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CLOSED HEAD INJURY

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JUSTICE, JURIES AND MEDICAL MALPRACTICE LITIGATION

Frank D. Heckman

The intricacies of legal proceedings and court protocol are often *terra incognita* to health care providers, though defense counsel bridge for them the gap between the world of clinical medicine and the patients who file law suits against medical actors. Nearly all health care providers expect the court system to dispense at best rudimentary justice. Of course, a wide range of feelings arise because of this, which are exacerbated by a seemingly unstoppable expansion of litigation and prominent media coverage of enormous plaintiffs' verdicts.

This article, like its predecessors, is not intended to publish once again the complaints (constructive or otherwise) of health care providers and their insurers, and bemoan seemingly irrational jury awards. Most jurors are rational. The goal should be to understand how society and the legal system may have changed and initiate systematic preparation to defend medical malpractice law suits more effectively.

Justice is a relative, not an absolute, concept. It does not exist in a vacuum, apart from the society that gives it definition and reality. Therefore, any action the defense might attempt in the name of ideal equity or justice would seem of extremely

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WHIPLASH INJURIES REVISITED

Richard Patterson

In the 1980s, some members of the plaintiffs' bar began complaining that many of their colleagues were taking whiplash cases too lightly; that they were failing to investigate the medical aspects of these claims thoroughly and were settling the cases too quickly. It was even suggested that, in failing to pursue whiplash cases more vigorously, these lawyers might be inviting legal malpractice claims.¹ Part of the reason for this attitude, said the complaining lawyers, was that the whiplash injury had become something of a joke, that the term "whiplash" had become a term of derision, frequently the object of scorn by the medical profession and even the subject of comedy plots.²

One reason whiplash claims are frowned upon by many in the medical profession is the tendency of these cases to end up in court. It has been hinted that, in the absence of indications of spinal cord or other serious injury, some treating physicians conduct cursory examinations of whiplash victims with the hope of reporting negative findings and thus avoiding time-consuming entanglement in later litigation.³

The litigation rate is indeed high in whiplash cases. In one follow-up study of 144 whiplash patients who had received hospital emergency room treatment, it was found that over 80% were claiming compensation.⁴ Whiplash does spawn more

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COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAD)

Medical, Ethical, Cultural and Legal Issues

Peter G. Bernad, M.D.,
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An Emerging Trend No Longer

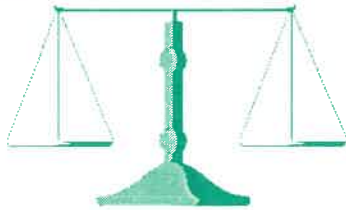
Mainstream medicine is beginning to realize that it can no longer ignore the new phenomenon of complementary and alternative medicine (CAM). This is by no means an enthusiastic endorsement: rather it is a response to the popularity of therapies until recently thought, in professional

circles, to be beyond the pale, irredeemably unscientific and sought only by the unenlightened and dangerously gullible. At the heart of this process of grudging acquiescence lies the growing acknowledgement in the medical profession that "[R]esponsible clinicians must be able to help their patients sort through all therapeutic options, including those they may find unconventional, because patients increasingly want informed and shared decision-making about their health."¹

The Generational Effect

Part of the enthusiasm for this "new medicine," with its herbs, supplements and nutrients, is

driven by the aging of the baby boomers. The baby boomers generally do not want to get old, and certainly, they do not want to get sick. The notion, developed from the mentality of the 60s, that you must take your destiny in your own hands, mistrusting authority and all accepted systems, has become part of the zeitgeist. The idea of building health by returning to means of healing that are closer to nature, as opposed to derived from Paracelsus's pharmacological thinking, are also part of the ethos. Whatever the draw, consumers of the new medicine, many of whom are now 50 or older, have not only engaged



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in, but documented and fostered the development of alternative and complementary medicine, seeking for themselves everlasting life, at peak quality. These consumers are spending an estimated twelve to twenty billion dollars on natural supplements each year. Sales of these products continue to grow at more than ten percent a year. For example, two preparations made from herbs, aloe vera to facilitate intestinal regularity, and valerian for restless sleep (an alternative is Melatonin) are being used by millions of Americans on a daily basis. Mainstream journals have become interested: *The Journal of the American Medical Association* (JAMA) recently released an issue devoted entirely to the study of herbs and alternative medicine. *The New England Journal of Medicine*, perhaps the most prestigious mainstream medical journal, has devoted numerous articles and editorials to the subject. Americans spend as much out of pocket that is not reimbursed by health insurance on alternative medicines as they do on all unreimbursed physician services. David M. Eisenberg and colleagues estimated that in 1990, the number of visits to providers of unconventional therapy in the United States exceeded the number of visits to all U.S. primary care physicians. (*Unconventional Medicine in the United States*, 1993, vol.)²

In Praise of Modern Medicine

Since CAM is clearly becoming mainstream, many of our patients are raising these issues and bringing these topics with them directly into the consultation room. Therefore, it behooves all

providers and practitioners to develop awareness and even become experts on this new and burgeoning field. There is no need to point out that there are actually only two kinds of medical care, "good medicine" and "bad medicine" even though good medicine may at times be hard to take. Some forms of standard medical treatment, such as certain chemotherapeutic agents used in oncology may result in nausea, vomiting, and other side effects, but will nonetheless be considered good medicine because ultimately, they are supposed to help the patient. As part of the therapeutics of twentieth century medicine, these medications, pharmaceutical or other, have been evaluated and assessed using scientific methodology. This is not the case with most alternative therapies. These too should be evaluated using double blind methodology and other techniques developed over the years to prove effectiveness and minimize side effects.

It is no accident that the life expectancy of men and women has virtually doubled since the beginning of the century. Improvements in sanitation, epidemiologic advances, and the development of successful antibiotics (a scientific use of organisms found in nature) are part of the reason, of course. But these striking improvements in the quality and length of life are also direct results of technological advances in health care achieved through scientific research and continuous reassessments of treatment protocols and methodologies, medications, and treatments. In a prom-

ising recent breakthrough, meta-analysis, which correlates studies on related subjects by scientists who use differing methodologies, has launched databased medicine, providing much-enhanced tools for comparative analysis of seemingly disparate scientific research. Is this science's path to holism? The immensely promising fields of microcellular and genetic biology are also now opening up new frontiers likely to revolutionize if not unsettle pharmacology-based medicine. What will be discovered about the effects of herbal remedies at the cellular level? Finally, on the delivery side, quality assessment and outcome measurement geared to total quality improvement have also been introduced and have improved the overall success of mainstream medicine. Does this suggest that western scientific medicine is good medicine while others are bad medicine?

The Office of Alternative Medicine

The Office of Alternative Medicine (OAM) was created by Congressional mandate in 1992 to evaluate current complementary and alternative medicine approaches in health care.³ The NIH is one of eight health agencies of the US Public Health Service (PHS) and is part of the US Department of Health and Human Services. According to the official Congressional mandate that established OAM, the stated purpose of the Office is to "[f]acilitate the evaluation of alternative medical treatment modalities" to determine their effectiveness. To state that the creation of the OAM was a major break from traditional

medicine is an understatement. The government's decision to fund the OAM was born of the realization that the public is not only interested in new forms of treatment but is frustrated with some of the failures of the mainstream therapies and treatments now available.

HMOs & CAMs

It seems apparent that the revolution in medical health care delivery now under way, with its introduction of HMOs (Health Maintenance Organizations) has brought the concept of complementary and alternative medicine to the forefront of the awareness of people seeking alternatives. Patients are frustrated with their health care providers. They are frustrated with mainstream medical services or the lack thereof. There is a perception, however inaccurate, by the public that doctors are busier, less caring, more distant and more impersonal than they used to be. Complementary and alternative medicine practitioners, on the other hand, seem to have more time, be more diligent, be more "hands on" and softer, more feeling, and more in tune with the needs of their clients. The advent of the Internet, the popularity of PCs, the increased availability of information in the form of constantly renewed streams of accessible data, as well as the connectiveness of people on the local, regional, national, and international levels have added to this sudden surge of interest in complementary and alternative

medicine by hastening the rate of change in people's thinking and introducing them to new modalities for almost everything.

There are obviously marketplace effects to this surge toward CAM. In fact, for many people today, the well-established mainstream health-care systems are only used when someone has an acute problem such as crushing chest pain, bleeding from various orifices, paralysis of one side of the body or other potentially catastrophic symptoms. Ordinarily, when seeking relief from lesser illnesses or illnesses that are self-limited, people turn to complementary and alternative care.

Alternative Health Care Gains Ground in the Workplace

On January 31, 1999, *The Washington Post* published an article on alternative health care in its business section. The author, Amy Joyce, asks the question: "Does a world in which acupuncture, massage therapy, and nutritional counseling are covered by your employer's health insurance sound unrealistic?" She then answers the question by saying that businesses know the subject is timely. Companies get tired of "the regular old health care policies" that provide doctors who prescribe penicillin and aspirin. Alternative health care policies are now being offered to complement traditional policies by many of the more progressive firms. It is interesting that because of the limitations managed care has put on companies, some people feel that

this diminishes their ability to pick new and non-traditional health plans. Apparently the employees love the concept. One company gives its employees a 50 percent discount for holistic medicines, including acupuncture, nutritional counseling, yoga, and even holistic medicine for a dog or cat. There is a slight cost of \$36 for a single person per year, \$60 for two people, and \$72 for a family. I wonder if this includes the dogs and the cats? "The strategy behind offering alternative options," according to Joyce, "is to decrease employee absenteeism and cut down on health care costs in the long run. Apparently, this is a way to manage health." One executive vice president agreed, saying that healthier employees don't have to move on to more expensive care. Apparently, some of the programs that are touted and included in health care packages include massage therapy, chiropractor treatment, acupuncture therapy, and nutritionist advice.

Physicians, Teach Yourselves

Special training programs in complementary and alternative medicine that are recommended for physicians are already in existence. One such program includes a historical perspective on "scientific medicine," followed by an overview of complementary and alternative medicine. Then come the concentrations, or sections, the first being the mind-body medicine (or mind-body intervention) program. It includes a sub-program on psycho-neuro-endocrino-immunology, but also one on art-dance-music therapy, on spirituality-religion-health,

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(Complementary, cont'd from Page 9)

meditation, relaxation, imagery, hypnosis, biofeedback, prayer, mental healing, and support groups.

Another section centers on herbal medicine and nutrition. The 20 most commonly used herbs described and studied are Chamomile, Valerian, Kava, St. John's Wort, Ginkgo, Echinacea, Feverfew, Ginseng, Siberian Ginseng, Korean Ginseng, Gøtu Kola, Green Tea, Bilberry, Grapeseed, Horsechestnut, Hawthorn, Black Cohosh, Saw Palmetto, Milk Thistle, Ginger, and Garlic. A subdivision of the section covers diet and nutrition and the prevention and treatment of chronic diseases. This section includes a discussion of nutritional supplements, vitamins, and hormones such as melatonin and DHEA. Another term that has been used is "nutraceuticals" (Pine Bark, Coenzyme Q, Glucosamine, Chondroitin, and Red Yeast Rice would be classified here).

The next section includes alternative systems, such as different traditions in Asian medicine, acupuncture, ayurvedic medicine, homeopathic medicine, and naturopathic medicine. The manual healing methods are then taught, including osteopathic manipulation, chiropractic manual therapies, massage, pressure point therapies, and postural re-education. Under this heading would be biofield therapeutics, such as therapeutic touch and Reiki and combined physical and biofield methods, such as applied kinesiology and craniosacral therapy. Finally, usually, in the meetings, there is an area called fringe medicine, including such therapies as bio-electromagnetic applications in medicine, magnets,

and pharmacological and biological treatments such as anti-neoplastins, cartilage and chelation therapy, neural therapy, apitherapy, and other therapies grouped under unconventional cancer therapies.

An Herbal Clinical Trial for Alzheimer's Disease

The herb Ginkgo Biloba forms an extract that has been known to have small but significant effects on cognitive function in people with Alzheimer's disease after 3 to 6 months of treatment. This was reported in the November 1998 issue of *The Archives of Neurology*. More than 50 articles describing the use of the extract in patients with dementia or cognitive impairment were reviewed. Only four clinical trials met conclusive criteria for this meta-analysis. These trials involved a total of 212 Alzheimer's disease patients treated with Ginkgo Biloba extracts of 120 or 240 mg per day and 212 patients treated with a placebo. The extract appeared to have "a modest effect" with an effect size of 0.41, which translates into a 3 percent difference in the cognitive subset of the Alzheimer's Disease Assessment Scale (ADAS). None of the subjects in the clinical trials identified by the literature review experienced significant adverse effects. However, bleeding complications were noted in two case reports, which raise the issue of a possible combination of medications, for example, aspirin with Ginkgo Biloba, that may have been contraindicated.

Spinal Manipulation for the Treatment of Episodic Tension-Type Headaches

In a recent study reported in *The Journal of the American Medical Association* of November 11, 1998, 75 patients with tension-type, headaches were randomized to receive joint manipulation of the cervical spine, deep friction muscle massage, and placebo laser therapy. All the subjects underwent 8 treatments over a four-week period, during and after which they completed a headache diary. There were no significant differences between the groups in terms of daily hours of headaches, pain intensity per episode, or daily analgesics before or following treatment. Both groups showed a significant reduction in the mean number of daily headache hours and the mean number of analgesics taken per day at one week post-treatment. These findings contrast with those found in other studies of cervicogenic headaches where spinal manipulation produced dramatic improvement. The data certainly suggest the importance of accurate diagnosis in the selection of headache patients for spinal manipulation, but to me they also imply that further studies will be necessary to evaluate spinal manipulation; and this is an example of how the notion of complementary and alternative medicine begins to find validity through scientific testing schedules.

A New Opportunity for Lawyers?

Certain nutrients and alternative therapies have provoked the ire of the FDA and of some in the legal profession. How lawyers will act on this new scene is unknown but

they doubtless will. The future may see them championing purity and the testing of alternative health products with the same vigor they have used in fighting the tobacco industry, the hand guns lobby, and ensuring the safety and efficacy of motor vehicles. They undoubtedly will defend the right of individuals not only to use complementary and alternative therapies but also to be vindicated if in such use they are abused, hurt, damaged or even killed.

Government will doubtless continue to carefully monitor the field. Barrie Cassileth claims that "few physicians and patients are aware that the Dietary Supplement Health and Education Act of 1994 eliminated the requirement that these products be reviewed by the Food and Drug Administration. As a consequence, she cautions, they are no longer evaluated for either safety or purity; sometimes they contain none of the advertised components, and they are not evaluated to determine whether they support a promoter's claims. Furthermore, labels on these products rarely include information about risks, side effects, or possible harmful interactions with other substances."

Nonetheless, on January 29, 1999, the FDA announced that it was sending a warning to makers of a "health supplement" called gamma butyrolactone (GBL), to include a warning or face court action. The FDA warned that the supplement was dangerous and had killed one person and that nineteen other

people had become unconscious and gone into coma after using the product. GBL is allegedly used to help build muscles, improve physical performance, reduce stress, and induce sleep. This is a typical example of a supplement now in use without FDA approval or concrete medical data in support of its safety. In the body, GBL is converted to gamma hydroxybutyrate, or GHB. GHB is a very potent unapproved drug. It is currently being investigated under the supervision of physicians for the treatment of narcolepsy but has serious side effects that may include seizures, vomiting, slowing of heart rate and of breathing.

Approaches will develop to protect public health, but a vigorous segment of the public can be counted on to fight the imposition of tight controls in a field where many conscientious manufacturers and packagers have operated for years in safe and beneficial ways.

Credence Where It Is Due

In his book review, Dr. Bluming has these words for the sceptics:

As we deal with the issues raised by complementary and alternative medicine, we must be prepared to give credence where it is due. Many of the currently approved remedies originated, after all, in folk traditions: digitalis, chloroquine, and aspirin are examples. Other treatments that may have

originated as alternative approaches include use of a form of vitamin A to treat acute promyelocytic leukemia, application of electric currents to speed the regrowth of bone, and use of high-intensity light to treat some forms of depression.

As philosopher Carlyle Marney wisely cautioned, "A window stuck open is as useless as a window stuck closed. In either case, you've lost the use of the window." We must continue to insist on the painstaking accumulation of evidence in the scientific testing of each new breakthrough, especially since, according to a recent article from the National Institutes of Health Office of Alternative Medicine, complementary and alternative approaches are amenable to the same testing used for standard medical treatments.⁴

We can only wait and learn, remembering that it is conceivable that when patients turn to complementary health care and alternative medicine, they may not be telling their doctors what they are taking, and a combination of traditional and alternative drugs may prove harmful. One of the potential pitfalls in this new field is that people may be oblivious to possible drug interactions and side-effects. One drug's metabolism can affect that of another, as the Fen-Phen case dramatically demonstrated.

The journey into CAM has fascinations, elements of the bizarre (high coffee enemas come to mind) and much that is worthwhile and good material for the mainstream.

Peter G. Bernad, M.D., M.P.H., F.A.C.P., practices neurology in the D.C. area and is associate professor of clinical neurology at George Washington University. He serves on the Physician Leadership Committee of INOVA Health Systems, pursuing there his interest in Complementary and Alternative Medicine. Dr. Bernad is also on the pharmacology and therapeutics committee of Fairfax Hospital in Northern Virginia and the author of two books published by Lexis Law Publishing: **Closed Head Injury: A**

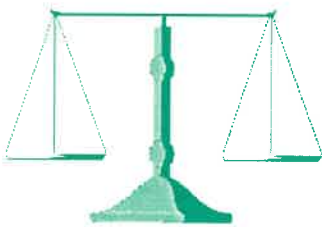
Clinical Source Book, now in its second edition, and **Neurotoxicology: A Clinical Sourcebook**.

1. Avrum Bluming, M.D., in a review in *THE NEW ENGLAND JOURNAL OF MEDICINE*, September 17, 1998, of two books: *The Alternative Medicine Handbook: The Complete Reference Guide to Alternative and Complementary Therapies* by Barrie R. Cassileth (Norton, 1998), and *Alternative Medicine and Ethics* (Humana Press, 1998)

2. *Id.*

3. 1992 National Institutes of Health appropriation bill.

4. J.S. Levin, et al. *Quantitative Methods in Research on Complementary and Alternative Medicine*, *MEDICAL CARE* 1997, vol. 35, pp. 1079-1094.



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