

*The Journal of*  
**Legal Nurse  
Consulting**

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- ▲ Acupuncture in the Contemporary Health Care System
- ▲ Chronic Pain Medications: Current Trends LNCs
- ▲ Vioxx Withdrawn from the Market
- ▲ The Clinical and Legal Aspects of Massage Therapy
- ▲ The Art of Jury Selection
- ▲ Copyright Compliance: No Fair...Use?



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The purpose of the Journal is to promote legal nurse consulting within the medical-legal community; to provide both novice and experienced legal nurse consultants (LNCs) with a quality professional publication; and to teach and inform LNCs about clinical practice, current legal issues, and professional development.

### **Manuscript Submission**

The Journal accepts original articles, case studies, letters, and research. Query letters are welcomed but not required. Material must be original and never published before. A manuscript should be submitted with the understanding that it is not being sent to any other journal simultaneously. Manuscripts should be addressed to [JLNC@aalnc.org](mailto:JLNC@aalnc.org).

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Submissions are peer-reviewed by eminent professional LNCs with diverse professional backgrounds. Manuscript assistance can be provided upon request to the editor. Acceptance is based on the quality of the material and its importance to the audience.

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The Journal of

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# LEGAL NURSE CONSULTING

Volume 16 ▲ Number 1 ▲ Winter 2005

## Features

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### Acupuncture in the Contemporary Health Care System . . . . . 3

*Douglas R. Briggs, DC Dipl.Ac.(IAMA) FASA; Dolly M. Curley, RN BSN DABFN LNCC; & John A. Amaro, DC FACC  
FLAMA Dipl.Ac.(IAMA)(NCCAOM) LAc*

A significant part of the Chinese health care system, acupuncture has gained much popularity in the United States in recent years. A basic understanding of complimentary and alternative medicine treatments is critical for LNCs, given the potential inter-relationship with allopathic medical treatment and the increasing frequency with which it is encountered in the medical record

### Chronic Pain Medications: Current Trends for Legal Nurse Consultants. . . . . 10

*Marilyn T. Oakes, CRC, LPC, CLCP*

Pain and suffering are cornerstones of legal damages, yet chronic pain cannot be treated the same as acute pain. Once pain becomes chronic, most patients require daily medication, and rational polypharmacy is the treatment approach of choice. The goals of chronic pain management are to increase function and daily activity and, by doing so, to help patients gain better pain control.

### Vioxx Withdrawn from the Market: Controversies Continue to Involve Merck & FDA . . . . . 19

*Mary A. O'Connor, PhD, RN*

As this special themed edition of *The Journal of Legal Nurse Consulting* on Pain Management went to print, Vioxx (rofecoxib), a nonsteroidal anti-inflammatory drug (NSAID) was withdrawn from the market by its manufacturer, Merck & Co., Inc. On September 30, 2004, Merck announced the withdrawal of Vioxx based on the results of the APPROVe (Adenomatous Polyp Prevention on Vioxx) trial.

### The Clinical and Legal Aspects of Massage Therapy. . . . . 23

*Deborah Gritzmacher, RN MT MSN & Debra Cody RN MSN*

This article discusses historical uses of massage, specific applications for pain, the different types/techniques of massage therapy, and physiological responses to massage. The legalities of regulation, licensure, certification, and education will be covered, as well as contraindications to massage and its relationship to traditional medicine. The article points out the importance of federal agencies and organizations that are supportive of massage therapy, including the legal benefits of expanding its use among overstressed and underserved individuals

## Departments

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### Editorial . . . . . 2

A New Year, a New Beginning, a New Transition

*Marguerite Barbacci, BSN RNC MPH LNCC, Chair*

### Legalese . . . . . 27

The Art of Jury Selection

*MarSue Chustz, BSN RN CCRN CLNC*

### Point of Law . . . . . 30

Copyright Compliance: No Fair...Use?

*Diane M. Ellenberger, MS RN LNCC, & Arnold B. Silverman, Esq.*



# A New Year, a New Beginning, a New Transition

It is with great anticipation that I begin my tenure as editor of *The Journal of Legal Nurse Consulting*. I look forward to working with the Editorial Board and the AALNC membership at large in promoting our journal and expanding its horizon. I want to thank my predecessor, Lynda Kophiske, and former Editorial Board member Regina Noonan for their years of dedication and service to the journal.

This issue of the journal focuses on the subject of pain management, exploring conventional and alternative therapies utilized today. Deborah Gritzmacher and Debra Cody provide an informative overview of the clinical and legal aspects of massage therapy. Once considered an alternative treatment therapy, massage therapy is now considered part of mainstream medical care. The article highlights the potential legal issues associated with the practice, something many of us wouldn't readily consider.

Another alternative therapy gaining wider acceptance is acupuncture. The edifying piece in this issue by Douglas Briggs, Dolly Curley, and John Amaro describes the use and advantages of the ancient practice for a variety of medical conditions.

Marilyn Oakes, a Certified Pain Practitioner, prepared an article about current trends in chronic pain medications. This article discusses treatment modalities used in managing chronic pain, a subject likely to be particularly applicable to LNCs who prepare life care plans or work in case management.

One of the challenges of writing for a quarterly journal is to stay a step ahead of litigation trends and anticipating issues that will be relevant to the reader when the issue is published, months after the work is submitted. Along those lines, we present two timely articles. The first topic on copyright fees impacts all of us who provide the service of medical research in our practice, and Dianne Ellenberger and Arnold Silverman review the legalities of copyright compliance and recent legal cases involving LNCs sued for copyright infringement.

Hours before the deadline for submitting articles for this issue, Merck Pharmaceuticals announced the voluntary market withdrawal of Vioxx; Editorial Board member Mary O'Connor volunteered to write an article on this issue at the eleventh hour. Since the September 30 recall, new information has been available almost daily. The article you'll read here is merely an introduction to a subject that will surely capture headlines for months—and years—to come.

The theme for the 2005 AALNC educational conference is *Your Potential, Your Commitment, Your Impact*. This timely theme not only describes the practice of legal nurse consulting but the ability of every LNC to shape our organization and journal. AALNC is only as strong as its membership. Don't be deterred if you don't have years of experience. Begin your journey by seeking to uncover your hidden talent. Realize your potential by getting involved. In the words of Henry Van Dyke (1852-1933), "Use what talent you possess: the woods would be very silent if no birds sang except those that sang best."

Finally, I ask that all AALNC members consider writing an article for the journal. You may think of writing as a chore, something for which you have no time or "just one more thing" to add to your list. Almost weekly, the LNC list serves contain posts by new LNCs lamenting that they have no work product to show a potential employer. Forget the fancy chronology formats and tables. Your potential client wants to know if you can write! What better way to prove it than by presenting a reprint of an article written by you and published in a peer reviewed journal? The words of author Barbara Kingsolver sum it up the best: "There is no perfect time to write. There is only now."

*Marguerite Barbacci*

Marguerite Barbacci, RNC MPH BSN LNCC  
Editor, *The Journal of Legal Nurse Consulting*

## Attention Interested Reviewers!

Are you looking to get involved with *The Journal of Legal Nurse Consulting*? The Editorial Board is seeking readers interested in acting as content reviewers for specialized topics within the legal nurse consulting field. For more details and responsibilities, contact Journal Management at [JLNC@aalnc.org](mailto:JLNC@aalnc.org) or 877/402-2562.

# Acupuncture in the Contemporary Health Care System

Douglas R. Briggs, DC Dipl.Ac.(LAMA) FASA; Dolly M. Curley, RN BSN DABFN LNCC; & John A. Amaro, DC  
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KEY WORDS

Acupuncture, Ah-Shi, Bioenergy, Meridian, Qi, Pain Management, Point

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*Acupuncture is a part of the rich tapestry of Chinese history. A significant part of their health care system, acupuncture has gained much popularity in the United States in recent years. Although it is a legitimate treatment modality, the vocabulary and protocols of acupuncture do not readily translate into the terminology of Western medical science. Despite these complications, recent public acceptance, clinical response, and NIH recognition require that the medical community further investigate the effectiveness of acupuncture as legitimate treatment within the scope of modern health management. Legal nurse consultants (LNCs) are often asked by attorneys to review a medical record and comment on medical issues and standards of care. A basic understanding of complimentary and alternative medicine treatments is critical, given the potential inter-relationship with allopathic medical treatment and the increasing frequency with which it is encountered in the medical record. The purpose of this article is to explain acupuncture, both as a part of a traditional system of Chinese medicine and as a contemporary health care modality, in order to provide the LNC with the backup needed to make informed reviews and comments.*

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Acupuncture has gained recent popularity in the United States as an isolated treatment for any number of conditions, yet historically it is only a part of the system of traditional health care that has evolved in China over the last 6,000 years. Oriental medicine (often referred to as Traditional Chinese Medicine or TCM) is a coherent and independent system of thought and practice; however, the methodology that guides physicians' clinical decisions differs radically from Western medical science.

In the practice of Oriental medicine, physicians look beyond symptomatic complaints for a causal condition. Evaluation of any complaint considers the complete physiological and psychological individual. To Chinese medicine, understanding means perceiving the relationships between all the patient's signs and symptoms—no single part can be understood except in its relation to the whole person (Kaptchuk, 1983). Within this context, a symptom is understood as a sign of imbalance in the physiology of the individual. It should be understood that this philosophy of health care extends beyond China, and includes Japan, Korea, Tibet, and many other nationalities and cultures.

"Acupuncture" is a general term that refers to no specific style of treatment, and may encompass hundreds of geographical variations and different styles vaguely based on similar ideas. For simplicity, this article will continue to refer to acupuncture as a part of Chinese medicine, with the understanding that the principles discussed may be applied to these other parallel arts.

## Background

The Chinese system must be approached and dealt with on its own terms. The greatest problem with this system is that it does not use the technical, scientific vocabulary of Western medical science, instead relying on a pre-scientific tradition of conscious observation of natural phenomena

guided by a rational, logically consistent, and communicable thought process.

In ancient times, complex studies of blood chemistry or diagnostic imaging were not available. A patient's condition was evaluated and defined in terms of the macrocosm of nature. Thus, inflammation could be described as an "excess of fire and water" or a "yang condition of the water element." Health, in this system, is a theoretical state in which none of the bodily signs are abnormal. Health may also be defined as the homeostatic balance of the body's physiology. The detail and precision of a diagnosis depend on the skill of a physician to observe and correlate nuances in the physical condition and define them as a specific "pattern of disharmony."

Oriental medicine understands illness as a disruption or imbalance in an individual's Qi ("chee"), the Chinese term for life force or vital energy. This approach also involves the application of different modalities for different facets of a patient's condition. Tui Na, which has evolved into the modern practice of chiropractics, was used to address myofascial adhesions and articular dysfunctions. The use of medicinals helped facilitate internal processing and healing. This methodology of treating with foods and plants has evolved into the modern disciplines of herbology, homeopathy, and pharmacology. Energetic healing methods (including acupuncture, acupressure, qigong, etc.) were slowly developed over time to work with the body's subtle energy fields to harmonize the functions of the individual, codependent systems of the body. Oriental practitioners also considered shen, the attitude or psychological state of the patient, when performing an evaluation or rendering treatment.

Much of the knowledge and historical data of acupuncture has been lost to the ages. Wars, conquerors, and time have all taken a toll on the historical documents. What remains today is a small part of the practical information, observation and clinical trial data, and treatment protocols

that were once available; however, acupuncture is a living art and continues to be researched and developed.

It is interesting to note that the contemporary term “Traditional Chinese Medicine” is itself a misnomer. TCM is the title Chairman Mao gave to the practices of a select group of traditional physicians during the Cultural Revolution. Many other practices exist that are just as traditional but were not granted the government’s approval. Much of the TCM education today comes from the Chinese government-endorsed practices of that time. There is also a common misconception that acupuncture involves religious practices. Although acupuncture has historically been practiced by devout followers of Eastern religious philosophy, acupuncture itself is not tied to any religious tradition.

As discussed above, acupuncture is the branch of classical Chinese medicine concerned with restoring balance to the meridian system. This concept of an energetic system is foreign to Western medical science but continues to be researched throughout Asia, primarily Japan. Described simply, there is a network of “bioenergy” called qi, which flows in a regular pattern around and through the body. At times, these pathways run parallel to circulatory and nervous systems, yet they are independent from them. If there is an imbalance in the natural flow of qi, there will be a spillover effect into the associated bodily region or system. The goal of Oriental medicine is to restore homeostasis to the body as a whole. When it is determined that there is an energetic imbalance, acupuncture is used to clear the blockage and facilitate healing.

To draw an analogy, consider a pile of leaves clogging a rain gutter. This blockage will produce a back-up along the channel and may cause flooding or drainage in the wrong areas, possibly at a place far removed from the actual blockage. This back-up and flooding could be considered a symptom but is obviously not the root of the problem. To scoop out the water or drill new drainage holes never truly addresses the actual cause: the blockage. Complete healing cannot take place until the blockage is cleared and the water has time to drain and normalize the system.

## Diagnosics

Historically, diagnosis of a patient’s internal condition was performed by a careful evaluation of the patient’s physical presentation. Diagnosis in the traditional model is theoretical and, from a western perspective, very vague, focusing more on the interrelations of the organ systems than a specific diagnosis. The method of correlating the outward findings and the internal condition was developed over millennia. The two most common types of traditional evaluation were pulse and tongue diagnosis.

Pulse diagnosis is a highly developed art. It involves not only the palpation of the radial pulse bilaterally, but also the palpation of a deep and superficial pulse at three locations along the radial artery. The practitioner must evaluate each of these 12 different pulses for 28 qualities before rendering

a diagnosis. Clearly, this complex system is very time-consuming. Not only does it require years to master, but an accomplished practitioner may take up to an hour to come to a working diagnosis.

Tongue diagnosis is the evaluation of the tongue for signs of altered metabolism. One of the principal concepts of Chinese medicine is that there are correspondences among various parts of the body. The tongue is seen as a map of the body, reflecting the general health of the organ and meridian systems. Certain parts of the tongue reflect the health of other parts of the body, or of certain internal organs (Maciochia, 1995). Different regions of the tongue are evaluated for color, shape, coating, and moisture to gain an insight into the internal constitution of the rest of the body.

Another simple form of evaluation is the palpation of ah-shi (ouch) points, commonly referred to as trigger points in Western medicine. These points are often both diagnostic (indicative of a condition) and therapeutic (promoting a benefit) when handled properly.

Perhaps the most modern of acupuncture diagnostic procedures is the Japanese art of Ryodoraku (aka Electronic Meridian Imaging or EMI). This technique involves the use of a probe to test the electrical resistance to current at specific points on the wrists and ankles. The theory is that this evaluation will provide a representation of the relative imbalances of the primary energetic system as a whole. While this type of evaluation will provide direction to treat meridian imbalances, it does not indicate all the points that might be treated for a specific condition. There has also been some recent publicity that this modality could also be used to indicate nutritional deficiencies, but there is no sound evidence to support this claim.

Much of acupuncture protocol is based in the empirical data of predictable results. Regrettably, there is little to no Western scientific verification of the complete physiologic effects of acupuncture. It is advised that practitioners utilize every diagnostic tool available to appropriately evaluate a patient’s condition. If there is any question of significant disease or pathology, acupuncturists are obligated to refer for appropriate medical evaluation and co-management.

## Modalities

Contrary to common perception, acupuncture is not only the use of needles. Needles are one modality the acupuncturist may use to treat the imbalances in the meridian system. Historically, finger pressure (called acupressure in this country) and blunt probe pressure were the original tools of acupuncturists. Referring back to the rain gutter analogy, one could use any number of different tools to clear the leaf blockage—a scoop, a power washer, etc. What is important is that one use the appropriate tool to clear the blockage.

Although needles are by far the most recognized of the acupuncture modalities, they are not the only or the most commonly used tool. Modern modalities also include the use

of laser (“cold” HeNe laser at a frequency of 632nm), microcurrent, and electric muscle stimulation. Vacuum cupping is used to pull circulation into an area of congestion. Vibration stimulation (128 cycles per second) is effective to reduce myofascial adhesion. Moxibustion and diathermy are used to promote regional circulation.

Acupuncture is historically credited with treating all manner of musculoskeletal and visceral conditions. It is important to recognize some of the more common modalities and their applications:

- Needle stimulation: the most recognized modality, used to reduce congestion along the path of a meridian. Type of needle and style of insertion will vary with practitioner’s technique.
- Electric muscle stimulation via needle: often used to create analgesia or anesthesia.
- Laser stimulation: to promote local vasodilation and reduce the irritation of adhesions.
- Auriculotherapy (ear point stimulation): often used for neurological situations.
- Piezoelectric stimulation: used to create a local stimulation of affected points.
- Vibration: often used to address myofascial congestion.
- Ryodoraku (Electronic Meridian Imaging): a reproducible method of evaluating meridian imbalances to define a course of treatment.

Acupuncture is also very effective at reducing muscular spasm and promoting regional circulation. When a patient is in an active rehabilitation program, these benefits may greatly accelerate the individual’s response to care. Beyond needle techniques, modalities such as vibration and percussion may be used to reduce adhesion formation and to allow greater mobility during rehabilitative exercise. Vacuum cupping has traditionally been used to “pull” circulation into an area of congestion or vasoconstriction. Modern cold-laser therapies have been shown to cause a localized vasodilation, as well as to increase the cell production rate in connective, tendinous and cartilaginous tissue. Cold laser therapy is known to stimulate sympathetic nerve fibers, enhance the synthesis of endorphin enzymes, and increase the rate of regeneration of injured nerve cells. Often, a combination of different acupuncture modalities will have an enhanced effect on the patient being treated.

## Treatment Protocols

Acupuncture first became widely known in the Americas in the early 1970s. It was heralded as a “mystical cure from the East” for any number of diseases and health care conditions. Unfortunately, some of the common sense thinking involved in patient care was lost in the rush to integrate acupuncture into Western medical practices. Practitioners began to look for “cookbook recipes” to treat a complaint (*this* point for *that* condition), instead of looking at the patient’s condition and determining what the right treatment should be. Nowhere in the scope of Oriental

medicine is there a protocol for “spontaneous healing.” Acupuncture is part of a system that may help to alleviate pain, reduce muscular spasm, and promote healing; however, there is no health care modality that will override the natural process of the healing cycle. The body follows an orderly cascade of events when healing, no matter what supportive or palliative measures are used to help along the way. It is vital that practitioners fully evaluate patients to determine the root of their complaints. Acupuncture may be effectively used to help with pain during the healing of a fracture, but the primary treatment must obviously involve the setting and stabilization of the area of injury. Evaluation within the scope of traditional practices is limited as modern diagnostic tools (ie: x-ray, MRI, blood labs, etc.) are much more specific.

A practitioner of any healing art is obligated to fully evaluate a patient’s condition to appropriately define the nature and extent of that condition; however, traditional evaluation methods may augment the exam and provide additional insight into the case. Traditional practitioners are often excellent interviewers and are able to gain insight into the subjective component of the patient’s complaint. With a thorough understanding of the patient’s condition, an integration of techniques may then be used to address the circumstance at hand. These treatments may include not only acupuncture, but also medication (including pharmacologic, herbal, and nutritional), chiropractic

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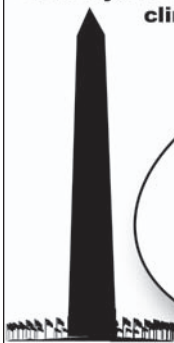
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therapies, the application of heat or cold, therapeutic modalities (electric muscle stimulation, ultrasound, and diathermy), traction, and necessary bracing or splinting.

The ideal frequency for acupuncture therapy depends on one's concept of the function of acupuncture therapy. It has been argued that therapies such as diet, exercise, sleep, herbs, vitamins, and common drug therapies are more like acupuncture treatments in their regulatory and recuperative effects, and a patient should be doing them almost every day for maximal benefit. The same is true of acupuncture. When a push toward balance and health is accomplished with one acupuncture treatment, it is best to "give a second push" before the effects of the first have worn off, thus making a cumulative impact. Traditional treatment protocols often involve almost daily treatment to facilitate the healing process. By contrast, many American practitioners routinely recommend treatments at a schedule of once or twice weekly. Although there is still a measured therapeutic benefit with this approach, the momentum of treatment is slower and results in a longer course of treatment (Dharmananda, 2003).

### **Standard Precautions, Clinician Criteria**

There are times when certain acupuncture treatments are not recommended. Standard precautions are indicated whenever utilizing needle therapies. Blood-borne diseases and clotting disorders are obvious health concerns that must

be ruled out during consultation. Contemporary practitioners must pass a national clean needle technique examination as part of the licensure requirements. Other contraindications include: deep needling over the thoracic cage, electro-stimulation across the cortex and cardiac regions, and heat modalities over areas of infection or inflammation. Additionally, there are more subtle precautions associated with the patient's condition, such as avoiding needle stimulation of certain points during pregnancy. As these points are different for the individual, it is the responsibility of the practitioner to act in the best interest of the patient.

Within the medical-legal realm today, there is also the concern regarding who is able to perform acupuncture. Currently, more than 50 schools specifically teach acupuncture as a primary profession, usually as a 3-year degree. Acupuncture has been taught at the graduate level at chiropractic colleges since the early 1970s and is still taught as an adjunctive therapy at more than half of the chiropractic colleges in North America. It is also offered as a graduate and postgraduate certification to both medical doctors and chiropractors. Licensure and scope of practice vary from state to state, and the statutes must be evaluated on a per-case basis.

Although TCM has been used to treat numerous medical conditions in the past, it is essential that practitioners are able to recognize serious medical conditions

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and refer the patient for the appropriate care. In such cases, co-management is often a possibility, but to not refer would indicate a breach of the standard of care in this country.

## Case Management Paradigm

Within the case management system, it is reasonable to expect that acupuncture will primarily be used for pain management. This does not preclude acupuncture as a legitimate modality for treating visceral or other organic conditions; however, extensive discussion in those directions is beyond the scope of this article.

Pain, either by traumatic injury or some pathologic process, is often the driving reason for a patient to seek care, and enter the case management system. Pain level is entirely subjective, and may often be modified by the patient depending on his or her perception, constitution, psychological state, and need for secondary gain. Although there is no serum pain level to monitor, there are a number of orthopedic maneuvers designed to screen for malingering that can be employed effectively (Briggs, 2003). The diagnosis of the cause(s) of pain depends on the skillful interpretation of its often-subtle features.

As acupuncture becomes more mainstream, it is imperative for the individual practitioner to appropriately evaluate the patient's complaint, validate the differential diagnosis, and recommend appropriate treatment. Almost 90% of all diseases either begin with pain or have pain as a prominent symptom at some time during their course (Jaskoviak, 1993). When a patient has pain, either acute or chronic, care must often focus on the alleviation of symptoms before other treatments can be incorporated to facilitate healing. Acupuncture, coupled with some forms of electrical stimulation, can be effective in the management and treatment of acute and chronic pain, in part at least, through the biologic activation of neurohormonal and neurotransmitter systems.

It is known that the hormone group endorphins are approximately 200 times more potent than morphine. Stimulation of the skin with a needle or an electric impulse triggers the brainstem to increase levels of endorphins in the bloodstream, cerebrospinal fluid, and the gastrointestinal tract. In this context, three points from Jaskoviak (1993) should be noted:

1. Levels build up in 30 seconds; however, the patient often does not appreciate clinical results until 12-24 hours later.
2. The site of stimulation determines the type of endorphin that is released and the area of the body that it will affect. Thus, endorphins are site-specific in their effect.
3. Since an active endorphin is a circulating hormone, the side of the body stimulated (when bilateral points exist) makes little or no difference (other than psychologically).

## Common conditions and treatment options:

- Pain Syndromes: needle stimulation, needles with electrical stimulation, and electro-acupuncture to treat pain conditions and decrease the need for strong medications such as Oxycontin.
- Whiplash: electric stimulation to decrease regional pain, stimulation of distal points to promote healing, conservative chiropractic manipulation to restore functional biomechanics.
- Lumbar Disc Syndrome (pre- and post-surgical): electric stimulation to reduce myospasm, stimulation of distal points to promote healing, passive traction, laser stimulation over scar tissue to promote vascular perfusion.
- Carpal Tunnel/Repetitive Motion Syndrome: needle stimulation, vibration over areas of myofascial congestion, functional bracing, muscular re-education.
- Headache/Migraine: stimulation of sub-occipital points to reduce pain; also points on the scalp, hands, and legs
- Sinusitis: treatment primarily of local points on the face to reduce congestion and promote drainage, often will supplement treatment with herbal therapies
- Digestive problems: Ryodoraku evaluation and appropriate meridian balancing, diet modifications

It is necessary for any health care practitioner, including those that practice acupuncture, to fully document the patient's condition and progress. Every provider in every discipline is accountable for the care provided to a patient. An acupuncturist must be able to consistently define the patient's condition, clearly objectify the findings during the course of treatment, and document the patient's progress. If a treatment plan has not made a documentable change in a patient's condition within a 6-week period, alternate modalities must be considered, including co-management with other para-professionals.

Clearly, acupuncture is a very diverse art. The numerous styles and modalities make it applicable to a broad range of patient complaints. When integrated into a progressive treatment regimen, acupuncture should speed patients' progress and yield better long-term outcomes. This not only allows a greater variety of treatment options, but also provides a cost-effective alternative to pharmacologic treatments that are known to have residual effects, including addiction and increased dosing due to tolerance. The diversity of treatment applications compared to the minimal risk of complications and the potential for patient benefit, coupled with recent public acceptance and NIH recognition, demand that acupuncture be considered a legitimate part of contemporary health care practices.

## Suggested Readings

- Neuro-Acupuncture* (2001, Cho, Wong, Fallon)  
*Acupuncture: The Special Function Points* (1996, Dale)  
*Grasping the Wind* (1989, Ellis, Wiseman, Boss)  
*How to See Your Health: Book of Oriental Diagnosis* (1980, Kushi)  
*Insights of a Senior Acupuncturist* (1992, Lee)  
*Close to the Bone – The Treatment of Musculoskeletal Disorders with Acupuncture and other Traditional Chinese Medicine, 2nd edition* (1997, Legge)  
*The Secret Power Within* (1996, Norris)  
*Acupuncture, a Comprehensive Text* (1981, O'Connor, Bensky)  
*Ryodoraku Textbook – Ryodoraku Autonomic Nervous System Therapy* (1989, Oda)  
*Reading the Body* (1991, Ohashi)  
*Chinese Wisdom* (2001, Too)  
*The Science of Acupuncture Therapy, 2nd edition* (1987, Wong, Cheng)  
*Chinese Acupuncture and Moxibustion* (1999, Xinnong)

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# Chronic Pain Medications: Current Trends for Legal Nurse Consultants

Marilyn T. Oakes, CRC LPC CLCP

## KEY WORDS

Chronic Pain, Pain Management, Pain Medications

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*Pain and suffering are cornerstones of legal damages, yet chronic pain cannot be treated the same as acute pain. Many treatments that are perfectly appropriate for acute pain do not help chronic pain and may make it worse. Once pain becomes chronic, most patients require daily medication, and rational polypharmacy is the treatment approach of choice. No cure currently exists for chronic pain, and the focus includes lifestyle and behavioral management. Medication regimens that support pain management goals are better than medications whose actions inhibit functional improvement.*

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The International Association for the Study of Pain (IASP) defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (Merskey & Bogduk, 1994). According to the biopsychosocial model, pain begins with input from sensory structures, which cognitive processes interpret. Next, individuals respond at a feeling level, then act on their feelings. The progression is sensory → cognitive → affective → illness behavior (Waddell & Turk, 1992). Recent research from the neurosciences is leading to profound changes in the way that chronic pain is conceptualized, researched, and treated. A key finding is the existence of both upgoing and downgoing pain tracks in the brain and spinal cord. Readers are encouraged to review the excellent discussion found at [www.medscape.com/viewprogram/2170?src=search](http://www.medscape.com/viewprogram/2170?src=search) (Schatzberg & Korn, 2002).

A second key finding is that pain processing structures in the brain and spinal cord can be molded during adulthood (cortical plasticity), a phenomenon once thought impossible (Flor, 2003). These changes appear permanent, both for musculoskeletal (nociceptive) pain patient and neuropathic (nerve) pain patients. Researchers found functional reorganization in both the somatosensory and motor systems. Behavioral interventions can modify cortical plasticity somewhat (Birbaumer, et. al., 1997; Wiech, Preissl & Birbaumer, 2000). Attempts to identify pharmacological agents that prevent or reverse maladaptive cortical reorganization are active areas in current research.

A third key finding is that humeral (blood) changes contribute to the formation and maintenance of chronic pain, occurring as early as the surgeon’s first incision (Reuben, 2004). New treatments are available for prevention and palliation, and research moves at a furious pace.

With so much new information, one would think that legal nurse consultants (LNCs) could easily research and address chronic pain medication questions as part of pain damages in litigated cases. Unfortunately, the challenge is often finding the pertinent information and identifying current pain practices. Effective treatments and new

applications are not yet in print, and some may never be (Raziano, 2004a). One factor is that many pain treatments are done off-label: legally prescribed but not specifically approved for that use by the Food and Drug Administration.

A common misconception is that off-label uses or treatments mean physicians have breached some standard of care. Off-label pain treatments are commonly accepted in professional pain circles. A 30-day outpatient headache clinic study found 47% off-label drug use (Loder & Biondi, 2004). Most neuropathic pain treatment is off-label (James, 2003), and off-label use may even be evidence-based (Dworkin, R., et. al., 2003). A 2-week study of inpatient pediatric pain treatment found 33% off-label drug use (Conry & Peden, 2001). An unusual off-label pain treatment for intractable discogenic pain is perispinal administration of etanercept, a biological inhibitor of tumor necrosis factor-alpha (Tobinick, E. & Britschgi-Davoodifar, S., 2003). Off-label pain treatments and uses are so commonly-accepted that they do not result in raging debates at professional pain meetings, where almost any current topic may spur raging debate.

The purposes of this article are to discuss current trends in pain medication management, such that LNCs become more familiar with current pain therapies, and to provide brief bibliographic references. This article will review classes of drugs, common pain treatment uses, novel approaches still in the pipeline, and, very briefly, nonmedication strategies that can improve the efficacy of medications.

## Drug Therapy

Drug therapy is indicated when the pain condition is substantial enough to affect the patient’s quality of life and cannot be treated adequately by physical therapy or similar physical interventions alone (Supernaw, 2002). Medications that work very well for acute or short-term use may not work well for chronic use, and may even serve to exacerbate or perpetuate pain complaints. (Raziano, 2004a; Rizor, 2004; Simone, 2004). Once initiated, drug therapy is usually lifetime and can result in significant costs. Chronic pain patients often do not have adequate treatment plans, especially those treated

by acute care providers (e.g., surgeons). A sound chronic pain treatment plan must be addressed before damages presented at trial can be adequately assessed. Pain case management may be necessary before legal nurse consultants can get a clear picture of future treatment needs.

Medication selection for specific pain conditions is beyond the scope of this article. The author encourages LNCs to review the excellent treatment algorithm presented at [www.medscape.com/viewarticle/441743\\_9](http://www.medscape.com/viewarticle/441743_9) (Gallagher, 2002). Another excellent medication review article may be found at [www.hospitalphysician.com/pdf/hp\\_aug02\\_principles.pdf](http://www.hospitalphysician.com/pdf/hp_aug02_principles.pdf) (Supernaw, 2002).

To outsiders, pain treatment philosophy may seem to vacillate between no medication and high dose opioids. Neither extreme works very well. Rational polypharmacy, the strategic use of multiple medications, is often what work the best, especially for neuropathic pain (Bajwa, 2001). Agents that work especially well for chronic use with chronic pain include antidepressants, anti-inflammatories, antiseizure drugs, atypical antipsychotics, non-sedating muscle relaxers, and strategic use of opioids. We will examine each category and its utility in chronic pain.

## Antidepressants

Antidepressants are excellent drugs for use in chronic pain, and pain physicians have employed them for many years. Until August 2004, however, no antidepressant had formal approval for any chronic pain treatment from the Food and Drug Administration (FDA). In August 2004, Cymbalta® (duloxetine) received FDA approval for painful diabetic neuropathy, but no other chronic pain conditions (Latner, 2004).

The negative impact of anger, anxiety, and depression on chronic pain management is well-known and widely reported in the literature (Price & Harkins, 1992), and theorists once believed pain was a variant of depression (Hendler, 1990). Although researchers have not yet shown such a unitary psychological profile (Turk & Melzack, 1992), the links between somatic (physical) symptoms and depression appear strong. Dysregulation of serotonin and norepinephrine may be the biochemical links (Greden, 2003; Montano, 2003), and dopamine may also be a culprit (Barkin & Barkin, 2001). In ways that researchers do not yet fully understand, antidepressants seem to modulate the pain signal in the brain, perhaps by acting on serotonin, dopamine, and/or norepinephrine receptors.

Current pain practice includes tricyclic antidepressants (TCAs, and the newer selective serotonin reuptake inhibitors (SSRIs) and dual serotonin-norepinephrine (SNRI) antidepressants; dopamine agents also have utility. The old monoamine oxidase inhibitors (MAOIs) are not currently used, largely because of management complexities. High side-effect profiles, and risks of drug-to-drug or drug-to-food interactions make MAOIs impractical, especially when several other good choices exist. TCAs have long been the drugs of choice for

opioid-insensitive pain syndromes such as neuropathic pain.

Patients who perceive depression, anger, or anxiety as pejorative labels will often try antidepressants when the drugs are presented as a pain signal modulator. Once they experience results with an antidepressant, patients usually want to continue because the perceived benefits easily overcome pejorative labels. Seven broad classes of antidepressants are:

1. Mixed and neuroreceptor antagonists plus sodium fast channel inhibitors (amitriptyline, doxepin, imipramine);
2. Norepinephrine selective reuptake inhibitors (desipramine, nortriptyline);
3. SSRIs (citalopram, escitalopram, fluoxetine, paroxetine, sertraline);
4. Dual serotonin and norepinephrine reuptake inhibitors (venlafaxine, duloxetine);
5. Serotonin 2A (5 HT<sub>2A</sub>) receptor blockers and weak serotonin reuptake inhibitors (nefazodone);
6. Serotonin (5 HT<sub>2A</sub> and 5 HT<sub>2C</sub>) and norepinephrine alpha<sub>2</sub> receptor blockers (mirtazapine);
7. Dopamine and norepinephrine reuptake inhibitors (bupropion) (Preskom, 1999).

Current antidepressants commonly used in pain clinics include Lexapro® (escitalopram), Effexor® (venlafaxin), and Wellbutrin® (bupropion). Cymbalta®, a similar antidepressant to Effexor®, reports pain reductions in female patients with fibromyalgia (Arnold, et. al., 2004). FDA approval for painful diabetic neuropathy may cause Cymbalta® to become first-line treatment for other neuropathies. Lexapro®, a subsequent-generation SSRI, is the single isomer of the (slightly) older drug Celexa® (citalopram). Single isomer antidepressants have a lower side-effect profile with equivalent treatment efficacy and are probably the direction of future research. Effexor® and Cymbalta® act on both serotonin and norepinephrine (SNRI); Effexor also acts on dopamine receptors at higher doses. Wellbutrin® acts on dopamine and norepinephrine receptors, with lower side-effects than older TCAs (Barkin & Barkin, 2001). Lexapro®, Effexor® and Cymbalta® may not be used simultaneously, but each can be used concurrently with Wellbutrin®. Lexapro® has faster onset and a cleaner side-effect profile, Effexor® has more research on its positive effects on somatic disturbance, Cymbalta® seems to help female, but not male, fibromyalgia patients for reasons that are not clear, and Wellbutrin® is excellent for the weepy chronic pain patient. Wellbutrin® may help counteract sexual side-effects of SSRIs.

A common treatment strategy is to start either Lexapro® or Effexor®, titrate to maximum doses, and allow 6 or 8 weeks for an adequate trial. When a patient gets no results in 8 weeks, the usual strategy is to switch to the other drug. When the patient gets results but not enough relief, a common strategy is to augment the SSRI or SNRI with Wellbutrin®. Observationally, starting antidepressants several weeks before functional improvement (“work hardening”) programs can dramatically improve physical outcomes.

As a practical matter, the best antidepressant is the one the patient will take. Patients who feel they are doing well with older antidepressants may not want to change drugs. Most pain patients will be on antidepressant therapy at least a year and some will require lifetime treatment. After the first year, the only sure way to tell whether a patient can discontinue antidepressants is for physicians to titrate the medications down, watch the patient carefully, and make appropriate changes.

**Severely Depressed Patients.** Treatment-refractory depression, when all else has failed, may respond to Zyprexa<sup>®</sup>, an atypical antipsychotic, or the newer combination drug Symbyax<sup>®</sup>, which combines Zyprexa<sup>®</sup> with Prozac<sup>®</sup>. Zyprexa<sup>®</sup> and Symbyax<sup>®</sup> are not first-line treatments for depression, but have tremendous utility for treatment-refractory chronic pain patients, for reasons we will discuss in a later section.

**Antidepressants and Anxiety.** The neurobiology of anxiety is not as well-researched as that of depression. Besides the obvious effect of lessening depression, SSRIs are also the current drugs of choice for anxiety (Andrews, 2004). Although observationally, one angry anxious patient significantly improved her behavior with Effexor<sup>®</sup> and group patient education, research literature is sparse on anger and SSRIs/SNRIs. Benzodiazepines were the traditional choice for medicating acute anxiety, but these drugs are not good for chronic use because of dose escalation, inhibition of activity levels, and the potential for abuse and habituation (Raziano, 2004a; Rizor, 2004; Simone, 2004). Two antidepressants, Lexapro<sup>®</sup> and Effexor<sup>®</sup>, have FDA approval for Generalized Anxiety Disorder, and both may help anxious pain patients. Lexapro<sup>®</sup> works a few days faster, and with some extremely anxious patients, time can be a crucial factor. Around 8 weeks, treatment results even out, and both are excellent drugs.

**Antidepressants and Sleep.** Sleep disturbance is a chronic problem for many pain patients, both sleep onset and early awakening. Sleep deprivation, by itself, can cause pain in otherwise-healthy people, exacerbating and perpetuating chronic pain complaints. Sleep medications should be addressed as part of pain damages. Benzodiazepines and hypnotic drugs may be helpful for a few days (14 days or less), but are not generally useful for chronic administration. A subset of pain patients may benefit from Ambien<sup>®</sup> or Sonata<sup>®</sup> for occasional use. Both are hypnotics with lower side-effect profiles than the older hypnotics.

Patients should avoid SSRIs at night because they can cause insomnia if taken too late in the day or at bedtime. In contrast, the older antidepressant drugs had often limited utility as antidepressants because drowsiness was such a pesky side-effect. Older antidepressants make wonderful sleeping aids for chronic use and should be included in pain damages. Trazadone is a serotonin agonist, a drug that triggers a reaction from a cell or hormone, and works very well as a first-line sleep agent, when taken in low doses at bedtime. Trazadone is well-tolerated in low doses and can be used

chronically without serious risks of abuse, accelerating doses, or habituation common to benzodiazepines and older hypnotics. Amitriptyline is a tricyclic antidepressant, another older drug that works well in low doses for sleep; amitriptyline also has utility for reducing pain intensity in neuropathic pain. Remeron<sup>®</sup>, taken in low doses at bedtime, is a second-generation SSRI that seems to have a stronger sleep action than either Trazadone or amitriptyline, and should probably be used as a second-line sleep agent after Trazadone or amitriptyline have failed. Patients taking therapeutic doses of newer SSRIs or SNRIs can use either trazadone or Remeron<sup>®</sup> in low doses at night. Once started, a patient will probably need low dose antidepressants for sleep on a daily basis, to lifetime.

## Anti-Inflammatories

**Anti-Inflammatories and Inflammatory Disease.** Nonsteroidal anti-inflammatories (NSAIDs) date from the ancient Greeks and Romans, who used willow bark, a natural source of salicylic acid (aspirin). An excellent discussion and review of NSAIDs, including doses and dosing schedules can be found at [www.hospitalphysician.com/pdf/hp\\_aug02\\_principles.pdf](http://www.hospitalphysician.com/pdf/hp_aug02_principles.pdf) (Supernaw, 2002). These drugs treat any painful condition with an inflammatory component, especially arthritis or rheumatic diseases. NSAIDs are both primary prevention drugs and acute treatment for migraine. The mechanism of action is to inhibit cyclooxygenase, a biological component of inflammation. Researchers have identified at least three COX enzymes, with evidence pointing toward more, so even more specific NSAIDs are in the research pipeline. Although both physicians and pain patients tend to overlook NSAIDs, NSAIDs have significant utility for chronic use (Raziano, 2004a).

Older NSAIDs may be useful for patients with limited funds. Used with appropriate precautions (food or milk), older NSAIDs are reasonably manageable when no other good choices exist. Nevertheless, the optimum treatments are the newer NSAIDs, cyclo-oxygenase-2 (COX2) inhibitors. COX2s reduce incidences of gastric distress, the major side-effect of NSAIDs, though none are perfectly side-effect free. The two available COX2s are Bextra<sup>®</sup> and Celebrex<sup>®</sup>. Mobic<sup>®</sup> and Lodine<sup>®</sup> act much like COX2s but do not have the correctly-shaped molecule to meet the definition; technically, Mobic<sup>®</sup> and Lodine<sup>®</sup> are COX1-sparring. Vioxx<sup>®</sup> was recently removed from the market by its manufacturer, on their own volition. Coxibs (COX2s) still in the research pipeline include parecoxib, etoricoxib, and lumiracoxib (Stichtenoth & Frolich, 2003). Once instituted for chronic pain, patients will probably use NSAIDs daily, to lifetime.

As mentioned, the primary complication of NSAIDs is gastric distress. However, a subset of patients will experience rebound pain from NSAIDs, greatly restricting NSAIDs' utility for these patients. Rebound pain occurs when the patient becomes habituated to painkillers that are not

ordinarily habituating; instead of the drug treating the patient's pain, absence of the drug causes the patient's pain, often as headache. Rebound pain may occur with over-the-counter preparations such as aspirin, acetaminophen, and non-prescription strength ibuprofen or naproxin. Current medical research cannot predict which patients will rebound. Once rebound pain occurs, the patient is at-risk for future rebound pain to lifetime. Some physicians believe that the best management course for rebound patients is to provide as-needed NSAIDs for use in pain flare-ups, but no more than two weeks at a time, and weeks or months between courses of treatment. Other physicians believe that rebound precludes use of NSAIDs. After clarifying the patient's status with treating physicians, pain damages should include as-needed NSAID use with rebound patients. One should not assume that patients successfully using daily NSAIDs will suffer rebound.

**NSAIDs and Preemptive Analgesia.** Anesthesiologists have long used ketamine, an n-methyl-d-aspartate (NMDA)-inhibitor, to prevent the brain from processing and interpreting pain signals during surgery. Without NMDA-inhibitors, surgical patients are unconscious but their brains continue to read and store pain signals, a process many researchers believe predisposes later development of chronic pain.

However, protecting the brain is not enough. Preventing the humeral (blood) system from starting the inflammatory cascade is also key to preventing chronic pain. Surgeons typically tell patients to stop all NSAIDs before surgery because the older NSAIDs prevent blood clotting. However, the COX2 NSAIDs do not prevent blood clotting and may be used for preemptive analgesia of postsurgical pain. Patients who received COX-2 NSAIDs within 24 hours before surgery had less pain and used fewer opioids postsurgically (Fenton, Keating & Wagstaff, 2004). Parecoxib, an injectable form of Bextra®, is in the research pipeline, and will permit administration just before surgery. Peri-operative administration of NSAIDs does not work as well because the inflammatory cascade starts with the first surgical incision (Reuben, 2004). Preemptive analgesia is a major step toward primary prevention of chronic pain, and pain damages should include these costs for any proposed surgery.

## Antiseizure Medications

Antiseizure (neuroleptic) drugs are excellent choices for neuropathic pain, trigeminal neuralgia, migraine prevention, diabetic neuropathy, postherpetic neuralgia, nerve injuries, and other opioid-insensitive pain syndromes. Patients may report pain reductions within 48 hours. Common neuroleptic drugs are carbamazepine (Tegretol®), gabapentin (Neurontin®), lamotrigine (Lamictal®), zonisimide (Zonogran®), topiramate (Topamax®) and tiagabine (Gabitril®). Used less often and best reserved for use after treatment failures with other neuroleptics are phenytoin (Dilantin®) and valproic acid (Depakene®) (Supernaw, 2002).

Neuropathic pain patients tend to experience better relief with antiseizure drugs than they do with opioids. The exact mechanisms of the drugs are unknown. Observationally, pain patients either love neuroleptic drugs or hate them because of side effects. Lower doses may not work and patients must reach peak doses before deciding that a neuroleptic drug does not help. When patients do not respond at peak doses of one neuroleptic, systematically titrate other neuroleptics to peak doses before abandoning this class of drugs. Like many treatments in pain management, drugs that work for one patient may not work for another; trial-and-error is inherent in pain management. If carbamazepine (Tegretol®) is the neuroleptic of choice, then damages must also include regular lab work.

## Atypical Antipsychotics

Older antipsychotic drugs have no utility in chronic pain management because the side-effect profile outweighs the benefit, primarily tardive dyskinesia, an abnormal movement syndrome that may be irreversible. An intriguing class of drugs for pain management are the atypical antipsychotics. While not side-effect-free, atypicals are less likely to cause tardive dyskinesia. Use of atypical antipsychotics requires patient preparation and education. Patients (or professionals) who read the package inserts without knowing their use in pain management become justifiably confused. As the name implies, atypical antipsychotics treat schizophrenia and other psychotic disorders. Olanzapine (Zyprexa®) and quetiapine fumarate (Seroquel®) have gained FDA-approval for bipolar mania, with fewer side-effects than the older antipsychotics. Their exact mechanisms of action are unknown, but both are dopamine and serotonin antagonists, which block or nullify the action, which may play roles.

Both drugs work very well for extremely difficult-to-treat pain patients. These patients typically have some combination of treatment-resistant depression, bipolar disorder, and/or severe sleep disturbance. Patients whose pain medications have reached maximum doses but who continue to crave narcotics, seem to especially benefit. With the most complex pain patients, atypical antipsychotics may help when all else fails (Hall, 2004). Besides psychiatric rehabilitation and chronic pain management, Zyprexa® and Seroquel® have proven useful for drug rehabilitation centers and post-traumatic stress disorder clinics. Side-effects seem to be weight gain and metabolic slowing, though a raging debate is currently ongoing about the connection between atypical antipsychotics and diabetes. The treatment gains so thoroughly outweigh the risks for intractable patients that the author would not hesitate to recommend atypical antipsychotics for the most difficult patients.

In contrast with SSRIs, atypical antipsychotics should be used at bedtime. Many patients experience somnolence, and this side-effect can be used to their benefit. Patients who complain of sleeping no more than two or three hours nightly gain sound sleep with atypical antipsychotics. The extra sleep

when first taking the drugs is both common and beneficial, but decreases to more normal levels after the first few days. For purposes of calculating pain damages, once treatment starts, patients can expect to use atypical antipsychotics daily, to lifetime. Pain damages should also take into account dietitian assistance for atypical antipsychotic patients for weight gain and metabolic slowing.

## Opioids

Opioids' primary function is analgesia, or pain relief. Useful opioids for pain management are pure agonists of the opioid mu receptor in the brain. Examples include codeine, oxycodone, hydrocodone, fentanyl, dilaudid, and the opioid gold standard, morphine. Opioids are always federally-regulated, scheduled drugs, Schedule II or Schedule III.

Chronic use of opioids can be problematic for reasons that include legal, criminal, sociocultural, and medication side-effects, detailed discussions of which are beyond the scope of this article. No topic in chronic pain management is more emotionally loaded than discussion of opioids. To gain a more clear view of this very complex picture, the author encourages legal professionals to read the position statement of the American Academy of Pain Medicine and the American Pain Society, also adopted by the American Academy of Pain Management. The opioid position statement can be found at [www.ampainsoc.org/advocacy/opioids.htm](http://www.ampainsoc.org/advocacy/opioids.htm).

Legal professionals rarely make treatment decisions about opioids but must be aware of the issues. Pain damages that include opioid medications invariably raise questions about appropriateness, addiction, abuse, habituation, dose escalation, diversion, and complications. Detailed discussion could be the subject of another article.

Opioids are excellent drugs for acute pain such as postsurgical pain or for acute pain flares. A subset of pain patients benefits from chronic opioid management. In contrast, another subset is recovering persons with pain who should never attempt chronic opioid therapy. Few pain patients find that opioids, alone, address their complaints, and many pain patients fare better taking drugs more suited to chronic use. Rational polypharmacy may include both opioid and non-opioid medications. For our discussion, we will divide opioids into short-acting, long-acting, and novel delivery systems.

**Short-Acting Opioids.** Short-acting opioids have been around since the Greeks and Romans used poppy juice for pain relief. As the name implies, these drugs have fast onset and short half-life, typically four to six hours. Short-acting opioids typically cause euphoria or somnolence, and some patients mistake euphoria for pain relief. Examples include Lortabs®, Vicodin®, and Tylenol® #3.

Ultram® (tramadol) and Ultracet® (tramadol and acetaminophen) are short-acting synthetic opioids useful for breakthrough pain. Tramadol's exact action is unknown, but may be a combination of affinity for the mu receptor and weakly inhibiting the reuptake of norepinephrine and

serotonin. Short-acting opioids are excellent for acute pain, postsurgical pain, breakthrough pain, or similar, but are not good choices for chronic use.

**Long-Acting Opioids.** Long-acting opioids first appeared on the market in 1995 with the introduction of Oxycontin®. For patients requiring chronic opioid management, long-acting opioids are excellent choices. These drugs have slow onset, long half-life up to 72 hours, produce no significant euphoria when used correctly, and greatly improve quality of life for appropriate patients. Despite its utility, Oxycontin® has produced raging debates, even litigation, about diversion, addiction, and abuse. To address this problem, in May 2004 Oxycontin's manufacturer formed a manufacturing alliance to explore abuse-resistant technology (Will, 2004).

Other long-acting opioids include Duragesic® (fentanyl) patches, Kadian® (kapanol), and MS Contin (morphine), all discussed below. Methadone is an old drug available in generic form that is useful for patients with limited funds, but is not the best opioid treatment alternative available. Blood levels can vary widely with the same dose and methadone does not provide the comfort level of the newer long-acting opioids. However, methadone is the most inexpensive alternative for nociceptive pain when other drugs have failed.

**Novel Delivery Systems.** The hot debate about diversion, abuse, and criminal concerns has generated intense research for novel delivery systems that reduce diversion and abuse. Human nature being what it is, no drug delivery system is foolproof. Documented cases of entrepreneurial uses of novel drug delivery systems are already appearing. However, novel drug delivery systems may slow diversion.

Duragesic® patches are one such novel delivery system. The medication is stored in gel form in a protected reservoir, then released slowly through an absorption membrane. The patches release medication over a period of 72 hours. Medication release is so slow that patients report little euphoria.

Kadian® capsules are a second novel delivery system for long-acting morphine. Administered at 12 hours or 24 hours, time release pellets deliver oral morphine sulfate. Polymer shells enclose the pellets and break down to release the drug in the digestive tract. The opioid cannot be extracted from the polymer casing except in the digestive tract (Kaplan, Miliman, Kaplan, & Collins, 2004). In theory, the polymer pellets preclude a euphoric dose if crushed.

Actiq® (fentanyl) is a transmucosal delivery system for short-acting fentanyl. The drug is released only when swabbed against the mucus membrane inside one's cheek. The transmucosal mechanism delivers a lower dose, if crushed, and in theory, delivers a subeuphoric dose.

**Mixed Agonist-Antagonist Opioids.** Re-introduction of mixed agonist-antagonist opioids is a recent development in pain management. Mixed agonist-antagonist opioids are those that partially target the mu opioid receptor in the brain but also partially block it. Buprenorphine is a mixed agonist-antagonist



opioid, with trade names including Nubain®, Stadol®, Buprenex®, and Subutex®. A related drug, Suboxone®, combines buprenorphine with naloxone (Narcan®), a pure opioid antagonist used to counteract overdoses. The theory behind Suboxone® is that the antagonist effect of naloxone further reduces chances for euphoria.

Occasionally, one may see mixed agonist-antagonist drugs in treatment plans. As pain drugs, mixed agonist-antagonist drugs work poorly and may be most appropriate for the small subset of pain patients who were substance abusers before their pain started. Mixed agonist-antagonists provide some analgesia and are safer to use when the medical providers treat an unknown patient, as in an Emergency Room visit. Because of their mixed effect, they are harder to abuse and make diversion less likely. The best use for mixed agonist-antagonists is to cushion the detoxification process for substance abusers. Patients on chronic opioid therapy with pure agonist opioids cannot take mixed agonist-antagonists because a dose of mixed agonist-antagonist will trigger withdrawal.

**Novel Delivery Systems in the Pipeline.** Research continues on a miniature implanted osmotic medication pump delivering sufentanil (Sufenta®), a stronger drug than fentanyl. The osmotic mini-pump is the size of a matchstick implanted under the skin and is designed to deliver medication for 90 days (Fisher, Kellett, & Lenhardt, 2003). Researchers are working on a controlled-release version of tramadol (Ultram®) (Tiwari, Murthy, Pai, Mehta, & Chowdary, 2003). Sublingual buprenorphine is in the research pipeline (Das & Das, 2003).

### Non-Sedating Muscle Relaxers

Presently, Skelaxin® (metaxalone) is the only available non-sedating muscle relaxer and is, therefore, the most appropriate choice for chronic use. Older muscle relaxers are fine for acute use, but are sedating, reduce physical activity and blunt feelings. Older muscle relaxers are not appropriate for chronic use.

The best plan is to identify the pain generator causing the chronic muscle spasm, so the patient may not need Skelaxin® daily. However, daily use to lifetime would be acceptable, if that is what works best for the patient.

### Laboratory Tests

Beyond general cautions, none of the drugs discussed require laboratory tests except Tegretol®. Patients on long-term Tegretol® require quarterly complete blood counts (CBC) (Raziano, 2004b).

### Non-Medication Pain Management

Detailed discussion of non-medication pain management is beyond the scope of this article. However, optimum pain medication management greatly depends on optimum lifestyle management. Determined pain patients can successfully defeat the best pain medications, if they poorly manage

behavioral factors. Immune system function is not purely biological and, to paraphrase St. Augustine, drugs act on the nature that they find. A flu shot is about as biological an intervention as one can find. Researchers from the University of Wisconsin identified that thinking about positive or negative events in one's life affected how robustly study participants produced antibodies (Fauber, 2003). Although no similar research exists for pain medications, ignoring the implications would be unwise.

Detailed discussion of non-medication strategies will be the subject of a future article. Many non-medication strategies are evidence-based with published peer-reviewed journal articles. Non-medication treatments that can improve efficacy of pain medication and/or reduce its need, are as follows:

- |  |   |
|--|---|
| Ablative procedures<br>(radiofrequency, etc.)  | Movies  |
| Acupuncture  | Multidisciplinary pain management   |
| Anesthetic blocks  | Occupational therapy  |
| Behavioral counseling  | Patient education   |
| Biofeedback  | Physical therapy  |
| Electrical stimulation technologies<br>(TENS, Alpha-Stim®, muscle stimulators, etc.) | Pool therapy  |
| Exercise   | Positive self-talk  |
| Family therapy   | Prayer and spirituality   |
| Guided imagery   | Relaxation  |
| Heat   | Self-hypnosis   |
| Humor  | Specialty interventions<br>(rape survivor counseling, Eye Movement Desensitization Reprogramming, etc.) |
| Hypnotherapy   | Stress management   |
| Ice  | Twelve-Step Programs  |
| Implanted technologies<br>(dorsal column stimulators, pain medication pumps)         | Vocational rehabilitation   |
| Marriage counseling  | Volunteer work  |
|  | Work  |

### Drugs Not Useful for Chronic Administration

Thus far, we have confined our discussion to drugs useful for chronic administration. Drugs that may have excellent uses acutely often have little utility for chronic use. Usual problems include tendencies to habituation or abuse, decreased activity levels, need to escalate doses, and potential for diversion. Such drugs include benzodiazepines, most muscle relaxers, short-acting opioids (except sparingly for breakthrough pain), hypnotics, and mixed agonist-antagonist opioids (except a small subset of patients). A suggested chronic pain drug formulary is included in Table 1, and classes of drugs to avoid are listed in Table 2 (both on the following page).

### Summary

Chronic pain cannot be treated the same as acute pain. Many treatments that are perfectly appropriate for acute pain do not help chronic pain and may make it worse. Once pain

**Table 1: Recommended Drug Formulary for Chronic Pain**

Class of Drug	Chronic Pain Use	Recommended Brands
<b>ANTIDEPRESSANTS</b>	Anxiety Depression Modulation of pain signal	Effexor Lexapro Wellbutrin
<b>ANTIDEPRESSANT</b>	Modulation of fibromyalgia pain signal (female patients)	Cymbalta
<b>ANTIDEPRESSANTS AS SLEEP PREPARATIONS</b>	Improve patient sleep	Trazodone (low dose) Remeron Solutabs (low dose)
<b>ANTI-SEIZURE DRUGS</b>	Neuropathic pain Opioid-resistant pain syndromes	Gabapril Neurontin Tegretol Topamax Zonogran
<b>ATYPICAL ANTIPSYCHOTICS</b>	Borderline Personality Disorder Drug-craving patients whose meds are already at maximum doses Drug detoxification Treatment-refractory depression	Seroquel Zyprexa
<b>HYPNOTICS</b>	Short-term use, acute insomnia flares, use limited to <2 weeks	Ambien Sonata
<b>MUSCLE RELAXER (NON-SEDATING, ONLY)</b>	Relieve muscle spasms	Skelaxin
<b>NONSTEROIDAL ANTIINFLAMMATORIES – COX2</b>	Arthritic and rheumatic pain Relieve pain via reducing inflammation Preemptive analgesia	Bextra Celebrex
<b>NONSTEROIDAL ANTIINFLAMMATORIES – COX1 SPARRING</b>	Arthritis and rheumatic pain Relieve pain via reducing inflammation Preemptive analgesia Patients whose insurance will not approve COX2s Similar side-effect profile to COX2. Mobic has been shown not to raise blood pressure.	Lodine XL Mobic
<b>NSAIDS – COX1</b>	Low income patients Patients whose insurance will not approve COX2s Higher side-effect profile than COX2 but good drugs when used with precautions	All the rest
<b>OPIOIDS (LONG-ACTING)</b>	Relieve musculoskeletal pain	Avinza Duragesic Kadian Oxycontin MS-Contin
<b>OPIOIDS (SHORT-ACTING)</b>	Relieve acute pain flares Control breakthrough pain	Actiq Oxy-IR MS-IR

**Table 2: Drugs Generally Not Appropriate for Long-Term Use With Chronic Pain Patients**

• Benzodiazepines
• Hypnotics
• Mixed agonist-antagonist opioids except with a small subset of patients
• Most muscle relaxers
• Short-acting opioids, except sparingly for breakthrough pain

becomes chronic, most patients require daily medication, and rational polypharmacy is the treatment approach of choice. The goals of chronic pain management are to increase function and daily activity, and by doing so, help patients gain better pain control. Even those patients who do not gain lower pain levels can often gain better quality of life through increased activity.

When reviewing pain cases, LNCs should start with the usual search techniques. After exhausting those, LNCs may require review assistance from experts skilled in multidisciplinary pain management. Pain management may be evidence-based, even when done off-label, but sometimes anecdotal accounts may be the only proof.

LNCs should remember that pain case analysis and management may be necessary before damages can be adequately quantified. This is especially true when patients have been treated mostly by surgeons or by single-discipline (“needle clinics”) pain treatment centers.

Pain diagnostics is a young science, and all pain centers are not created equal. Indeed, some approaches are considerably less equal than others (with apologies to George Orwell).

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# Vioxx Withdrawn from the Market: Controversies Continue to Involve Merck & FDA

Mary A. O'Connor, PhD RN

## KEY WORDS

Class Action Suit, Cox-2 Inhibitors, FDA, Merck, Pain Management, Pain Medications, Rofecoxib, Vioxx

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*As this special themed edition of The Journal of Legal Nurse Consulting on Pain Management went to print, Vioxx (rofecoxib), a nonsteroidal anti-inflammatory drug (NSAID) was withdrawn from the market by its manufacturer, Merck & Co., Inc. On September 30, 2004, Merck announced the withdrawal of Vioxx based on the results of the APPROVe (Adenomatous Polyp Prevention on Vioxx) trial.*

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The APPROVe trial, which was stopped prematurely, “was designed to evaluate the efficacy of Vioxx 25 mg in preventing recurrence of colorectal polyps in patients with a history of colorectal adenomas. In this study, there was an increased relative risk for confirmed cardiovascular events, such as heart attack and stroke, beginning after 18 months of treatment in the patients taking Vioxx compared to those taking placebo” (Merck, 2004). Data analysis of study participants treated for less than 18 months did not show increased risk of cardiovascular events in the Vioxx treatment group (Merck, 2004).

## A Wonder Drug No Longer

“APPROVe was a multi-center, randomized, placebo-controlled, double-blind study to determine the effect of 156 weeks (3 years) of treatment with Vioxx on the recurrence of neoplastic polyps of the large bowel in patients with a history of colorectal adenoma. The trial enrolled 2,600 patients and compared Vioxx 25 mg to placebo. The trial began enrollment in 2000” (Merck, 2004).

Peter S. Kim, PhD, President of Merck Research Laboratories, announced the withdrawal of Vioxx at the Merck news conference: “If Vioxx were the only drug available for patients experiencing arthritis pain, that risk might be worth taking. But there are plenty of other alternatives...” namely Celebrex and Bextra from the COX-2 class and naproxen or ibuprofen from the lower class of NSAIDs (DeNoon, 2004).

The Federal Drug Administration (FDA) Public Health Advisory of September 30, 2004, announced that Merck & Co., Inc. was “[voluntarily withdrawing] Vioxx (rofecoxib) from the U.S. and worldwide market due to safety concerns of an increased risk of cardiovascular events, including myocardial infarction (MI) and stroke, in patients on Vioxx” (FDA MedWatch, 2004). Of note, Merck made the decision to withdraw the drug independent of the FDA.

On October 5, 2004, the first worldwide class action lawsuit against Merck was filed in the Federal District Court for the Northern District of Illinois, known as “Vioxx Class Action” on behalf of all persons who were prescribed rofecoxib

(Moll, 2004.) Other lawsuits are also being filed, with the expectation that Merck shareholders will also file suit (Canadians, 2004; Merck Faces Lawsuits, 2004). The claims in the lawsuits include that Merck knew about the cardiovascular risks as early as 2000 but did not issue adequate warnings (Canadians, 2004).

Vioxx was first introduced by Merck & Co., Inc. in 1999 and was considered a breakthrough in pain medications. The FDA approved Vioxx following a safety study of the drug on approximately 5,000 patients. Vioxx is classified as a Cox-2 selective inhibitor, a type of pain reliever that works by inhibiting an enzyme (cyclooxygenase-2) that causes pain and swelling. Vioxx was determined to be highly effective in alleviating osteoarthritis pain, menstrual cramps, and rheumatoid arthritis pain in adults and children.

Almost 33 million Americans were taking it, and it had been marketed in more than 80 countries. (In some countries, the product is marketed under the trademark CEOXX.) “Worldwide sales of Vioxx in 2003 were \$2.5 billion” (Merck, 2004). The impact of the removal of this drug is just now being realized, with doctor’s offices being deluged with phone calls from patients who were prescribed Vioxx for pain. Patients will need to be individually evaluated to determine future pain management therapy (Merck, 2004).

Many physicians had already stopped prescribing Vioxx over the past year due to medical journal articles related to the cardiovascular risks (Mamdani, et al., 2004; Schmidt, et al, 2004).

Merck maintains that it has yet to see the impact of the withdrawal of the drug and its \$2.5 billion/year in sales on its 3rd quarter earnings (Ozols, 2004). In June 2004, Merck’s stocks declined about 9%, “after warning it would miss earnings targets for the quarter and year because of sluggish sales of its key arthritis drug Vioxx and the strong dollar” (Markets, Merck Warning Sends Stocks Down, 2004).

Merck’s response to the APPROVe study findings seemed like a reasonable response; however, both Merck and the FDA are currently embroiled in controversy over the number of cardiovascular deaths purportedly linked to the drug.

Dr. Eric Topol, Chief of Cardiovascular Medicine at the Cleveland Clinic Foundation, has been described as Merck's first and most persistent critic (CBS 60 Minutes, 2004). Dr. Topol co-authored a 2001 article published in the *Journal of the American Medical Association* that discussed cardiovascular risks associated with use of Vioxx. In an editorial published in the October 21, 2004, *New England Journal of Medicine*, Dr. Topol called for "a full Congressional review of this case." In his opinion, "The senior executives at Merck and the leadership at the FDA share responsibility for not having taken appropriate action and not recognizing that they are accountable for the public health. Sadly, it is clear to me that Merck's commercial interest in rofecoxib sales exceeded its concern about the drug's potential cardiovascular toxicity." Dr. Topol cited Merck and the FDA as "failing the public health" and suggested a "congressional review...to avert such a catastrophe in the future."

## Early Warning

On September 17, 2001, Thomas Abrams, RPh MBA, Director of the FDA's Division of Drug Marketing, Advertising, and Communications, sent a Warning Letter to Raymond Gilmartin, President and CEO of Merck about the promotional activities and marketing of Vioxx (Abrams, 2001).

The FDA cited a Merck press release dated May 22, 2001, entitled *Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx*, as "promoting [information] that is...false or misleading...[The] claim in the press release that Vioxx has a 'favorable cardiovascular safety profile,' is simply incomprehensible, given the rate of MI and serious cardiovascular events compared to naproxen. The implication that the cardiovascular profile of Vioxx is superior to other NSAIDS is misleading. In fact, serious cardiovascular events were twice as frequent in the Vioxx treatment group as in the naproxen treatment group in the VIGOR study" (Abrams, 2001).

Dr. Abrams noted that Merck's "promotional activities and materials...minimize the potentially serious cardiovascular findings that were observed in the VIGOR study...omit crucial risk information associated with Vioxx therapy, contain unsubstantiated comparative claims, and promote unapproved uses" (Abrams, 2001).

The FDA objected to Vioxx promotional materials disseminated by Merck, stating that they "misrepresented Vioxx's safety profile, contained unsubstantiated comparative claims, and lacked fair balance" (Abrams, 2001).

Dr. Abrams requested that Merck take specific actions including immediate cessation of promotional activities deemed false or misleading. Merck & Co., Inc. responded to Abrams' Warning Letter through its spokesperson Chris Fanelle, who claimed initially that Merck "continued to stand behind the overall and cardiovascular safety [claims of Vioxx]" (Rubin, 2001).

The FDA Arthritis Advisory Committee Meeting reviewed the findings from the VIGOR study in February, 2001, and recommended that Merck warn patients and doctors about an increased heart attack risk (Abrams, 2001; Rubin, 2001). After these combined warnings, Merck developed pamphlets that cautioned patients about "serious but rare and potentially life-threatening side effects including...heart attacks and other serious cardiovascular events, such as blood clots" (Patient Information about Vioxx, 2002). As noted in Vioxx prescribing information, published by Merck in 1998 and revised in 2002, "The VIGOR study showed a higher incidence of adjudicated serious cardiovascular thrombotic events in patients treated with Vioxx 50 mg. once daily as compared to patients treated with naproxen 500 mg twice daily. This finding was largely due to a difference in the incidence of myocardial infarction between the groups."

Dr. David Graham, a 20-year employee of the FDA and Associate Director for Science, Office of Drug Safety, Center for Drug Evaluation and Research (CDER), testified in a Senate Finance Committee investigation on October 8, 2004, that he was "ostracized," "subjected to veiled threats" and "intimidation" regarding what he wanted to report about Vioxx and the cardiovascular risks. Graham was the principal investigator of a research project that reviewed records of 1.39 million Kaiser Permanente patients, including 40,405 treated with Pfizer's Celebrex and 26,748 treated with Vioxx.

The study found that high doses of Vioxx, known as rofecoxib, tripled risks of heart attacks and sudden cardiac death. The research team's original conclusion recommended that "high doses of Vioxx should be ended and that lower-dose rofecoxib should not be used by physicians or patients. If lower-dose rofecoxib remained on the market, physicians and patients needed to understand that risk of acute myocardial infarction (AMI) and sudden cardiac death (SCD) was substantially increased and that there were safer alternatives" (CBS News, 2004; Graham, 2004). Dr. Graham, who was scheduled to present his findings in late August 2004 at an epidemiology conference in France, said he ran into resistance when the FDA reviewed his abstract (CBS News, 2004).

## Much More to the Story...

The first chapter of this story is barely written. As new information is released almost daily, the eventual litigation stemming from this controversy will likely provide LNCs with opportunities for years to come. Manufacturers must exhibit certain conduct with respect to marketing their drugs. If the risk is known or scientifically foreseeable, manufacturers have an ongoing duty to warn about the risk. Manufacturers are responsible for conveying adequately and in the appropriate context, and the warning must be conspicuous and prominent in order to convey the risks.

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# The Clinical and Legal Aspects of Massage Therapy

Deborah Gritzmacher, RN MT MSN & Debra Cody RN MSN

## KEY WORDS

Complementary/Alternative Medicine (CAM), Massage Therapy, Pain Management

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*This article discusses historical uses of massage, specific applications for pain, and the different types of massage therapy. This includes highlighting where it is offered, commonalities found in different techniques, and physiological responses to massage. The legalities of regulation, licensure, certification, and education will be covered, as well as contraindications to massage and its relationship to traditional medicine. The article points out the importance of federal agencies and organizations that are supportive of massage therapy, including the legal benefits of expanding its use among overstressed and underserved individuals.*

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The legal aspects of massage therapy are complicated, even though massage is one of the most commonly seen complementary/alternative medicine (CAM) therapies recognized in the United States. There are more than a hundred types of massage offered. Widely available in urban centers and fast becoming common in rural settings, massage therapy is used to treat multiple maladies, most frequently for relaxation, stress relief, and in the treatment of pain. It is effective for many individuals with various physical conditions, typically stress, pain, or injury related. Standards of practice are suggested through several professional associations and organizations that regulate education, licensure, and certification. The most efficient way to evaluate legal issues relative to massage is on an individual basis.

## Definitions, Applications

According to the American Massage Therapy Association (AMTA), "Massage is manual soft tissue manipulation, and includes holding, causing movement, and/or applying pressure to the body." Additionally, "Therapeutic massage involves manipulation of the soft tissue structures of the body to prevent and alleviate pain, discomfort, muscle spasm, and stress" ([www.amtamassage.org](http://www.amtamassage.org)).

Although massage therapy is a commonly sought stand-alone treatment today, it has been a tool used in nursing for years. Some 30 years ago, massage was provided by nurses as part of morning bath time and evening/bedtime care. Morning nurses gave a back rub after the bath to get the patient ready for the activities of the day. Evening nurses used massage to help patients get ready for sleep. It gave the nurse a chance to assess the patient, and opened an opportunity for talk about concerns or to discuss educational needs. As nursing practice evolved to high-tech/low-touch, that part of caring was left behind.

It might be a good practice to reintroduce and evaluate, whether or not it would decrease litigious thoughts in overstressed and underserved clients/patients. Unfortunately, it is unlikely that massage as a part of nursing care will return.

Empiric research about the effectiveness of therapeutic massage is being done through the National Institutes of Health (NIH) in the Center for Complementary and Alternative Medicine (NCCAM, 2000). Eisenberg, Kessler, and Foster (1993) site the most common complaints that convince the public to seek CAM for treatment are back complaints, anxiety, headache, chronic pain, and cancer. These conditions are closely associated with pain, and massage has been found to be effective in relieving pain in some cases.

Davis and Srivastava (2003) state that "The prevalence of pain increases with each decade of life." Their research identifies cancer as the leading cause of pain and mentions lower back pain as a frequently seen sign of aging. Massage is sited by the elderly in this study as one of their preferred strategies to control pain.

While Ernst (2004) finds "no convincing evidence" that there is significant relief of pain during or after massage, other professionals concerned with pain control issues disagree. Previous and ongoing research supports the benefits of massage used in conjunction with other therapies and its effectiveness in the relief of pain (Aronoff, 1982; Berman, 2003; Mobily, Herr, & Nicholson, 1994; Piotrowski, Paterson, Mitchinson, Kim, Kirsh, & Hinshaw, 2003; Rusy & Weisman, 2000; Walach, Guthlin, & Konig, 2003).

Massage for specific medical conditions is shown to have a beneficial effect. Pain is improved in patients with sickle cell disease using neuromuscular trigger point techniques (Bodhise, Dejoie, Brandon, Simkins, & Ballas, 2004). Pain in cancer patients, both in-patient and out-patient, is improved with massage.

Additionally, patients with less pain are not as depressed (Cassileth & Vickers, 2004). Post-White, et. al., (2003) found reduced pain after massage with cancer patients receiving chemotherapy. Multiple sclerosis patients with long standing pain show improvement in pain control with massage (Howarth, 2002). Headaches respond favorably to massage therapy (DeSousa & Chatap, 2004). Project Inform

perspective (1997) suggests deep tissue massage as a solution for HIV treatment caused peripheral neuropathy. Forchuk, et.al., (2004) studied massage in the post operative patients who had lymph node dissection and reported pain reduction and better shoulder function with massage.

Reflexology—massage done specifically on the hand or foot—is linked to pain reduction in cancer patients, post-operative patients, and patients with back pain (Degan, et. al., 2000). Wang and Keck (2004) found that postoperative pain relief was enhanced with reflexology. Stephenson, Dalton, and Carlson (2003) discuss reflexology relating to improved immediate pain relief in cancer patients with metastasis.

Health care professionals support the use of massage for pain control among their patients. Nurses in Britain are increasingly using CAM, including massage, for pain relief (Malkin, 1994). Gordon, Sobel, and Tarazona (1998) surveyed 624 practicing providers and adult members of a health maintenance organization (HMO) in southern California and found overwhelming support for incorporating CAM reimbursement, specifically massage for pain management, into their system.

Massage is offered in many settings including day-spas, beauty salons, holistic health centers, wellness centers, chiropractic offices, and free-standing independent practices known as chair/on-site/corporate massage centers. The types of massage techniques available vary widely but most commonly include Swedish, deep-tissue, neuro-muscular or trigger point therapy, reflexology, cranio-sacral, myofascial release, shiatsu or acupressure, lymphatic drainage, and sports massage.

There are commonalities among the massage techniques. Clients are encouraged to breathe deeply during massage, be hydrated, and consume extra fluid after massage. The therapist's touch or rub causes an increase of circulation to the skin and the underlying tissue during and immediately after massage. These simple actions allow the cells to be better oxygenated and nourished. Toxins are transported out of the body because of the increased circulation and hydration. Endorphins are released and touch increases feelings of well-being.

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## Educating Therapists

Education for massage therapists can be completed through a training program, a school of massage, or in an on-the-job situation. Ways to accomplish education credentialing are not stressed for licensure and certification as much as the extent and quality of the training. AMTA recommends "...a minimum of 500 hours of in-class training in subjects including a specified number of hours in anatomy and physiology, the theory and practice of massage therapy, and elective subjects" ([www.amtamassage.org](http://www.amtamassage.org)).

Currently, 33 states and the District of Columbia regulate massage therapy by offering a license to the therapist. The therapist must contact the state individually because the process and requirements vary. States, counties, and cities may require a business license to open a business offering massage as a service. There is a difference between being a licensed massage therapist and having a business license to offer the service ([www.amtamassage.org](http://www.amtamassage.org)).

"Licensure is a non-voluntary process by which an agency of government regulates a profession. It grants permission to an individual to engage in an occupation if it finds that the applicant has attained the degree of competency required to ensure that health, safety, and welfare will be reasonably protected. Licensing is always based on the action of a legislative body. Once a licensing law has been passed, it becomes illegal for anyone to engage in that occupation unless he or she has a license. The healing professions are typically licensed at the state and/or local level, but not usually at the federal level" ([www.amtamassage.org/findamassage/whatiscert.html](http://www.amtamassage.org/findamassage/whatiscert.html)).

National certification for therapeutic massage and bodywork is accomplished by meeting the standards of education, passing the national exam, participating in ongoing continuing education, and abiding by the standards of practice and code of ethics established by the National Certification Board for Therapeutic Massage and Bodywork. Certification is required in some states for licensure and may be a job requirement for employment ([www.ncbtmb.com](http://www.ncbtmb.com)).

## Risks & Liabilities

Since massage is non-invasive and makes few—if any—curative claims, it seems that there are limited areas that could put practitioners at risk for liability. Ernst (2003) concludes that while massage is not risk-free, it would be rare for a therapist to precipitate a serious injury.

The few contraindications to massage are logical, making them hard to overlook or ignore. All schools of massage and massage organizations recommend that therapists first obtain a health history on their clients. If the therapist finds facts in the health history that would contraindicate massage, it would be malpractice for the therapist to provide massage.

If the client is aware of the contraindication and requests massage, the therapist has several choices that lessen

liability. The first and safest choice is to refuse massage. The second choice would be to talk with the client and their primary health care provider regarding the risk of massage versus the benefits. If the client and the primary care provider request that massage be provided, the therapist should proceed only after a waiver of liability has been signed by all parties. Therapists are educated to refuse to massage any acute injury or any area of the body that is red and warm indicating inflammation. There are special considerations for cancer patients due to increased lymphatic drainage and for women who are pregnant. Some therapists prefer not to massage clients who have skin irritation or if the client has viral symptoms.

The litigious tendencies of U.S. consumers make practitioners of any service wary. The ATMA recommends that members carry a \$2 million malpractice policy. Because they are insured, they become somewhat vulnerable. Additionally, since there are standards of care, practice guidelines, and a code of ethics established for massage therapists, they can be held to a standard of care appropriate to the profession.

While readily available as a part of medical care, massage remains somewhat subversively hidden and under-financed through traditional reimbursement methods. A few insurance companies, however, include CAM in their benefits packages (Eldin, 2001). Traditional-medicine physicians do not readily admit that they recommend massage as a therapy, but financial managers recognize it as a lucrative offering.

Most often, massage services are offered in wellness centers or as a referral therapy for patients with pain control issues. There are 12 medical schools that have integrated CAM in their curriculum, participating in a Consortium of Academic Health Centers for Integrative Medicine (Horrigan, 2001). If physicians recommend massage as therapy or refer patients to a specific therapist, they may be liable under a vicarious liability or borrowed servant theory (Doyle, 2001; Studdert, et al., 1998).

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# The Art of Jury Selection

MarSue Chustz, BSN RN CCRN CLNC

*April 18, 1998* – Randi Mebruer, a 28-year-old home health nurse, disappeared from her home near Baton Rouge, LA. Signs of a bloody struggle were found in her home. As of this printing, her body has still not been found.

*September 23, 2001* – Gina “Gigi” Green, a nurse who specialized in infusion therapy, was strangled to death in her Baton Rouge home.

*January 12, 2002* – GERALYN Desoto, a Louisiana State University (LSU) graduate student, was murdered in her home near Baton Rouge. She was stabbed seven times and her throat was cut.

*May 31, 2002* – Charlotte Pace, 22 years old, was found dead at her home in Baton Rouge. She was sexually assaulted, stabbed 81 times, and beaten.

*July 12, 2002* – Pam Kinamore, 44-year-old wife and mother, was abducted from her Baton Rouge home. Her body was later found and her throat had been cut, and she had been sexually assaulted.

*November 21, 2002* – Trineisha Colomb, 23-year-old from Lafayette, LA, was reported missing. A hunter found her body in the woods 3 days later. “She had been sexually assaulted and beaten to death.”

*March 3, 2003* – Carrie Yoder, 26-year-old LSU doctoral student, was last seen alive. Investigators said Yoder was abducted from her home near campus and then beaten, raped and strangled before her body was dumped.

(“A Look at the Cases,” 2004.)

The people of South Louisiana, especially near Baton Rouge, feared for their lives as a serial killer preyed on its residents. On May 28, 2003, finally an arrest was made. Derrick Todd Lee, a 35-year-old African American male from St. Francisville, Louisiana, was arrested for the murder of GERALYN DeSoto. In August, Lee was convicted in the second degree murder of DeSoto, which carried a mandatory life sentence in the state.

In the fall of 2004, Lee went to trial for the murder of Charlotte Pace. The prosecution introduced DNA and other evidence in an attempt to link Lee to the murders of six other women. If convicted, he faced the death penalty. To obtain a death penalty sentence, prosecutors must obtain a unanimous jury decision for both the conviction and the death sentence (Adrian, 2004).

So what do attorneys look for when selecting a jury for a death penalty trial? What distinguishing techniques are utilized when making such a critical decision? In this case, it will be difficult to find an impartial jury due to the large amount of publicity surrounding the murders, coupled with

the fact that the residents of Baton Rouge had to change their lifestyles to protect themselves. These circumstances, in addition to the trial being a capital murder trial, make selecting a jury in Baton Rouge even more challenging.

Bruce Unangst, Esq., the defense attorney for Derrick Todd Lee, states, “The jury selection process for a death penalty case is different from any other case...While in other cases, I may look for a juror with favorable opinions toward legal issues, like reasonable doubt, in capital cases, the sole determining factor in evaluating a juror is his/her opinions towards the death penalty...I am looking for someone who has the courage and compassion to give a life sentence despite the horrific nature of the crime that is necessarily a part of any capital prosecution.”

John Sinuefield, Esq., the assistant District Attorney and lead prosecuting attorney for this trial, states, “When selecting potential jurors in a capital murder case, I’m really just interested in their attitudes on the death penalty...I ask very few other questions.” Many times, attorneys seek advice from trial consultants, also called jury consultants. Mr. Sinuefield states that he has never used a jury consultant. He affirmed that jury selection “is an art, not a science...It sometimes takes years to master it...You learn through the years and make lots of mistakes; but you learn from the mistakes and master the art.”

Mr. Sinuefield states that prior to reporting to the courthouse, the potential jurors from the jury pool answer a questionnaire consisting of 68 questions. The information gives the attorneys a head start in trying to ascertain the significant characteristics of each potential juror and helps them guide their questioning accordingly. The questionnaire in this case was submitted by Mr. Sinuefield and agreed upon by the defense and the judge. The questions covered a wide range of topics, with the last question simply asking, “How do you feel about the death penalty?”

The potential juror’s assessment comes to a peak during voir dire, the process through which potential jurors are questioned by either the judge or a lawyer for suitability of jury service. After voir dire, each party may excuse a certain number of jurors without assigning a reason. These dismissals are called preemptory challenges. The number of preemptory challenges is set by law and varies according to the type of crime. Typically, no explanation is required by the attorney to strike a juror. However, if the opposing party suspects purely biased reasons (race or gender) for the preemptory challenges, the attorney may be challenged to explain his cause for striking the juror.

## Characteristics of a Juror

In both the O.J. Simpson and Rodney King criminal cases, trial consultant Dr. Jo-Ellan Dimitrius was used for jury selection. According to Dr. Dimitrius, she never guesses about who should sit on a jury (Dimitrius, 1999): "I've identified three key characteristics that provide consistently reliable insight into almost everyone, almost all the time: (1) compassion, (2) socio-economic background, (3) satisfaction with life" (p. 36). "If I peg someone as either very compassionate or unusually cold and harsh I already know more about them and how they are likely to behave than their age, educational background, employment, physical appearances and sex combined could ever tell me" (p. 39). "Generally, a person's socioeconomic background will have significant impact on his outlook and behavior. People who had to fight for survival may become hardened and lack confidence; they may be insecure, unkind, inconsiderate, stingy, intolerant, defensive, and unwilling to reveal much of themselves. They tend to be more watchful and to believe the ends justify the means. However, people who have always had their needs fulfilled tend to be more confident, secure, kind, generous, tolerant, forgiving, and open" (p. 40). Satisfaction with life "almost always has a wide-ranging effect on how people think and how they treat others...Those who have not achieved their goals often have a victim mentality. They can

be quick to place blame on others and may be bitter, angry, negative, pessimistic, and vengeful. Usually, they are less industrious and more critical and cynical than achievers...It's usually not difficult to find out how satisfied someone is. A few simple questions, such as 'What did you want to be when you were in high school?' or 'How do you like your job?' or 'If you could change your life, what would you do?' will usually prompt responses that make it clear whether someone has achieved personal success" (p.41). "As I try to identify patterns in someone's characteristics, I always focus intently on these traits, because they are blind to race, gender, age, sexual orientation, and other characteristics by which we often stereotype those who belong to an identifiable group. Concentrating on these three traits forces me to look through any stereotype and to the person's underlying qualities and experiences" (pp. 36-37).

Dr. Dimitrius firmly stresses that single traits or characteristics seldom hold the key to someone's character or emotions. True understanding comes from identifying recurring themes (Dimitrius, 1999). She analyzes everything from sex, race, age, employment history, education, and marital status to favorite TV shows, movies, social organizations, and life experiences. This information is the foundation for identifying themes as noted above. When reviewing the questionnaire used for the Derrick Todd Lee jury pool, I noted

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a similarity in the types of questions asked to the type of questioning Dr. Dimitrius suggested would reveal these traits.

Social psychologist Neil Kressel, PhD, and Dorit F. Kressel, JD, published a book entitled *Stack and Sway* that focuses on jury consulting. The authors propose that “the simplest rule regarding the relationship between the juror and the defendant is what social psychologists call the similarity principle.” The premise is that people prefer others who are similar to themselves. This principle governs how we choose our friends and mates, and to that extent, it also influences our initial inclinations to acquit or convict. We typically like people who resemble ourselves in background, ethnicity, and beliefs but accept people who resemble us on only a few dimensions and who are different on others. Despite the authors’ premise about the similarity principle, they conclude that there is no reliable way to predict when a psychological bond or identification will form (Kressel and Kressel, 2002). They also state that “scientific jury selection, even when practiced by the very best consultants, rarely turns a clear losing case into a winner in civil or criminal trials” (Kressel and Kressel, 2002).

Even though most attorneys and trial consultants strive for an impartial jury, we continue to have biased jurors, inept deliberations, and manipulative actions that make it challenging to receive a fair trial. When the trial is highly publicized, especially a death penalty trial, scrupulous jury selection becomes even more essential.

After 120 prospective jurors were questioned over 12 days, the Derrick Todd Lee trial in Baton Rouge completed jury selection on September 29, 2004. The various techniques discussed above were utilized by the attorneys. I had the opportunity to listen to the questioning of the potential jurors, and I quickly realized how difficult it can be to establish a pattern of characteristic traits or a recurring theme unique to each person in such a short amount of time.

For instance, I observed a gentleman that had a slightly unusual affect and demeanor. He answered each question thoughtfully and respectfully, stating several times that he could be fair and unbiased; however, his body language and facial expressions didn’t seem to match his statements, and he was strategically questioned about numerous topics. For example, the prosecution asked him if he read the newspaper. He replied that he only read the comics. The defense was quick to reveal that, according to his questionnaire, he had

previously stated that he read the newspaper from front to back. This potential juror was found by the attorneys to be dishonest. Upon deliberation, he was quickly dismissed from the jury pool. The attorneys’ meticulous questioning was an example of the art of jury selection.

## Conclusion

On October 12, 2004, Derrick Todd Lee was convicted of first degree murder of Charlotte Pace; and on October 14, 2004, the jury voted to execute Derrick Todd Lee. Jurors took just 1 hour and 33 minutes to reach the verdict (Adrian, 2004).

Each attorney or jury consultant has his or her own technique when selecting jurors for trial. To accomplish this, most utilize very similar methods to those presented in this article. For justice to be served, the goal is simply to obtain 12 impartial jurors to represent the community.

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# Copyright Compliance: No Fair...Use?

Diane M. Ellenberger, MS RN LNCC, & Arnold B. Silverman, Esq.

The role of the legal nurse consultant (LNC) may include retrieval and use of scientific literature for research of medical and other scientific issues in legal cases. This practice as it pertains to the copyright law, “fair use,” exemption, copyright compliance, and infringement is discussed in this article. When using medical literature to research medical issues for a legal case, the assumption has generally been that fair use allows a person one copy of an article for personal use without permission. That assumption may not necessarily be correct.

Several months ago, the Katy, TX-based legal nurse consulting business Medical Review Services (personal communication, April 25, 2004 & May 24, 2004) was sued in Federal Court by five scientific, technical, medical publishers—American Chemical Society, Elsevier, Inc, Marcel Dekker, Inc, SAGE Publications, Inc, Wiley Periodicals, Inc—coordinated by the Copyright Clearance Center (CCC) for copyright infringement as a “document delivery service” (American Chemical Society, et al v. Loren Mateo Roundy dba Medical Review Services, 2003; see also Copyright Clearance Center, 2003; EContent, 2003).

Medical Review Services was apparently found through their Web site and contacted by a new client for a “rush” request of five articles each from a different publisher, which were to be provided by e-mail in Portable Document Format (PDF). The request was apparently a “sting” by the CCC with a complaint issued 4 months later. The firm was sued for copyright infringement for photocopying the articles without permission and also for infringement by sending the articles electronically (Medical Review Services, personal communication, May 24, 2004). During discovery, the list of Medical Review Services’ clients was requested (personal communications, April 25, 2004, May 24, 2004). The CCC indicated in a press release (2003) on their Web site ([www.copyright.com](http://www.copyright.com)) that the lawsuit is “part of the company’s ongoing enforcement and education programs that promote copyright compliance.” Medical Review Services is no longer in business (personal communication, May 24, 2004).

The CCC provides for compliance with reproduction and transmission of copyrighted materials in both print and electronic formats. Whether copyrighted material is photocopied or sent by digital means via the internet, a permission to duplicate and/or transmit the material needs to be obtained along with payment of fees. According to the CCC, a fee is to be paid to the publisher through the CCC when photocopying an article or book chapter. If the article

or book chapter is not among those registered by the CCC, either the CCC can contact the publisher as a special request or the publisher can be contacted individually. Not only do the publishers want to encourage compliance with collection of fees, but they want to encourage subscriptions.

According to the CCC, reproduction of copyrighted works for commercial gain, such as a person who retrieves an article for another and charges a fee, is not fair use and requires permission and payment of fees to the copyright holder (personal communication, April 22, 2004). LNCs who retrieve scientific literature for a case, in order to provide literature for the attorney’s education, are considered to be “selling the articles” as a “document deliverer” in the eyes of the CCC (CCC, personal communications, 2004).

Document delivery services have been sued by multiple publishers, coordinated by the CCC, for making money from other people’s property without paying the copyright fees. A suit against LMS Information Services, a San Francisco document delivery service, (*American Chemical Society, et al v. LMS Information Services*, 2003) was filed at the same time as the suit against Medical Review Services in late 2003. The suit against LMS Information is still pending (CCC, 2003).

A Washington, DC, intellectual property law firm, Collier Shannon & Scott was sued by Washington Business Information (Washington Business Information Inc. v. Collier, Shannon & Scott, 1991) for in-house photocopying of the Washington Business Information newsletter (Heller, 2002). LeBoeuf, Lamb, Green & MacRae, New York, another intellectual property firm, settled with the CCC and four publishers for an undisclosed amount and by purchasing an internal license in order to avoid an infringement suit for in-house photocopying (Heller, 2000; Heller, 2002; Copyright Clearance Center, 1999).

## 1976 Copyright Law

A copyright law was passed by Congress in 1976 as the Copyright Act of 1976, enacted October 19, 1976, as Public Law No 94-553, 90 Stat. 2541 (Preface, Title 17 of the U. S. Code), based primarily on input from publishers, librarians, and, as an afterthought, in the public interest. But attorneys, scientists, and other commercial users of copyrighted materials were not specifically included in the process. The copyright law was written to protect the copyright of the owner of original works from others who copy all or significant part of the protected work (Title 17, U. S. Code; United States Copyright Office, 2004).



In 1978, the CCC was organized at the suggestion of Congress as a not-for-profit organization to assist with copyright compliance (CCC, 2004). The Digital Millennium Copyright Act, passed in 1998, amended the 1976 copyright law and provides for protection of digital works as Public Law No 105-304, 112 Stat. 2860, 2887 (Title 17 U. S. Code).

The only case of copyright infringement that has come to court since enactment of the Copyright Act of 1976 was brought against Texaco in 1985 by the American Geophysical Union, coordinated by the CCC, for in-house photocopying of scientific articles. Initially, six publishers joined in the suit; later, 82 other publishers were included (American Geophysical Union v. Texaco, 1992; Heller, 2000; Heller, 2002; University of Texas System, 2004; Wiant, 1995). Until that time, many professionals and scientist—including doctors, teachers, and lawyers—thought they had fair use. Texaco used a fair use defense. The court found that photocopying was not directly related to laboratory research, was archival in nature, and deprived the plaintiffs of revenue from either additional subscriptions or payment for permission to photocopy.

Texaco lost their case. The court decided that for-profit use of photocopies of scientific and technical journal articles violates fair use of the 1976 Copyright Act. The court also found that the CCC provided a convenient and nominal method for seeking copyright permission (American Geophysical Union v. Texaco, 1992; American Geophysical Union v. Texaco, 1995). After losing at trial in New York's Southern District Court, with the decision upheld on appeal in 1994 in the Second Circuit Court of Appeals, Texaco settled the case for an undisclosed amount and agreed to purchase an internal license from the CCC (American Geophysical Union v. Texaco, 1995; Heller, 2000; Heller, 2002; Wiant, 1995).

## “Fair Use”

Section 107 of the Copyright Law (U. S. Code Title 17, Copyright Law of the United States, 2004, page 18) provides for “fair use” by the public of copyrighted materials. The limitations on exclusive rights or fair use indicate that “criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research is not infringement of copyright.” Four factors are taken into account to determine fair use:

1. Purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
2. Nature of the copyrighted work;
3. Amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
4. Effect of the use upon the potential market for or value of the copyrighted work.

For discussion of the specifics of copyright law and the issues involving nurse consultants and attorneys, this article enlists the services of intellectual property attorney Arnold Silverman, Esq.

*Question: What is intellectual property?*

**Silverman:** Intellectual property embraces intangible property such as copyrights, trademarks, patents, and trade secrets as contrasted with tangible personal property such as furniture, automobiles, clothing, and the like.

*Question: What was the copyright law prior to 1976?*

**Silverman:** The Copyright Act of 1976 was the first major revision to the federal statute since 1909.

*Question: What was the impetus for a new copyright law in 1976?*

**Silverman:** The impetus for the act centered on changing concepts of commerce, property, and technology. The Act both reflected changing needs with changing times and codified a number of concepts which existed only as a matter of court decisions such as the concept of “fair use.”

*Question: Could you define the concept of “fair use”?*

**Silverman:** “Fair use” is a statement of principles which under certain circumstances results in the conclusion that conduct which would otherwise be deemed to be an infringement of a copyright is excused due to the minor nature of the activity.

*Question: What is considered personal use of copyrighted material?*

**Silverman:** “Personal use” covers a broad spectrum of activity. In one context, it may be considered to be a non-commercial activity that does not in any way have a negative impact on the commercial potential for a copyrighted work. For example, if a book is purchased and read, this might be considered personal use. If one, as a matter of convenience, performs research and rather than taking copious notes, photocopies selected portions of works, employs them in writing a report, and subsequently destroys the photocopied work without in any way violating a copyright in any of the works through carrying material over into the report, this might be deemed “personal use.”

*Question: For the purposes of legal research or investigation, does “fair use” apply? And if so, how would it apply?*

**Silverman:** Whether “fair use” applies or not depends to a great extent on whether the activity falls within one of the exclusive rights granted to the copyright owner: the right to reproduce the work, distribute the work, make derivative works, and, in connection with certain types of work, to publicly perform or display the work. A derivative work

carries over a sufficient portion of another work, as to be recognizable as being a work derived therefrom and generally contains either modifications or additional material. If the use for legal research or investigation does not involve any of these exclusive rights, there would be no infringement of the copyright and, therefore, no need to get to the issue of whether something which otherwise might be deemed an infringement will be “fair use.”

In considering the “fair use” test set forth in Section 107 of the Copyright Act, the four tests identified hereinbefore need to be evaluated in the context of specific facts. The first test is generally given substantial weight with a profit motive weighing heavily away from “fair use.” The nature of the copyrighted work is considered. The amount and substantiality relate to both quantitative and qualitative misappropriation of the work. Finally, the impact upon the potential market for or value of the copyrighted work is considered. For example, a current issue of a news magazine would have greater potential value than a 5-year-old issue.

Copyrights do not protect facts, although they do protect a tangible mode of expression. To the extent to which there is a practical matter or only one way of expressing a concept, this moves away from that mode of expression being copyrightable. With regard to legal research or investigation to the extent that facts or uncopyrighted works are involved, there would be complete freedom to use these materials. As to substantial copying of protected works, the “fair use” standards would have to be applied on a case by case basis.

*Question: Would lawyers, law firms, and independent LNCs be considered “commercial” for the purposes of determining fair use of scientific literature?*

**Silverman:** In general, any sort of non-charitable activity intended to produce a profit would be deemed “commercial.” To the extent to which, rather than making copies of entire articles, one would be reproducing unprotected court opinions or limited portions of a number of works as contrasted with the entire work, this would tend to move toward “fair use” as to insofar as the second and third tests are applied.

*Question: Is the use of a photocopy of a medical article in litigation considered commercial?*

**Silverman:** Applying the “fair use” test, one might state that the activity is commercial. The nature of the work is such that for use in litigation, Standards 2 and 4 might apply depending on whether the publisher of the article offers reprints for a fee. If it does, the safer approach would be to obtain reprints as this would clearly cleanse the use of the articles. To the extent that the publication is out of print, the publisher cannot be located, or reprints are not available, it could be argued that the limited use for purposes of litigation—even if considered “commercial”—would not have a negative impact on the potential market for or value of the copyright.

*Question: For purposes of copyright infringement, what determines “commercial use”?*

**Silverman:** Once one concludes that an activity, if not a “fair use,” would infringe a copyright, one then looks to whether a non-profit organization or activity is involved and whether a profit motive is involved.

*Question: When a LNC, either working in a law firm or in their own business, photocopies an article for research purposes, is that considered “fair use” or “commercial use”?*

**Silverman:** It is difficult to give a specific answer for all circumstances. If the purpose is to make complete copies of an article for research in a commercial context—as would generally be the case with a law firm or business—the issues would involve whether the work is protected by copyright; whether the conduct, if not cleansed by “fair use,” would be an infringing activity; and whether it will be used solely as a substitute for hand-copying, fax, or other concepts as contrasted with photocopying the entire work in lieu of purchasing reprints from the publisher. Also, the extent to which the copies are destroyed after the limited use would tend to maximize the likelihood of “fair use” existing.

*Question: In the Texaco case, a distinction was made between research of literature and laboratory research. Could you explain what the court decided on that issue?*

**Silverman:** If one merely photocopies literature for research and archival purposes, this could be considered to be a substitute for handwritten copies that would be distinguishable from reproduction of articles on a sustained or regular basis. For example, if a research facility cancelled nine of ten subscriptions to the publication *Science* and permitted large-volume systematic copying of articles from each issue, it would be clear that the main motive is to avoid paying for the nine cancelled subscriptions but, nevertheless, wishing to obtain the benefit of such a volume by alternate means. This would not be fair use. If, however, copies of the table of contents are made and circulated, that would be fair use.

*Question: If a profit is not made from copyrighted material, can the copyright still be infringed upon by using it for research in the legal arena?*

**Silverman:** In the first test regarding “fair use,” part of the question is the purpose and character of the use. A dominant aspect of this issue is whether the purpose is commercial or for non-profit educational purposes. To the extent to which the copying does not involve an activity that would impact the market for the copyrighted work, such as where the copyright owner offered reprints, this could be deemed to be a non-commercial use. On the other hand, if one is charging primarily for the research activities and the report writing which follows with only incidental reproduction of portions of copyrighted works, this would move toward a “fair use.” It is improper to conclude that

there is a hard and fast rule regarding application of the standard, as the decision is so heavily based on an analysis of all of the facts.

*Question: What does “transformative use” mean in the context of fair use?*

**Silverman:** The reference to “transformative” generally makes reference to a derivative work that, in essence, transforms the original work into something else. The extent and nature of the transformation would be considered in evaluating the issue of “fair use.”

*Question: In the context of fair use, what is the meaning of “the nature of the work?”*

**Silverman:** “The nature of the work” involves the specific type of work. Obviously, there is a difference between a news magazine that might have a useful life for most purposes of 4 - 6 weeks, as contrasted with a treatise on constitutional law having a market and value for many years.

*Question: In the context of using publications for legal purposes, how does the third factor in Section 107, “the amount and substantiality of the portion used in relation to the copyrighted work as a whole,” apply in determining copyright infringement?*

**Silverman:** The amount and substantiality refers to the qualitative and quantitative aspect of the work that was employed. Was the entire work reproduced? If not, are there certain portions which are qualitatively of much greater value than other portions thereby making it important to consider both quantity and quality?

*Question: What does the “effect of the use upon the potential market for or value of the copyrighted work” mean?*

**Silverman:** “Effect upon the potential market or value of the copyright” is very important. For example, it can be assumed that a bestselling book would have a much greater market for a publisher than an out-of-print book. In the context of periodicals, if reprints are available at a reasonable price, the number of copies could be employed directly to measure the effect in terms of reduced sales of reprints. On the other hand, it is conceivable that if certain types of enhanced publicity regarding the work resulted from the copyright infringement, more people might become aware of the copyrighted work and the market could be enhanced.

*Question: William Strong, Esq., the attorney for the law firm that represented the publishers in the suit against Medical Review Services, stated in a 1994 workshop presentation (Strong, 1994) that “the touchstone of fair use is whether there is harm to the copyright owner’s market. If there is no harm, then the use is much more likely to be fair.” If what Mr. Strong indicates is true,*

*would that then preclude “fair use” for anyone wishing to have a photocopy of an article without paying the copyright fee, if the publisher maintained that their market was harmed?*

**Silverman:** The principle stated by Mr. Strong has merit in the “fair use” context in that it might be likened to a “no harm, no foul” situation. This concept runs directly and indirectly through the four-pronged “fair use” test, in terms of was it a commercial use, the nature of the work, the amount of substantiality taken, and the effect on the potential market or value of the copyrighted work. It is important to bear in mind, however, that a publisher merely alleging that the market was harmed in a meaningful way is not the same as the degree of proof required to prevail in a legal controversy.

*Question: How does one determine if they have “fair use” according to Section 107 of the Copyright Law of 1976?*

**Silverman:** One applies the statutory test as interpreted by the courts and as summarized in some of the answers to the questions set forth herein.

*Question: Of the four factors used in determining fair use, how many factors need to be applied?*

**Silverman:** There is no absolute quantitative standard, but a commercial activity tends to be reviewed more carefully than a non-profit educational purpose, for example.

*Question: If the LNC performs a service for an attorney by going to various medical libraries to photocopy articles used for preparation of medically involved legal cases, are they infringing on the copyright law when they charge for their time and reimbursement of copying costs?*

**Silverman:** The answer depends on what is done with the copies and if the primary compensation is for time, with the photocopying being merely incidental and serving as back-up documentation for a report to be provided and the copies can be deemed a substitute for handwritten notes with the primary focus being research. It would appear that Tests 2 and 4 would weigh toward fair use and Tests 1 and 3 might move toward the other direction. On balance, one would have to determine what occurs with the copies downstream after delivery by the LNC.

*Question: Why does the CCC consider that retrieval of articles for another while charging for time and photocopying costs is “selling articles” and considered commercial gain?*

**Silverman:** Some of this would depend on how specific the assignment is, what percentage of the total charge is for the professional services of performing the research as contrasted with photocopying charges, and some of the secondary factors mentioned hereinbefore such as the publisher offering reprints for a reasonable fee.

*Question: When sending material over the Internet such as in PDF format, is that transmission protected by fair use?*

**Silverman:** Sending material over the Internet involves making a copy. The standards applicable regarding infringement of copyright and “fair use” would not differ from the other tests merely because of the mode of transmission.

*Question: Are articles downloaded from the Internet from a publisher’s Web site protected by fair use, or does a copyright fee need to be paid?*

**Silverman:** This depends to a great extent on whether the publisher’s placing the article on the Web site can be reasonably deemed to be making a gift or offering a free license of the articles. Otherwise, one would assume that one would have to pass through some sort of electronic security and make payment before access would be granted.

*Question: Have any Supreme Court decisions been handed down concerning copyright law and fair use?*

**Silverman:** As far as is known, the United States Supreme Court has not made decisions on the fair use aspect of copyright law.

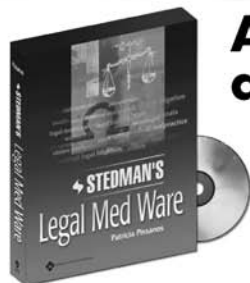
*Question: Has litigation such as the Texaco case made any changes in the way the copyright law is interpreted?*

**Silverman:** The Texaco case, as well as all other fair use cases, and the statute create the law governing “fair use,” but the case should be deemed more in the nature of clarifying the law under certain facts than as making changes in the way the law was interpreted.

*Question: In terms of copyright law, infringement has been described as strict liability law. Would strict liability apply?*

**Silverman:** “Strict liability” would not apply in this context. There are areas of torts law, such as if one were to keep a lion on their premises, that they would be absolutely liable for any harm the lion did to someone without the need to show that the owner of the animal was negligent. The mere fact that fair use may exist moves away from any concept of strict liability.

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*Question: Can copyright infringement be criminal as well as civil? If so, under what circumstances would infringement be criminal?*

**Silverman:** There are criminal sanctions for copyright infringement. Willfully engaging in copyright infringement, with a profit motive, can be a criminal action resulting in fines and imprisonment.

*Question: What are the penalties for copyright infringement?*

**Silverman:** The remedies for civil copyright infringement include compensation for damages suffered by the copyright owner, profits of the infringer attributable to the infringement, an injunction which is a court order requiring termination of the infringing activity, destruction of infringing articles, and—within the discretion of the court, if willful infringement exists—trebling of damages, assessing court costs, and making the infringer pay reasonable attorneys' fees of the copyright owner. Also, the statute provides for certain minimum damages even if one is unable to prove that the copyright owner suffered damages or that the infringer made profits. The penalties range from \$750 to \$30,000 and, in the case of willful infringement, may be increased up to \$150,000.

*Question: What is the statute of limitations for copyright infringement?*

**Silverman:** The statute of limitations is 3 years for civil actions and 5 years for criminal.

*Question: Are the penalties less if one was not aware of the infringement?*

**Silverman:** As stated earlier, enhanced remedies are available within the discretion of the court, if it is concluded that the infringement was willful. Also, criminal consequences can occur.

*Question: For a nurse working with a law firm who photocopies a large volume of articles, would an internal license with the CCC for the law firm be advisable?*

**Silverman:** This would depend on how much of the copying would involve infringing activity that would not have the benefit of the fair use defense. If a meaningful risk exists, either a license with the CCC or modification of the practices such as by purchasing reprints in those instances where an activity would infringe and not be excused by fair use should be considered.

*Question: What exemption does a library have regarding copyright law?*

**Silverman:** Section 108 (U. S. Code Title 17, 1976) provides immunity for public libraries in respect of certain reproductions and archives. The section is sufficiently extensive that all of the terms would have to be compared with the particular factual situation. Also, there is an exemption for liability for a library's permitting unsupervised use of copying equipment provided that a notice regarding copyright law is displayed.

*Question: Should a library also be required to pay copyright fees if they provide document delivery services for profit?*

**Silverman:** One would have to determine how the exemption of Section 108 applies. One of the conditions of immunity is that the reproduction or distribution is made without any purpose of direct or indirect commercial advantage. There is a limitation on the number of copies.

*Question: How can LNCs protect themselves from being sued for copyright infringement when photocopying articles for research in a legal case?*

**Silverman:** It would be wise to initially have a brief consultation with an attorney knowledgeable in copyright law so that the general nature of the LNC's business activities can be evaluated in terms of potential risk of infringement. Beyond that, an inquiry of the law firm, as to whether it has a license immunizing the consultant, would be appropriate or an inquiry as to whether the law firm client would be willing to indemnify the consultant. For reasons stated hereinbefore, it is difficult to give any blanket answer regarding a wide range of activities other than to have someone knowledgeable in the law counsel regarding the types of activities engaged in by the legal nurse consultants.

*Question: Because of the requirement by the CCC and publishers for the payment of copyright fees by the document retriever, even though the end user is also responsible for their payment, if clients refuse to pay the fees, would that not be restraint of trade on the part of the CCC and the publishers?*

**Silverman:** Proper effort to enforce the rights granted to a copyright owner would not be regarded as a restraint of trade, as the owner may go after any level of infringer. There is also a concept of contributory infringement in the copyright law that broadens the scope of people who may be pursued in the event of an infringement.

## Conclusion

Regardless of the use of the photocopied publication, the CCC contends that a document delivery service is obligated to pay the fees for copyright permission. If the LNC uses the services of a document delivery service or engages in document delivery as an LNC role, the copyright fees need to be paid.

The CCC fees are determined by the publishers. For individual copies, a transactional customer account can be established with the CCC to pay the fees. Information concerning a transactional account can be found at [www.copyright.com/PDFs/TRSC1002EU.pdf](http://www.copyright.com/PDFs/TRSC1002EU.pdf). The fees range from \$9 to \$35 per copy of an article and a charge by the page for book chapters. An additional handling charge of \$3 per item is added by the CCC. According to the CCC, if multiple copies of the article are then made, a copyright fee should be paid for each copy. If the book or article is not handled by the CCC, the publisher can be contacted for photocopying permission and fee assignment. When contacting the publisher directly for photocopy permission, the fee can be waived when permission is granted. Reprints of articles can also be requested and purchased from the publisher.

Law firms can purchase an internal license from the CCC, based on the size of the firm and the number of professionals. Information concerning an annual license can be found at [www.copyright.com/Services/ALS.asp](http://www.copyright.com/Services/ALS.asp). An independent consultant can be added to the license as an "other" and would not be responsible for paying the transactional fees for each copy (CCC, 2004). The license then would allow for all in-house copying of an article or other publication registered by the CCC. Working with a retained intellectual property attorney, a contract for personal practice can be developed regarding payment of fees for the CCC, by either the client agreeing to pay on a transactional basis or including the LNC and document retriever on their internal license.

Photocopying and Internet transmittal of materials for use by LNCs and others in the legal arena is complex. A considerable grey area exists in the "fair use" exemption of the copyright law regarding medical-legal research and use of copyrighted material in the legal setting. Ultimately, only a judge or a jury can determine whether the use of the copyrighted material was subject to "fair use" treatment. Other than Texaco, no case law has further defined "fair use." Although an informational letter or notice of reprimand would be a kinder and gentler method of

encouraging copyright compliance, the CCC and publishers have chosen litigation as their educational and enforcement tool, with all but Texaco settling up to now.

A litigation exception would be desirable in the copyright law regarding photocopying solely for the purposes of direct use in litigated matters, but that has not been proposed as an amendment to the copyright law. An exception would also be desirable for individuals providing a service to attorneys by retrieving articles for those who do not have ready access to the literature. In the meantime, each LNC should consult with an attorney competent in copyright law regarding the practice of photocopying and use of copyrighted material in their practice.

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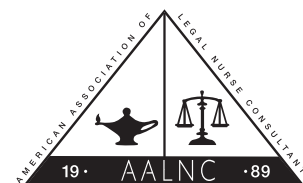
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# The Journal of Legal Nurse Consulting



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## Submission Guidelines

*The Journal of Legal Nurse Consulting (JLNC)*, a refereed publication, is the official journal of the American Association of Legal Nurse Consultants (AALNC). The journal's purposes are to promote legal nurse consulting within the medical-legal community; to provide both the novice and the experienced legal nurse consultant (LNC) with a high-quality professional publication; and to teach and inform the LNC about clinical practice, current national legal issues, and professional development.

The journal accepts original articles, case studies, letters, and research studies. Query letters are welcomed but not required. A manuscript must be original and never before published, and it should be submitted for review with the understanding that it is not being submitted simultaneously to any other journal. Once submitted, articles are subject to peer review (publication is not guaranteed).

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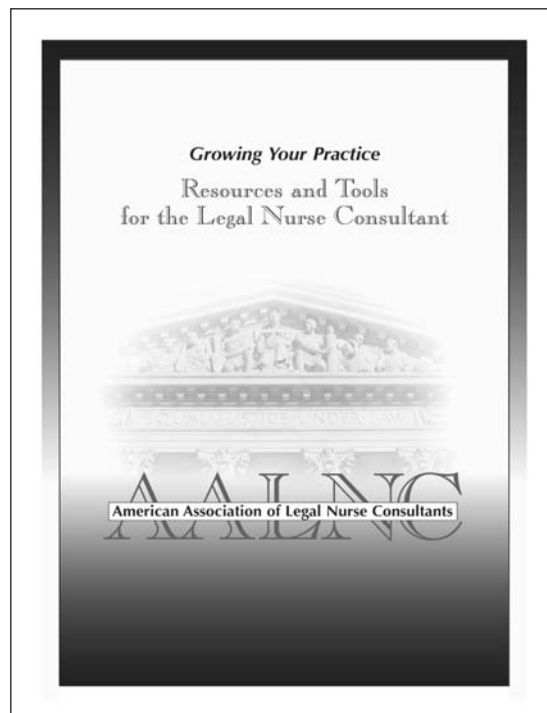
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