterans - a Brief Review
Testimony Submitted to the House Subcommittee on Crime
Alexander DeLuca, M.D., MPH; Senior Consultant, Pain Relief Network; 2007-07-12.

Table of Contents
Introduction // Opiophobia and Opioignorance //
Modern Understanding of Chronic Pain // Risk of Addiction in Opioid Therapy //
Treatment and Outcomes // Undertreatment of Pain is a National Scourge

Introduction
Two very similar articles were published in the first full week of June, 2007. On June 4, the cover story in Newsweek was, “The Changing Science of Pain” by Mary Carmichael. Three days later on June 7, the Associated Press (AP) published, “Doctors Urge Better Pain Care for Troops” by Lauran Neegaard. Both articles seem prompted by Lt. Col. Trip Buckenmaier, M.D., an anesthesiologist described in Newsweek as “sort of a pain czar for the Army” who is doing exciting research on battlefield placement of peripheral nerve blocking devices and on whether blocking acute pain early and continuously might decrease the incidence of the development of chronic pain later on. Hundreds of soldiers have so far received the battlefield block treatment, and preliminary results are expected over the next few years.

Both articles use a focus on this novel application of nerve block technology to quite aptly explain the modern understanding of the etiology of chronic pain, which truly represents a paradigm shift in pain management that is changing the medical standard of care (see: “A Modern Understanding of Chronic Pain,” below). Newsweek does an especially good job at this, employing well produced graphics to explain the medical-technical details clearly.

Medical and Lay Opiophobia and Opioignorance
Unfortunately both Carmichael and Neegaard perpetuate the popularly held opiophobic, war-on-drugs, worldview aggressively promoted by federal law enforcement for ninety years and currently enshrined in federal drug control policy based on the legislative foundation of the


“Principal among the attitudinal barriers of health care professionals to pain relief are misconceptions [collectively known as opiophobia] about [opioid] medications... [There exists] considerable [physician anxiety and] concern about opioid addiction, tolerance and hyperalgesia, including dose escalation and dependence [and] with side effects [and] about precipitating adverse side effects... There is also an unfounded assumption among physicians and patients that chronic opioid treatment necessarily impairs quality of life [and] belief that at least some pain is inevitable, and that opioid doses should be related to the severity of the disease rather than the intensity of the pain. These attitudes [do not reflect the standard of care and] recur in surveys of clinicians and patients about analgesia... Opiophobia among health care providers is compounded by opioignorance. Repeatedly, survey respondents acknowledge that they have received insufficient training in, or exposure to, pain management.”
Controlled Substances Act,\(^4\) as promulgated and disseminated by the Office of National Drug Control Policy (ONDCP),\(^5\) also known as the Office of the Drug Czar. These errors, especially when reinforced by experienced and prominent journalist like Carmichael and Neegaard, are important to examine as they underlie extensively documented barriers to pain relief faced daily by the majority of chronic pain sufferers.\(^6\)

The real life consequences of opiophobia and opioignorance to pain sufferers are horrific; studies have repeatedly shown the pain management customs and practice of physicians, even in cases of end-stage cancer, is extremely conservative and below the medical standard of care.\(^7\)\(^8\) This disturbing reality in which the medical community standard of care (what most reputable doctors do) is dramatically and widely below the medical standard of care (what the textbook say doctors should do) is the primary manifestation of the distortion of medical ethics and practice in response to defacto regulation of Pain Medicine by adversarial federal law enforcement. (See also: \textit{The Bounds of Medical Practice and the Standard of Care} - DeLuca; 2007)

I will use Ms. Carmichael’s Newsweek article for two examples of common opioid myths and misconceptions.

“Morphine, [used] in the Civil War, is still the Army’s most commonly used painkilling drug. It works, but compared with more-modern options, it's one step above chloroform and two above biting the bullet.”

Yes, opioids have been used by mankind, mostly to good effect, since recorded history. But the implication that they are crude or primitive is entirely false. Morphine, plain morphine, delivered according to modern, commonly taught medical principles, remains the most widely applicable and best treatment for a large majority of pain types, far more than any other class of medication or any interventional procedure. Opioids are the gold standard therapy. “Although there is currently no ideal analgesic for chronic pain, medications that act on µ-opioid receptors are the closest thing that we have.”\(^9\)

It is interesting that later in the article Ms. Carmichael describes at length a patient with fibromyalgia doing very well on a combination of powerful opioids where all other treatments had failed. She also describes recent alternatives to opioid therapy for chronic pain in these terms:

\(^6\) Rich, B.A. An Ethical Analysis of the Barriers to Effective Pain Management; Cambridge Quarterly of Healthcare Ethics; 9: 27-39; 2005; p. 66. Discusses 5 major impediments to pain relief: 1. The failure of clinicians to identify pain relief as a priority; 2. Insufficient knowledge among clinicians; 3. Fear of regulatory scrutiny; 4. Failure to hold clinicians accountable for pain relief; 5. Irrational beliefs and fears about addiction, tolerance, dependence, and adverse side effects.
\(^7\) SUPPORT Principle Investigators. A Controlled Trial to Improve Care for Seriously Ill Patients.; JAMA; 274: 1591-1598; 1995.
\(^8\) Marks,R.M., Sachar,E.J. Undertreatment of medical inpatients with narcotic analgesics; Archives of Internal Medicine; 78:173-181; 1997.
“Some of the most promising pain treatments of the past decade have turned out to be disappointments. Studies of some radiofrequency therapies show they work no better than placebos. Spinal-fusion surgery, a recent review found, has ‘no acceptable evidence’ to support it. And if a treatment does work, says Edward Covington, a pain specialist at the Cleveland Clinic, ‘for most people, the effect is temporary.’”

This next example from the Newsweek article is more subtle, but no less wrong and no less damaging:

“The military is pioneering its own new approaches. Since 2003, a small but growing number of soldiers in Iraq have been treated at the front with high-tech nerve-blocking devices that are effective but not addictive.”

First, there are many types of pain not susceptible to local, peripheral nerve blockade; the military’s experimental treatment will never replace opioids as the mainstay treatment for pain. The implication here, that opioids administered for severe traumatic pain under battlefield or MASH conditions are inherently ‘addictive’ is nonsense. This is the error of conflating the phenomenon of physical dependence on an opioid analgesic prescribed for pain with that of ‘drug addiction.’ Soldiers exposed to opioids under these conditions who become addicts because of such exposure are very, very rare. Even in non-veteran, non-cancer related, chronic pain populations exposed to high dosages of opioid analgesics continuously for many years, unexpected dose escalation and the development of substance use disorders by DSM-IV criteria is uncommon.

Pain patients responsive to opioid therapy need those medications every day in order to function in the world with any degree of comfort and efficacy. If they suddenly discontinue the medication the underlying pain returns, in some cases worsened by withdrawal symptoms; this is physical dependence. Most chronic pain patients on adequate, stable daily opioid therapy are not groggy or otherwise cognitively impaired, not sedated, are more alert, more active, more engaged in the world around them, are able to drive automobiles without impairment, and appear and feel well.

A Modern Understanding of the Etiology of Chronic Pain

Research into pathophysiology and natural history of chronic pain have dramatically altered our understanding of what chronic pain is, what causes it, and the changes in spinal cord and brain structure and function that mediate the disease process of chronic pain, which is generally progressive and neurodegenerative. Simply put, a continuous flow of pain signals into the pain
mediating pathways of the dorsal horn of the spinal cord alters those pathways through physiological processes described as central sensitization, and neuroplasticity.\textsuperscript{15 16 17}

The end result is the disease of chronic pain in which a damaged nervous system becomes the pain generator dissociated from whatever the initial pain source was. This understanding explains many clinical observations in chronic pain patients, such as phantom limb syndrome, that the pain spreads to new areas of the body not involved in the initiating injury, and that it generally worsens if not aggressively treated. The progressive, neurodegenerational nature of chronic pain was recently demonstrated in several imaging studies showing significant losses of neocortical grey matter in the prefrontal lobes and thalamus.\textsuperscript{18 19}

The implications for how acute and early chronic pain should be treated, the medical standard of care, are very serious. The analgesic effects of opioids are primarily mediated in the dorsal horn of spinal cord where they bind with receptors blocking pain transmission and thereby protecting the dorsal horn from being bombarded with pain signals which is believed to be the pathophysiological mechanism underlying the development of chronic pain, as just discussed. Dr. Buckenmaier’s experimental technique would protect the dorsal horn by another mechanism, but preliminary results are a year or two away and controlled studies of efficacy and outcome against an appropriate ‘gold standard’ regimen of opioid therapy will probably be several years in coming. Non-steroidal anti-inflammatory drugs (NSAIDs – for example: aspirin, ibuprofen, Vioxx), antidepressants, anticonvulsants and other commonly used non-opioid analgesics do not have this protective property, and treatment of persistent acute pain with these non-opioid classes of medications would not be expected to prevent the central nervous system damage understood to underlie the development of chronic pain.

Based on a modern, scientific understanding of the pathophysiology of chronic pain, delaying aggressive opioid therapy in favor of trying everything else first is not rational and is therefore not the standard of care. Delaying opioid therapy resulting in continuous pain signals overwhelming the dorsal horn, would be expected to promote the development of chronic pain and making the patient’s illness progressively more difficult to treat. This is why opioid analgesics are the cornerstone, and the gold standard against which all other analgesic medications are measured, in the treatment of chronic pain.\textsuperscript{20}

\textbf{Evidence Regarding the Risk of Addiction in Chronic Opioid Therapy}

Overwhelmingly, research has failed to show that chronic opioid therapy is associated with any significant level of addiction outcomes. This is consistent finding over decades.

1. In 1981, Medina and Diamond reviewed their experience with 2,369 patients treated in the 1970's at the Diamond Headache Clinic in Chicago for a NIDA Research Monograph: only two of 2,369 patients showed signs of psychological dependence (addiction)

\textsuperscript{17} Brookhoff; The Case for Opiates; 2000.
\textsuperscript{20} Brookoff; The Case for Opiates; 2000.
consequent to their receiving opioid or other pharmacotherapy.\textsuperscript{21, 22}

2. Moulin et. al. (1996) employed a randomized double-blind crossover study design to investigate whether oral morphine effectively relieved pain and improved quality of life in a group of chronic pain patients who had failed other therapies. Their findings: "[The] morphine group showed a reduction in pain intensity relative to placebo in period I (p=0.01) and this group also fared better in a crossover analysis of the sum of pain intensity differences from baseline (p=0.02). No other significant differences [including psychological symptoms, functional status, and cognition] were detected." \textsuperscript{23}

3. In a 2003 review article in the \textit{New England Journal of Medicine}, Ballantyne and Mao thoroughly examined the literature on opioid therapy. In none of the 37 articles reviewed by these authors was addiction as a consequence of opioid therapy a significant outcome. \textsuperscript{24}

**Treatment and Outcomes of Veterans with Chronic Pain**

What about the rank and file? What about the thousands and thousands of injured veterans with painful conditions who don’t get the experimental nerve block? What treatment are they receiving?

Consider “\textit{Long-term Oxycodone/Acetaminophen Prescriptions in Veteran Patients}” by Gagnon et al., published in 2004 in the Archives of Internal Medicine. It is an interesting article. The authors went looking for prescription drug abuse in a large sample of chronic pain patients, but found dose-stability rather than dose-escalation, and acknowledge, “the apparent long-term dose stability that we have demonstrated supports previous observations from both VA and non-VA settings” citing six references that together are overwhelming evidence that dose-stability is the rule in opioid therapy for chronic pain, and prescription drug addiction is uncommon in this population.

But along the way, this study of did turn up this highly revealing datum:

“In aggregate, 2195 patients (31\% with cancer diagnoses) received oxycodone/acetaminophen for more than 9 months at a \textbf{mean prescribed daily dose of 3.9 tablets per day} (range, 0.5-13.0 tablets per day) with minimal changes in daily prescribed mean dose over time.” (emphasis added)

This is quite remarkable. Veterans in chronic pain are prescribed an average of four oxycodone/acetaminophen pills, for example, Percocet, daily from VA medical providers; and 31 percent of this sample had cancer-related pain. “Oxycodone/acetaminophen” means low potency opioid compounded with acetaminophen (Tylenol). Assuming 7.5mg of oxycodone per tablet (the larger commonly available formulation of this medication), four pills daily = 30mg oxycodone

\textsuperscript{21} Medina JL, Diamond S. Drug dependency in patients with chronic headaches. Headache; 17(1):12-14; 1977

\textsuperscript{22} Medina JL, Diamond S. A headache clinic's experience: Diamond Headache Clinic, Ltd. NIDA Res Monogr; 36:130-136; 1981.


daily, which is the analgesic equivalent of approximately 45mg of morphine, a day. Patients with chronic severe pain commonly require dosages 25 times as high - over a 1000mg morphine equivalent daily, and some require and tolerate three to four grams a day.

Low potency compound opioids are properly prescribed for mild to moderate acute pain. They are not very useful in severe pain because the total daily dose is limited by the liver toxicity of the acetaminophen part of the compound, to about 10 pills a day (less in drinkers and patients with liver disease), which in total contain 75mg of oxycodone, the analgesic equivalent of approximately 112 mg of morphine daily, meaning the maximum analgesia achievable is some 10 times lower than that commonly required by patients in moderate to severe chronic pain. Low potency compounded opioids are likewise a poor choice for chronic moderate pain, again due to acetaminophen toxicity.

Four pills a day of oxycodone/acetaminophen is a low, not moderate, not adequate, dosage. Oxycodone is a short acting opioid in this preparation, with an effective duration of action of about three hours. One pill every six hours of oxycodone/acetaminophen for chronic pain guarantees that the patient will be in unacceptable pain 50 percent of the time, at best. That’s not treatment, its mis-treatment; it could not possibly be adequate.

How are our injured veterans with chronic pain faring under medical VA auspices? Not too well if you ask them. From a 2005 study of 348 patients entitled, “Prevalence And Characteristics Of Chronic Pain in Veterans with Spinal Cord Injury” we learn that 75 percent of this population reports pain, 83 percent of which is round-the-clock daily, of average intensity of 6.7 out of 10, and two thirds of which interfered with daily activities. The pain was most commonly described as “aching,” “sharp,” “hot-burning,” and “tiring-exhausting.” The authors’ conclusion is darkly humorous: “More research is needed to identify better ways to prevent, assess, and treat chronic pain in the veteran SCI population.” I suggest we start by researching whether the veterans would have less pain and higher quality of life if their pain medication were simply titrated to analgesic effect, which is the standard of care for the treatment of chronic pain.

A 2007 article from the Journal of Rehabilitation Research and Development, published by the Department of Veteran Affairs, entitled "A Closer Look at Pain and Hepatitis C: Preliminary Data from a Veteran Population" reviews the literature on the relationship between HCV and pain, and presents preliminary findings from a survey conducted at two Department of Veterans Affairs facilities to assess the scope and impact of pain on functioning in veterans with HCV.

The prevalence of hepatitis C virus (HCV), a leading cause of cirrhosis and hepatocellular carcinoma and death from liver disease, among veterans who use Veterans Health Administration (VHA) facilities are more than double that of the general population, and affect 5.4 to 6.6 percent of veterans. Treatment for HCV is a rigorous 6-month to 1-year regimen of pegylated interferon and ribavirin which, unfortunately, is expensive, often poorly tolerated and painful in its own right, and is only successful in 54 to 61 percent of patients. Symptoms of HCV include weakness, fatigue and general malaise, muscle, joint and abdominal pain, and anorexia. HCV infection is associated with immunological manifestations, psychiatric disorders, and negative

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26 Silberbogen; Pain and HCV in Vets; 2007.

27 Silberbogen; Pain and HCV in Vets; 2007.
changes in self-perception that have pronounced implications for quality of life, psychological health, and mortality.

“Preliminary results from this study demonstrate that 82.7 percent reported pain symptoms… Even on their "good" pain days, patients with HCV and pain symptoms reported pain intensity levels that met VHA criteria for comprehensive pain assessment and intervention. Patients with HCV reported that their pain symptoms interfered with their daily activities and relationships. [These] preliminary data strongly suggest that pain is highly prevalent and significantly affects patients' functioning and experience of HCV.” 28 (emphasis mine)

Moving from spinal cord injury and hepatitis C, conditions known to be commonly associated with chronic pain, to a general medical population, consider a 2006 study undertaken to determine the prevalence, morbidity, and pervasiveness, of pain in a random sample of veterans registered at a VA primary care clinic, entitled “Survey of Pain among Veterans in Western New York.” The results in this population are startling:

“… 71% reported having pain. The average number of body parts affected was 4.4 of a possible 11. The average intensity of pain was moderate; 35% reported constant pain, and 85% reported the pain to be occurring for years. Seventy-nine respondents [53%] described their pain to be interfering with their life and well-being. Medication was the primary treatment approach and was reported as ineffective by 48%.” 29

The finding that pain medication was reported ineffective by 48 percent of those in the NY primary care study does not surprise me. Opioid analgesics work well if prescribed in proper dosages at proper intervals and titrated to analgesic effect, as discussed above, otherwise not so well. More importantly, the percentage of patients in chronic moderate to severe pain in these three very different VA populations ranges from 71 to 82.7 percent. This is very high. In normative healthcare-seeking populations, directly comparable to the NY general-medical VA sample, persistent pain is among the most commonly reported health problems with an estimated prevalence of 22 percent. 30

Rampant Undertreatment of Pain is a National Scourge
Four surveys of various VA population samples, two of them quite small, are conclusive of nothing. However, these four studies, taken together with an awareness that pain management exists in a cultural and political environment of opiphobia and opioignorance, strongly suggest that such unnecessarily poor treatment and unnecessarily bad outcomes might very well be endemic in the VA. Unfortunately, this should not surprise us. Rampant undertreatment of pain is a national scourge exacting a terrific toll on both the public health and on our national financial health:

1. Stewart et. al., in a 2003 cross-sectional study using 2001 - 2002 data from the American Productivity Audit on 28,902 working adults, revealed that thirteen percent experienced a loss in productive time during a 2-week period due to a common pain condition. (Most,

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28 Silberbogen; Pain and HCV in Vets; 2007.
76.6 percent, of the lost productive time was explained by reduced performance while at work and not work absence). Lost productive time was estimated to cost $61.2 billion per year. They concluded that pain "is an inordinately common and disabling condition in the US workforce...”  

2. Reports and statements from government, regulatory and academic bodies attesting to a massive problem of untreated and undertreated pain abound. In 2004 Robert Meyer, Director of the FDA's Center for Drug Evaluation and Research, in testimony to the House Subcommittee on Criminal Justice, Drug Policy and Human Resources reminded legislators of a Consensus Statement from the National Cancer Institute Workshop on Cancer Pain over a decade earlier (1990) which indicated that the "undertreatment of pain... is a serious and neglected public health problem.”

3. The Agency for Healthcare Research and Quality (AHRQ) reported in 1992 that, "half of all patients given conventional therapy for their pain [are not getting] adequate relief.”

4. In 1999 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued a press release noting that unrelieved pain had huge physical and psychological effects on patients and increased health care costs. JCAHO at that time officially declared pain to be the "fifth vital sign" henceforth regarding the evaluation of pain a routine requirement of proper patient care as important and basic as the assessment and management of temperature, blood pressure, respiratory rate, and heart rate.

Disturbing as these academic findings are, at the level of the doctor-patient relationship opiophobia leads to unnecessary personal suffering and family tragedy for men and women who served their government and gave everything when called upon. Mr. James Fernandez, a marine helicopter door-gunner in the first Gulf War, involved in two helicopter crashes, resulting in well documented disabling back injuries and chronic severe pain, has submitted testimony to this committee. Mr. Fernandez, under continuous medical care of the VA, has been utterly compliant with that care, has exhibited no “ref-flag” or aberrant drug-related behaviors suggesting substance abuse and has no history of alcohol or drug problems.

Yet Mr. Fernandez, an uncomplicated case of chronic pain, has been allow to remain in agony, for decades, physically deteriorating from immobility due to pain, all under the watchful eyes of his VA providers. He believed VA doctors could do nothing more to help him, when the documented truth is that even fractional dosage increases make a significant positive difference in his life.

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Mr. Fernandez was abandoned to his pain by his physicians and his government because they were more concerned about a prescription drug abuse problem, that had NOTHING to do with him or his combat acquired medical conditions, than they were about the obvious suffering and deterioration of the obviously deserving patient before them. This is medically very wrong, and a national disgrace.

Mr. Fernandez, and thousands of veterans like him, and millions of their fellow citizens, have their lives destroyed for lack of a couple of hundred milligrams of morphine-equivalent analgesic medication because federal drug control regulations and DEA enforcement imperatives have changed pain management physicians into deputy lawmen whose primary obligation is to catch vaguely defined “addicts,” and whose concept of pain treatment is to prescribe the weakest opioids in the lowest possible dosages so as not to incur the wrath of federal law enforcement.

If Mr. Fernandez is denied basic compassionate medical care, what chance is there for the rest of us when our time of need comes? Mr. Fernandez was at least inadequately medicated. How much worse would his life have been if he had not been a marine, if his injuries were due to an auto crash instead of a military helicopter crash, if he didn’t have access to VA medical resources? What if he were alone, and poor and uninsured; or black, or a 20 year old recent immigrant whose English was poor?

Congress has the power to get DEA, a police agency of the Executive branch of government, out of the medical decision-making process. The authority to license and regulate medical practice is constitutionally reserved to the states who maintain the standard of care through state medical boards and whose enforcement powers rest with the state Attorney General. That system is in place. I urge you to return this authority and this power back to these more democratic institutions which are responsive to the will of the people, and which could function as laboratories of progress and change if freed to do so.

Until this is done, the pain crisis in America will worsen.

I want to thank the House Subcommittee on Crime, and its staffers, for considering my testimony.

Respectfully submitted,

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Alexander DeLuca, M.D., MPH

Alexander DeLuca, M.D., MPH
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New York City
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