Report to
The Vermont Legislature

Nonpharmacological Approaches to Treatment of Chronic Pain

In Accordance with Act 75, Sections 14(d)(2) and 14a
An Act Relating to Strengthening Vermont's Response to Opioid Addiction and Methamphetamine Abuse

Submitted to:	**House Committees on Health Care, on Human Services and on Judiciary;** **Senate Committees on Judiciary and on Health and Welfare.**
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Index

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Act 75, Sections 14(d)(2) and 14a

January 15, 2014

Executive Summary

In 2013, the Vermont General Assembly passed Act 75, *An Act Relating to Strengthening Vermont's Response to Opioid Addiction and Methamphetamine Abuse*. Among other initiatives, the Act created a Unified Pain Management System Advisory Council to advise the Commissioner of Health on matters relating to the appropriate use of controlled substances in treating chronic pain and addiction and in preventing prescription drug abuse. Section 14 (d)(2) further charges the Council with evaluating the use of nonpharmacological approaches to the treatment of chronic pain, including the efficacy and cost-effectiveness of using complementary and alternative therapies such as chiropractic, acupuncture and yoga. This report presents an overview of Complementary and Alternative (CAM) approaches to the treatment of pain and the initial findings and work of the Council on this subject.

The social, emotional and economic toll of chronic pain is discussed, as are the risks inherent in solely relying upon pharmacological treatment of pain. The use of opioids to treat pain carries risk of addiction, drug diversion, undesirable side effects and, often, poorly managed pain. Studies on the efficacy of evidence-based, and often cost-effective, complements to pharmacological control of pain are promising.

The report defines CAM, and its emerging legitimacy as an enhancement to traditional allopathic medicine. There are three categories of research being conducted on CAM: efficacy of specific treatments for specific conditions, meta-analyses and economic analyses to measure cost-effectiveness of CAM.

Systematic incentives to use pharmacological approaches to pain management exist in the insurance industry as do disincentives to use more time-consuming integrated medicine. These will need to be acknowledged and addressed to encourage the use of integrated medicine.

The report concludes with a recommended plan for the Commissioner of Health to convene a small working group to focus on and continue the study of nonpharmacological approaches to treating chronic pain. The culmination of the group's work will be a report due to the legislature in January 2015.

Nonpharmacological Approaches to Treatment of Chronic Pain

Act 75, Sections 14(d)(2) and 14a
January 15, 2014

Introduction

In 2013, the Vermont General Assembly passed Act 75, *An Act Relating to Strengthening Vermont's Response to Opioid Addiction and Methamphetamine Abuse*. Among other initiatives, the Act created a Unified Pain Management System Advisory Council with membership from a broad range of professions knowledgeable about the treatment of chronic, non-cancer related, pain. Section 14 (a) of the Act defines the purpose of the Council as advisory to the Commissioner of Health on matters relating to the appropriate use of controlled substances in treating chronic pain and addiction and in preventing prescription drug abuse. Section 14 (d)(2) further charges the Council with evaluating the use of nonpharmacological approaches to the treatment of chronic pain, including the efficacy and cost-effectiveness of using complementary and alternative therapies such as chiropractic, acupuncture and yoga. As required by Act 75, this report presents an overview of Complementary and Alternative (CAM) treatment of pain and the initial findings and work of the Council on this subject. Because the Council convened for its first meeting on November 26, 2013, this report will be followed by a more comprehensive evaluation of the efficacy and cost-effectiveness of CAM after the Council has had an adequate opportunity to research and discuss the subject during 2014.

Background

A 2010 report by the Office of the Army Surgeon General states that pain is the most frequent reason Americans seek physician care, and more than 50 million Americans suffer from chronic pain. The annual cost of chronic pain in the U.S. was estimated at

$100 billion, including health care expenses, lost income, and lost productivity.[1] Back pain alone is the leading cause of disability in Americans under 45 years of age. The report further states that the failure to adequately address pain in the health care system continues to result in unnecessary suffering, exacerbation of other medical conditions, and huge financial and personal costs.

Chronic pain, defined as pain that lasts for more than twelve weeks[2], involves physical, emotional, cognitive, social and economic costs. The interest in CAM reflects an increased awareness that complements to traditional medicine may have the potential to enhance the management of chronic pain. There is no doubt that prescribed opioids have a role to play in managing pain. The traditional prescribing of opioids to control chronic pain has, however, carried risks of dependence, diversion and addiction. Prescribed drugs do not always control chronic pain. In addition, the use of prescribed medications has other, often undesirable side effects. There is a growing body of evidence to suggest that the use of nonpharmacological treatments may augment the use of prescribed opioids in a cost-effective and safer manner. The clinical and policy challenge is to identify alternatives that will contribute to effective and safe pain management.

The intent of this report is to contribute to an understanding of how to balance effective clinical management of chronic pain with public health strategies to reduce misuse of opioids.

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[1] Pain Management Task Force, Office of the Army Surgeon General, Final Report, May 2010, http://www.regenesisbio.com/pdfs/journal/Pain_Management_Task_Force_Report.pdf

[2] National Centers for Complementary and Alternative Medicine, *Chronic Pain and CAM: At a Glance* http://nccam.nih.gov/health/pain/chronic.htm?nav=gsa

Definition and Evolution of CAM

The National Center for Complementary and Alternative Medicine (NCCAM), an organization within the National Institutes of Health, is the federal government's lead agency for scientific research on health interventions, practices, products and disciplines that originate from outside mainstream medicine. It defines CAM as follows:

> CAM refers to a broad range of healing philosophies (schools of thought), approaches and therapies that mainstream Western (conventional) medicine does not commonly use, accept, study, understand, or make available. A few of the many CAM practices include the use of acupuncture, herbs, homeopathy, therapeutic massage, and traditional Oriental medicine to promote well-being or treat health conditions. People use CAM treatments and therapies in a variety of ways. Therapies may be used alone, as an alternative to conventional therapies, or in addition to conventional, mainstream therapies, in what is referred to as a complementary or an integrative approach. Many CAM therapies are called holistic, which generally means they consider the whole person, including physical, mental, emotional and spiritual aspects. [3]

In an attempt to classify the range of various CAM treatments, NCCAM has developed the following five classifications:[4]

1. Alternative medical systems, such as traditional Chinese medicine or homeopathy
2. Mind- body interventions, such as meditation and prayer
3. Biologically-based treatments, such as specialized diets and herbal products
4. Manipulative and body-based methods, such as chiropractic
5. Energy Therapies, such as gigong, Reiki and therapeutic touch

Historically, conventional western allopathic medicine shunned CAM as unproven and unscientific. During the past two decades, however, skepticism has eroded and a willingness to consider the potential contributions of some complementary interventions for managing pain has evolved.[5] Although the term *CAM* continues to be used in the clinical and policy literature, there is a trend toward using the term *Integrated Medicine* to describe emerging models of complementing traditional medicine with more non-

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[3] Federation of State Medical Boards of the United States, Inc. *Model Guidelines for the use of Complementary and Alternative Therapies in Medical Practice,* April 2002

[4] Institute of Medicine, *Complementary and Alternative Medicine in the United States,* National Academies Press, 2005, p.18

[5] Maizes, V., Rakel, D., and Niemiec, C. *Integrative Medicine and Patient-Centered Care* IOM Summit on Integrative Medicine and the Health of the Public, February 2009

traditional interventions such as chiropractic, acupuncture, etc. A report on Integrative Medicine commissioned by the IOM states that, although definitions of integrative medicine may vary, they all have the following commonalities:

- reaffirmation of the importance of the therapeutic relationship
- focus on the whole person and lifestyle- not just the physical body
- a renewed attention to healing
- willingness to use all appropriate therapeutic approaches, whether they originate in conventional or alternative medicine[6]

Some eschew the term *Alternative*, as it suggests that CAM is used instead of conventional medicine. Especially in the case of pain management, that is rarely true. Rather, the two approaches ideally must work together to manage pain in the most effective, safe and cost-effective manner possible. The term integrated care incorporates this concept, yet much of the current literature continues to use the term CAM.

In 2004, the Academic Consortium for Complementary and Alternative Healthcare, an organization of CAM accrediting agencies, professional associations, councils of colleges, certifying and testing organizations and academic institutions, was formed. Its mission is to advance the academic needs and development of the evolving CAM professions and to foster a coherent, synergistic collaboration with academic institutions of the conventional medical, nursing, and public health professionals. It's work involved proposing the following principles for the use of integrated medicine:[7]

1. Patient and practitioner are partners in the healing process
2. All factors that influence health, wellness, and disease are taken into consideration, including mind, spirit, community and body
3. Appropriate use of both conventional and alternative methods facilitates the body's innate healing response
4. Effective interventions that are natural and less invasive should be used whenever possible
5. Good medicine is based in good science. It is inquiry-driven and open to new paradigms
6. Ultimately, the patient must decide how to proceed with treatment based on values, beliefs and available evidence

[6] Ibid
[7] Ibid

7. Alongside the concept of treatment, the broader concepts of health promotion and the prevention of illness are paramount
8. Practitioners of integrative medicine should exemplify its principles and commit themselves to self-exploration and self-development

Further indication of conventional western medicine's willingness to consider integrating complementary therapies into their treatment repertoire, is the Federation of State Medical Board's development of Model Guidelines for the use of CAM in medical practice. Acknowledging the responsibility of medical practitioners to use treatments in an ethical manner that avoids undue risks, the guidelines present standards for deciding when CAM might be helpful based on evidence of efficacy and safety.[8]

The organization that has not only conducted research into the use of CAM for managing chronic pain but also has translated research into practice standards and service systems is the US Military. Faced with thousands of veterans with wartime injuries and pain, the military has embraced a range of CAM treatments to complement more traditional treatment of pain. The work resulting from the 2009 Office of the Army Surgeon General's Pain Management Task Force will contribute to further knowledge about the efficacy of CAM.[9]

Research on the Effectiveness of CAM and Integrated Medicine

A body of scientific literature is beginning to accumulate on the effectiveness of various nonpharmacological interventions for chronic pain. However, it is not as vast as the literature on conventional medical treatments. Emerging research tends to fall into three categories: research on the efficacy of specific CAM treatments for specific conditions, meta-analyses of published research, and economic analyses of the cost-effectiveness of integrating CAM into medical practice. Each is discussed below.

[8] http://www.fsmb.org/pdf/2002_grpol_complementary_alternative_therapies.pdf

[9] Pain Management Task Force, Office of the Army Surgeon General, Final Report, May 2010, http://www.regenesisbio.com/pdfs/journal/Pain_Management_Task_Force_Report.pdf

I. Efficacy for Managing Pain- Research on Specific Treatments or Conditions

Much of the research on the effectiveness and safety of CAM involves studies of specific types of treatment and specific ailments. An example would be the use of acupuncture for back and neck pain. In research on acupuncture, important methodological issues must be addressed to control for the placebo effect of the intervention beyond having a no-treatment comparison group. This means that a control group of subjects must be exposed to an intervention that is mildly invasive like acupuncture, yet not intended to be therapeutic. This control strategy, known as "sham treatment", attempts to remove any placebo effect of intervention when measuring efficacy. [10] All sound research is based on rigorous efforts to control for any effect other than the one being studied. This standard is as applicable to CAM treatments as it is to other more traditional medical interventions.

Although a review of all clinical trials that evaluate various forms of CAM is beyond the scope of this legislative report, there is growing evidence that some forms of CAM, such as chiropractic and acupuncture and yoga, can be effective interventions for musculoskeletal pain. The nature of the research is such that each study focuses on one particular modality of treatment for a particular kind or location of pain. The accumulation of these studies will add an evidence-base to the effectiveness of various treatments.

II. Meta-Analyses

Meta-analyses involve a systematic review of many research studies focused on a similar issue. They rate the studies on their methodological design, weigh them for design strength and draw conclusions from the collective studies. As published studies on specific treatments accumulate, it is possible for researchers to conduct meta-analyses.

A high standard for conducting systematic reviews is the Cochrane Collaborative, an international group of professionals who not only perform meta-analyses but also set

[10] Vickens et. al. Acupuncture for Chronic Pain, *Archives of Internal Medicine, on-line JAMA Network,* September 10, 2012

standards for reviewing research studies. The Cochrane Library contains collections of reviews and its research methods are considered to be the highest bar for evaluating research quality.[11] Cochrane reviewers are able to assess if a research is worthy of consideration based on its design. For example, researchers with the Cochrane Collaborative conducted a systematic review of research designed to determine if acupuncture treatment was effective in treating asthma in children and adolescents. The reviewers found that none of the published studies met the stringent inclusion criteria, so no conclusions could be drawn about the efficacy of this treatment.[12] In terms of its contributions to science, the Cochrane Collaborative holds the highest standards for evaluating research findings and conclusions, and its published reviews are valuable resources.

III. Economic Analyses

A key policy question for government and insurance companies is whether or not, in addition to being efficacious, CAM is cost-effective. Between 2002 and 2008, CAM accounted for between 2.7% and 3.1% of national health care expenditures on ambulatory services, and about 1% of all health care expenditures.[13] A recently published study in *Health Affairs* found that between 2002 and 2008, U.S. spending on CAM actually plateaued. As a primarily cash market, CAM treatment demand did not continue to escalate after reaching a balance of supply and demand. The researchers suggest that future inclusion of efficacious and efficient CAM treatment modalities in health reform benefit packages may be a cost-effective strategy for treating pain.[14] Future policy initiatives that contemplate inclusion of insurance coverage of CAM for chronic pain must consider the findings of economic impact studies as well as studies on the efficacy of CAM or integrated medicine.

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[11] http://www.cochrane.org/

[12] http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007839.pub2/abstract

[13] Davis, M., Martin, B., Coulter, I., and Weeks, W. US Spending on Complementary and Alternative Medicine during 2002-2008 Plateaued, Suggesting Role in Reformed Health System. *Health Affairs,* January, 2013, Vol 32 (1), pp 45-52

[14] Ibid

System Incentives for Use of Pharmaceuticals for Chronic Pain

The role of economic and insurance incentives in driving prescribers to rely upon pharmacological approaches to treating chronic pain must be recognized as part of reforming a health care system. Health insurance policies have created incentives to use pharmacological approaches to treat chronic pain rather than use more time-consuming integrated medicine. For providers, the prescribing of pain medication is efficient and the time is covered by insurance. Although prescription drugs are costly and support a profitable market-based economy, the primary care physician, faced with time constraints resulting from productivity demands, is offered no incentive to spend time with chronic pain patients to understand the nature, dynamics and consequences of their pain. The use of integrated medicine and complementary treatments requires the provider to have a solid relationship with the patient and an understanding of lifestyle issues that must be addressed during the course of treatment. This takes time and is often not covered by insurance. If the practice of using integrated medicine is to become part of a reformed health care system, disincentives for practicing in a manner that involves more patient interaction and involvement will need to be removed.

Although prescription pain medications play a role in managing pain, the consequences of reliance upon prescription drugs can be serious. Dependence on and addiction to opioid drugs have physical, psychological, economic and social costs, and medications are not always effective in managing chronic pain. An evolving and reformed health care system must be open and responsive to nonconventional approaches to responding to chronic pain.

Conclusion and Plans for Continued Work

Chronic pain takes a toll on individuals, but also puts significant demands on the health care system. The use of opioids alone to address chronic pain, however, carries risks of addiction, drug diversion and, often, inadequate pain relief. The health care system is changing, and safer, more cost-effective means of managing chronic pain must be embraced. The use of integrated medicine offers complements to traditional medicine that are safer, and in many cases, more effective for managing chronic pain. Over time, providers of CAM will most likely seek insurance coverage for their services, so the government and insurers will need to carefully evaluate available research to determine what services should be covered and for what conditions. Vermonters and their health care system stand to benefit from efficacious and cost-effective treatment for chronic pain.

Plans for Continued Work- The Unified Pain Management System Advisory Council first met in November, 2013. Due to an extensive agenda, there was insufficient time for a detailed discussion of nonpharmacological approaches to treating chronic pain. With the other agenda items for the Advisory Council to discuss, a focused study of this subject may best be accomplished by a subgroup. The Advisory Council is composed of several individuals who are knowledgeable about CAM and integrated medicine, and other interested experts exist in Vermont. The Commissioner of Health intends to appoint a small workgroup to study this issue further and develop recommendations for the larger Advisory Group in 2014. The workgroup should prepare a summary of its findings for the Advisory Council no later than November, 2014.