Report to the General Assembly

A Report based on the Committee on the Practice of Naturopathy
Convened Pursuant to Special Act 16-3

Raul Pino, MD, MPH, Commissioner
February 17, 2017

State of Connecticut
Department of Public Health
410 Capitol Avenue
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Department of Public Health
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Introduction

Special Act 16-3, An Act Concerning a Committee on the Practice of Naturopathy, approved by the Legislature on May 26, 2016, charged the Department of Public Health with convening a committee to consider (1) the education and examination requirements and other qualifications necessary to allow someone licensed to practice naturopathy in Connecticut to prescribe, dispense and administer prescription drugs consistent with their scope of practice and (2) the development of a naturopathic formulary of prescription drugs for someone licensed to practice naturopathy, who meets those educational and examination requirements or other qualifications to prescribe, dispense or administer prescription drugs.

The Legislature constructed Special Act 16-3 similarly to the formal scope of practice process established in Connecticut General Statues (CGS) 19a-16d through 19a-16f, and allowed any health care professional or persons representing a group of health care professionals, who may be impacted by a change allowing naturopaths to prescribe, to submit a written impact statement to the Department by June 1, 2016, which provided them the opportunity to participate on the committee. The Department received statements from 13 Connecticut professional physician and nursing organizations, all expressing concerns regarding the concept of providing prescribing authority to naturopaths. (Appendix A)

The Department requested the names of two individuals from each organization that wished to participate on the committee. Based on the responses, the committee was established and consisted of representatives from the following organizations: (Appendix B)

American College of Surgeons Professional Association, Inc.
Connecticut Academy of Family Physicians
Connecticut APRN Society
Connecticut Coalition of APRNs
Connecticut Nurses Association
Connecticut Naturopathic Physicians Association
Connecticut State Medical Society
University of Bridgeport

The Department also invited the Department of Consumer Protection (DCP) Drug Control Division to participate, as DCP regulates pharmaceutical drugs and prescribing in Connecticut.

Additionally, the Connecticut Urology Society and the Connecticut Society of Eye Physicians attended and participated at the final meeting of the committee.

Background

The historic context of the practice of naturopathy is important to understand as a basis for the committee's discussions.

The following are examples of dictionary definitions of naturopathy:

- *a drugless system of healing by the use of physical methods, such as light, air or water.* Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing and Allied Health, Seventh Edition. ©2003 by Saunders, an imprint of Elsevier, Inc. All rights reserved.
- *a system of therapeutics in which neither surgical nor medicinal agents are used; reliance is placed only on natural (that is, nonmedicinal) forces.* Farlex Partner Medical Dictionary ©Farlex 2012.
- *a drugless system of health care, using a wide variety of therapies, including hydrotherapy, heat, massage and herbal medicine, whose purpose is to treat the whole person to stimulate and support the person's own innate healing capacity.* Dorland's Medical Dictionary for Health Consumers. ©2007 by Saunders, an imprint of Elsevier, Inc. All rights reserved.
- *a system of therapeutics based on natural foods, light, warmth, massage, fresh air, regular exercise and the avoidance of medications. Advocates believe that illness can be healed by the natural processes of the body.* Mosby's Medical Dictionary, 9th edition. ©2009 Elsevier.

The following are definitions related to naturopathy from the American Association of Naturopathic Physicians (AANP):

Naturopathic Medicine

- Naturopathic physicians work with nature to restore people's health.
- Naturopathic medicine is a distinct primary health care profession, emphasizing prevention, treatment and optimal health through the use of therapeutic methods and substances which encourage the person's inherent self-healing process, the "vis medicatrix naturae".
- Naturopathic medicine is a distinct method of primary health care - an art, science, philosophy and practice of diagnosis, treatment and prevention of illness. Naturopathic physicians seek to restore and maintain optimum health in their patients by emphasizing nature's inherent self-healing process, the "vis medicatrix naturae". This is accomplished through patient education and the rational use of natural therapeutics.

Naturopathic Methods (AANP)

- Naturopathic medicine is defined by its principles. Methods and modalities are selected and applied based upon these principles in relationship to the individual needs of each patient.
- Diagnostic and therapeutic methods are selected from various sources and systems, and will continue to evolve with the progress of knowledge.

Naturopathic Practice (AANP)

- Naturopathic practice includes the following diagnostic and therapeutic modalities: nutritional medicine, botanical medicine, naturopathic physical medicine including naturopathic manipulative therapy, public health measures and hygiene, counseling, minor surgery, homeopathy, acupuncture, prescription medication, intravenous and injection therapy, naturopathic obstetrics (natural childbirth) and appropriate methods of laboratory and clinical diagnosis.

Source: (http://www.naturopathic.org/content.asp?contentid=59)

According to the Federation of Naturopathic Medicine Regulatory Authorities (FNMRA), Connecticut is one of 17 states that regulate the profession of naturopathy. The District of Columbia, Puerto Rico and the United States Virgin Islands also regulate the profession. Of the 33 states that do not regulate the profession of naturopathy, South Carolina and Tennessee explicitly prohibit the practice of naturopathy (Appendix C). Of the 17 states that do regulate naturopathy, 11 states have provided various levels of prescribing authority to naturopaths (Appendix D).

The State of Connecticut has licensed naturopaths since 1923. The current scope of practice for naturopaths in Connecticut is defined in CGS Section 20-34:

> **Sec. 20-34. Practice defined.** (a) The practice of naturopathy means the science, art and practice of healing by natural methods as recognized by the Council of Naturopathic Medical Education and that comprises diagnosis, prevention and treatment of disease and health optimization by stimulation and support of the body's natural healing processes, as approved by the State Board of Naturopathic Examiners, with the consent of the Commissioner of Public Health, and shall include (1) counseling; (2) the practice of the mechanical and material sciences of healing as follows: The mechanical sciences such as mechanotherapy, articular manipulation, corrective and orthopedic gymnastics, physiotherapy, hydrotherapy, electrotherapy and phototherapy; and the material sciences such as nutrition, dietetics, phytotherapy, treatment by natural substances and external applications; (3) ordering diagnostic tests and other diagnostic procedures as such tests and procedures relate to the practice of mechanical and material sciences of healing as described in subdivision (2) of this subsection; (4) ordering medical devices and durable medical equipment; and (5) removing ear wax, spirometry, tuberculosis testing and venipuncture for blood testing.

(b) For purposes of subsection (a) of this section, "natural substances" means substances that are not narcotic substances, as defined in subdivision (30) of section 21a-240, do not require the written or oral prescription of a licensed practitioner to be dispensed and are only administered orally.

CGS Section 20-42a also permits a licensed naturopath to delegate colon hydrotherapy to a certified colon hydrotherapist.

In the fall of 2013, a scope of practice request submitted by the Connecticut Naturopathic Physicians Association (CNPA) sought to expand the scope of naturopathic practice to include prescriptive authority and the ability to perform minor in-office procedures. The Department convened a scope of practice review committee, during which representatives from the participating physician/surgeon organizations expressed significant concerns with the proposal to expand the scope of practice for licensed naturopathic physicians to include prescriptive authority and performing in-office procedures. Their objections were primarily based on what they believe to be deficiencies in naturopathic medical education and training, including a lack of post-graduate residency requirements and the lack of post-licensure certification requirements for NDs as compared to mandatory education and training requirements for licensed physicians/surgeons who practice primary care.

The 2016 committee based on Special Act 16-3 included members of physician/surgeon and nursing professional organizations. Although three years had passed since the 2013 scope of practice review committee, the concerns of both professions were very similar to the concerns raised during the 2013 process. Despite the concerns with expanding the scope of practice of naturopaths to include prescribing, the professions at the table expressed a commitment to work more closely in collaboration with naturopath colleagues to enhance the skills that are unique to each of the professions represented at the table. The group's commitment was focused on an interdisciplinary approach to patient care with a goal of broadening the benefit to patients.

Committee Process

Committee members met three times during July through September of 2016.

The Department of Public Health opened the first meeting with an overview of the legislation that led to the committee, an overview of current statutory language related to naturopathy, and a discussion of some of the research and literature review conducted by the Department prior to the meeting.

The Department found that most sources such as the National Cancer Institute and the National Institutes of Health National Center for Complementary and Integrative Health (*https://nccih.nih.gov/health/naturopathy*) do not describe prescribing as a component of naturopathy. However, naturopathic professional websites do include prescribing among the profession's modalities. (*http://www.naturopathic.org/content.asp?contentid=59*)

The Department shared that, in preparation for this committee, finding evidence-based literature on naturopathy is difficult as naturopathy is based more on philosophy compared to conventional medicine, which is based on science and research (Appendix E). However, the culture of naturopathy may be changing as it seems there is an effort to embrace evidence based practices (Appendix F).

The committee members from the naturopathic committee were asked to describe how prescribing prescription medication aligns with the philosophy and principles of naturopathy in the context of the six principles of naturopathy. The following excerpts are from the Association of Accredited Naturopathic Medical Colleges (*https://aanmc.org/6-principles*) and describe the six principles of naturopathy.

"Naturopathic medicine is dedicated to the study and celebration of nature's healing powers. It is as old as healing itself and as new as today's medical breakthroughs. It is a dynamic philosophy as well as a profession that recognizes the interconnection and interdependence of all living things. It utilizes the most natural, least invasive and least toxic therapies to treat illness and to promote wellness by viewing the body as an integrated whole.

Naturopathic medicine is defined by principles rather than by methods or modalities. Above all, it honors the body's innate wisdom to heal.

Naturopathic physicians practice the six fundamental principles of naturopathic medicine:

1. The Healing Power of Nature
   Trust in the body's inherent wisdom to heal itself.
2. Identify and Treat the Causes
   Look beyond the symptoms to the underlying cause.
3. First Do No Harm
   Utilize the most natural, least invasive and least toxic therapies.
4. Doctor as Teacher
   Educate patients in the steps to achieving and maintaining health.
5. Treat the Whole Person

   View the body as an integrated whole in all its physical and spiritual dimensions.
6. Prevention

   Focus on overall health, wellness and disease prevention."

Before proceeding further into the discussion of curriculum, a committee member representing the University of Bridgeport responded to the question of how prescribing prescription medications aligns with the philosophy and principles of naturopathy in the context of the six principles of naturopathy. The responses are summarized in italics:

1. **The healing power of nature** – *while naturopaths deal with natural substances, sometimes a prescription is more in line with what a patient needs.*
2. **Identify the illness and its cause** – *[Naturopaths] work hard to find out cause of disease. Sometimes natural substances, changes in diet, exercise program, botanical supplements, nutritional supplements, etc. will address an illness, but sometimes they are not enough.* An example provided was hypertension that could be treated with a prescription if naturopathic approaches do not work.
3. **Do no harm** – *As this principle applies to naturopathy, the practitioner starts with natural approaches that are less toxic than what prescription remedies might be. However, sometimes these approaches are not an adequate level of care and prescriptive authority is required. Naturopaths would use such tools (prescriptions) as judiciously and safely as any other health care provider does.*
4. **Doctor as teacher** – *Naturopathic practitioners help patients understand how they can help themselves with their choices in daily life including exercise, sleep, and eating habits. Naturopaths also look at nutritional and botanical support, as well as pharmaceuticals and how to properly take medications.*
5. **Treat the whole person** – A *naturopath spends a lot of time with patients treating the whole person in their entirety – physical, emotional, and mental wellbeing. Sometimes that may include prescriptive medications.*
6. **Prevention** – *An area of greatest concern from a naturopathic standpoint and sometimes pharmaceuticals enter into that.*

Considerations of the Education and Examination Requirements and other qualifications to allow persons licensed to practice naturopathy to prescribe, dispense and administer prescription drugs.

The committee discussed what educational and examination requirements would qualify those licensed to practice naturopathy in Connecticut to prescribe prescription drugs for patients. The stance of the representatives of the naturopathic community was that current licensure requirements are sufficient for naturopaths to prescribe safely. The basic requirements are 1) graduation from a school accredited by the Council on Naturopathic Medical Education (CNME), 2) successful completion of the Naturopathic Physician Licensing Examination (NPLEX), and 3) successful completion of the Connecticut jurisprudence examination for naturopathic physician licensing.

A CNME representative described that the organization is recognized by the United States Department of Education as an accrediting entity. The CNME specifies faculty credentials and the requirements for programs of study for Doctor of Naturopathy Degrees. The CNME representative explained the organization accredits four year graduate programs he described as consistent with MD/DO programs, and that cover a very similar curriculum during the first two years of study. The CNME currently accredits six programs in the United States and two programs in Canada. The CNME representative described how students are

trained to employ natural and holistic therapies and practices to benefit patients, including lifestyle counseling.

Proponents for naturopathic prescribing authority shared a document, created by the Connecticut Naturopathic Physicians Association and the University Of Bridgeport, College Of Naturopathic Medicine. The document compares the University of Bridgeport's Naturopathic Medicine program to conventional medical school curriculums, and describes that pharmacology is taught throughout the curriculum in both conventional medical and naturopathic medical training (Appendix G). According to the document:

University of Bridgeport College of Naturopathic Medicine (UBCNM) Curriculum
Two courses are dedicated to pharmacology and drug therapeutics totaling 72 hours. Another 86 hours of pharmacology and drug therapeutics is taught in cardiology, gynecology, endocrinology, pediatrics, rheumatology, EENT, neurology, gastroenterology, urology/proctology, oncology, dermatology, minor office procedures, emergency medicine, environmental medicine, obstetrics, geriatrics, clinical physical laboratory diagnosis I and II, and immunology. 158 hours of pharmacology and drug therapeutics is taught in total. Total Instructional hours at UBCNM are 4515 hours, comprising 765 hours of basic sciences; 2358 hours of clinical sciences and 1392 hours of clinical practice.

Conventional Medical School Programs
At Yale, UConn, and Quinnipiac University Schools of Medicine, pharmacology is part of a block format curriculum, and these schools do not identify hours specifically dedicated to pharmacology instruction. A commonly cited figure for total pharmacology instruction at conventional medical schools is 120 hours. Total Instructional hours at most conventional medical school programs ranges from 4300 to 5100 hours.

The representatives from organizations representing medical doctors and nurses, however, were not convinced the education and training of naturopaths was sufficient to allow naturopaths to safely prescribe prescription medications. The representatives from medicine and advanced practice nursing assert that safe prescribing requires more than courses on the principles of prescribing (pharmacology), and that some sort of residency, internship, or other route to gain practical prescribing experience under the guidance of an experienced practitioner should be a requirement. The main areas of concern related to the concept of naturopaths prescribing were:

- Medical students spend three years in a residency with licensed, experienced physicians watching over the resident to ensure they are prescribing appropriately. The physicians stressed that prescribing is more than an understanding of the principles of pharmacology and that advanced, hands-on training is necessary. One physician participant stressed that "the real learning and art of prescribing occurred during his three years of residency".
- Advanced Practice Registered Nurses (APRNs) are required to practice collaboratively with a licensed physician for at least three years prior to being able to practice independently.

- Lack of clarity on how prescribing prescription drugs align with the training and philosophy of naturopathy.

The representatives of the naturopathy community believe the current training provided at the six United States and two Canadian naturopathy programs accredited by the Council on Naturopathic Medical Education is sufficient for naturopaths to safely prescribe. The naturopaths refer to the lack of malpractice and regulatory actions taken against naturopaths in the 11 states where the profession is permitted to prescribe as evidence of their ability to prescribe safely. (Appendix H)

The representatives from the medical community assert that using the malpractice data as a measure of quality and safety is not a fair comparison with conventional medicine to use to determine if naturopaths can safely prescribe. One of the reasons the medical community believes the comparison is not fair is that medical malpractice data is skewed by high-risk practices such as 0B/GYN and neurosurgery, and cannot be compared to the practice of naturopathy or other medical/non-surgical medicine specialist. The group also noted that the profession of naturopathy is very small compared to medicine (e.g. there are 340 licensed naturopaths in Connecticut and over 15,000 licensed physicians).

Although the naturopaths expressed a belief that current training is sufficient for naturopaths to safely prescribe, they recognized that some long-standing licensed naturopaths may have been trained at a time before pharmacology was included in naturopathic program curriculums. Additionally, the naturopaths recognized the concerns regarding the lack of residency or other mechanism after graduation to learn the nuances of prescribing. In response, the following items were offered by the naturopaths to address the concerns of the physician and nursing professions represented on the committee:

- A requirement that any Connecticut-licensed naturopathic physician who wants to prescribe must take a three credit pharmacology review course for naturopathic physicians through the Massachusetts College of Pharmacy and Health Sciences (Appendix I);
- An increase in continuing education requirements for naturopaths licensed in Connecticut from 15 to 30 credit hours each year, with 15 of those hours in clinical therapeutics and pharmacology;
- A willingness to consider a time-limited collaborative relationship between a naturopath and a physician or APRN prior to independent prescribing by the naturopath; and,
- A restricted or limited formulary for naturopathic prescribing.

While the physician and nursing representatives on the committee were encouraged by the willingness of naturopaths to gain additional education and training regarding prescribing,

there were still concerns that the profession of naturopathy was not standardized enough yet to warrant prescribing authority. Some of the professions at the table felt that the profession of naturopathy should focus on becoming licensed in the 33 states that do not recognize naturopaths and on building national quality and safety standards that become accepted by the profession throughout the country. The naturopaths referred to documents they felt set standards for the practice including the *American Association of Naturopathic Physicians (AANP) Guidance Regarding Naturopathic Practice and Care* (2015). (Appendix J)

The group felt further discussion and planning would be necessary to create a collaborative agreement relationship model between naturopaths and physicians and APRNs. Some challenges identified include:

- Naturopaths typically work in private, ambulatory care settings. Any collaboration that would require a naturopath to go to practice in a medical office would be overly cumbersome. The arrangement would need to allow the naturopath to practice and prescribe from his or her own practice while collaborating with a physician or APRN.
- Professional liability and malpractice issues for physicians or APRNs who might be willing to collaborate with naturopaths on prescribing may be prohibitive.
- Due to the paradigm differences between naturopaths and the physicians and APRNs who would collaborate with naturopaths on prescribing, the collaboration must be clearly defined. For example, what happens when a physician or APRN in a collaborative agreement with a naturopath disagrees with the naturopathic treatments a naturopath is providing to his/her patients?

Opponents of naturopathic prescribing felt if the legislature made a decision to allow naturopaths to prescribe, some sort of collaborative arrangement with a physician or APRN was necessary to develop practical prescribing skills they say cannot be taught in a didactic pharmacology class. Medical doctors on the committee discussed the difference between education and training. According to the MDs, didactic coursework is education; clinical experience with medication is training. The naturopathic representatives described that they would like to be able to complete residencies, but are prohibited from obtaining privileges in the settings where residencies generally occur.

The development of a naturopathic formulary of prescription drugs for someone licensed to practice naturopathy who meets those educational and examination requirements or other qualifications to prescribe, dispense or administer prescription drugs.

The naturopathy representatives shared two proposed draft formularies for the committee's consideration. The second draft formulary included some minor revisions and clarifications (Appendix K).

The committee discussed the concerns raised during the meeting regarding what and how naturopaths would prescribe if the legislature provided them the authority to do so. There were still concerns from the physicians and APRNs about the differing paradigm of naturopathy compared to conventional medicine, and the absence of a residency or similar requirement for naturopaths. Other areas of concern included opioid prescribing and the use of chelation therapy outside of documented heavy metal poisoning.

The Department of Consumer Protection expressed concerns at one of the committee meetings about expanding controlled substance prescribing to another class of practitioners considering the current opioid crisis. Representatives of the naturopaths said they did not envision those practicing their profession adding to the opioid problem, but rather being able to help patients decrease their opioid use by offering alternative treatments. Naturopaths shared a document entitled *"Never Only Opioids"* that discusses non-pharmacological approaches for pain as an example of how naturopathic physicians may approach paint treatment (Appendix L). Most of the approaches described in this document are within the current scope of practice for naturopaths. Physician and APRN members of the committee felt that finding alternatives to opioids is important, and not having controlled substance prescribing rights might assist naturopaths in dealing with patients seeking alternatives as this relieves the pressure a prescriber may experience from someone seeking relief from opioids. Much of this discussion occurred at the final committee meeting when DCP was not in attendance, and the committee agreed to table the opioid discussion.

Concerns were also expressed about chelation therapy, a chemical process that involves a solution injected into the blood stream to remove heavy metals and minerals from the body. Chelation therapy is often promoted by alternative and complementary medical providers and suggested for uses other than severe heavy metal toxicity (Appendix M). The Department received a letter from a medical toxicologist urging decision makers to prevent naturopathic practitioners from diagnosing or treating patients with suspected heavy metal toxicity with chelation therapy (Appendix N). Representatives from naturopathy said naturopaths are not interested in using chelation to address health issues like cardiovascular disease, and there are rationales for using chelation for those with high levels of heavy metals or minerals that may have occurred from long term exposure.

The committee did not come to a final conclusion or recommendation about a formulary or the educational requirements for a naturopath to prescribe should the legislature decide to address the issue. There may be challenges to developing and maintaining a formulary specific to naturopaths that would require updates and regular review. Some members expressed that if a time-limited collaborative relationship model existed between a naturopath and a physician or APRN, a restricted formulary might not be necessary.

In the end, the group determined that it was unable to come to an agreement on a model to propose to permit naturopaths to prescribe. The committee members came to consensus on the two following items:

- Additional training is needed in order for a naturopath to prescribe
- A key component of allowing prescriptive authority would be a requirement for some sort of collaborative agreement between a naturopath and a physician or APRN.

The committee initially discussed the potential establishment of another committee to develop a formulary. However, after further discussion, the group felt it would be more beneficial to establish a workgroup to develop a model for a time limited collaborative relationship between a naturopath and a physician or APRN. The need for either committee would depend on a proposal by the legislature.

Conclusions

The Department of Public Health convened a committee based on Public Act 16-3 to consider prescribing authority for naturopaths licensed in Connecticut. The committee included organizations representing naturopaths, physicians, and Advanced Practice Registered Nurses (APRNs). The Department of Consumer Protection (DCP) also participated since they regulate prescribing practices in Connecticut.

Naturopathy is regulated in 17 states and has various levels of prescribing authority in 11 states. Connecticut has licensed naturopaths since 1923. The University Of Bridgeport College Of Naturopathic Medicine is one of six naturopathic programs accredited by the Association of Accredited Naturopathic Colleges (AANMC) in the United States. Graduation from a school accredited by the AANMC is one of the requirements for licensure in Connecticut.

Representatives from the naturopathic community believe that the training and education that naturopaths receive at an AANMC accredited program is sufficient for naturopaths to prescribe to patients. However, representatives from the physician and nursing communities feel that naturopaths do not receive sufficient training to prescribe medication safely.

The naturopaths proposed a requirement for a refresher course in pharmacology for naturopaths who want to prescribe, and an increase in required continuing education credits to include pharmacology and prescribing. The naturopaths also expressed a willingness to participate in a time-limited collaborative relationship with a physician or APRN prior to prescribing independently.

Opponents of naturopaths' prescribing felt that the didactic component of a refresher course would be helpful, but a collaborative relationship with an experienced provider would be critical should prescribing rights be granted by the legislature. The physicians and APRN representatives on the committee stress that the "real learning" about prescribing occurs during residency or a collaborative relationship and cannot be fulfilled through didactic education alone.

The committee was ultimately unable to reach a consensus on the qualifications necessary for a naturopathic physician in Connecticut to prescribe medications or a formulary of what those medications would be. The naturopaths strongly feel that they have the training and skills to prescribe medication and agree to consider additional requirements for naturopaths to earn the right to prescribe pharmaceutical medications to their patients.

On the other hand, the physician and APRN committee members unanimously assert that naturopaths do not have sufficient education and training at this time to safely prescribe the medications proposed. (Appendix O) The rationale for this opinion was the lack of scientific foundation of the profession of naturopathy, and a lack of commitment to evidence-based therapy. However, these professions expressed appreciation for the unique skills and perspective that naturopaths contribute to health care. They also commit to working more closely in collaboration with naturopaths to enhance the skills of each profession at the table in ways that will enhance preparation for safe prescriptive authority. However, they do not endorse a specific pathway or timeframe for this progression.

Should the Public Health Committee decide to raise a bill related to prescribing authority for naturopaths, the Department of Public Health respectfully requests the opportunity to work with the Public Health Committee on such a proposal. The organizations represented on the scope of practice review committee also expressed their interest in being involved should legislators decide to proceed with considering prescribing rights for naturopaths.

Appendices
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Appendix A
Impact Statements

E
N
T
Society

May 19, 2016

Raul Pino, M.D.
Commissioner of Public Health
410 Capitol Avenue
PO BOX 340308
Hartford, CT 06134

Dear Commisioner Pino,

As President of the CT ENT Society, I proudly represent over 120 practicing otolaryngologists throughout the state of Connecticut.

I am writing in regards to Substitute House Bill No. 5534 Special Act No. 16-3 An Act Concerning A Committee On The Practice of Naturopathy.

Our membership is concerned about changes to the general statute to allow persons licensed to practice naturopathy to prescribe, dispense or administer prescription drugs. In reviewing the curriculum of naturopathic school programs, there is no consistent teaching regarding current prescription medications if any teaching at all. One of the underlying tenets of naturopathy has always been an approach to healing without prescription medications.

The overwhelming majority of naturopathic practitioners do not go on to residency programs like allopathic and osteopathic physicians who on average spend an additional 12,000 hours on post doctoral training, sometimes even more with fellowship training. With the current lack of required post doctoral training for naturopathic providers, there is no way for naturopaths to have first hand knowledge of prescriptive medications and their potential interactions/side effects in the clinical setting once they have left school. This lack of practical education needs to be fully addressed as it may lead to unnecessary harm to patients.

The concerns of physicians who currently have prescriptive authority include the expansion of scope of practice for naturopathic providers without clear indications of prior education, testing of prescription medication knowledge prior to obtaining prescriptive authority or defined continuing medical education. In addition, it would be significantly outside of the scope of practice of naturopathic providers to have full access to prescriptive authority of all medications as allopathic and osteopathic physicians have received additional education after completing school. A limited naturopathic formulary needs to be developed and carefully monitored.

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Please do not hesitate to contact me with any further questions or to discuss this matter in further detail.

Sincerely,

Raymond Winicki, M.D.
President
Connecticut Ear, Nose and Throat Society

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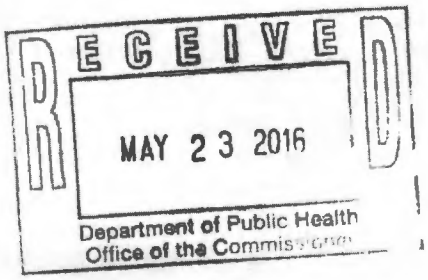

May 19, 2016

Raul Pino, M.D.
Commissioner of Public Health
410 Capitol Avenue
PO Box 340308
Hartford, CT 06134

Dear Commissioner Pino:

It is with significant concern that I write regarding substitute House Bill number 5534 special act No.16 – 3 an act concerning the committee on the Practice of Naturopathy.

As president of the Connecticut Dermatology and Dermatologic Surgery Society I represent the majority of dermatologists practicing in the state of Connecticut.
Our specialty training includes four years of medical school, followed by at least year of internship and three years of residency training in the specialty of dermatology after medical school.

During this training we are taught how to use many types of systemic and topical medications in the treatment of skin disease. There are multiple drugs that we use including topical and systemic steroids, antibiotics, as well as biologic and chemotherapy drugs which are used for the treatment of severe skin disease likes psoriasis, eczema, and bullous dermatoses. We also use medications such as isotretinoin for the treatment of severe acne.

All of these medications have the potential for causing significant side effects including but not limited to allergic reactions, drug to drug interactions, skin atrophy, immunosuppression, and birth defects. The practice of prescribing them requires significant training and expertise.

It is difficult for me to comprehend how a naturopath could have the training and experience required to prescribe such medications. They do not possess the rigorous training and knowledge that prescribing so many of these drugs require. Allowing naturopaths to have the responsibility of prescribing these medications would significantly expand their scope of practice and have the potential of causing significant harm to patients.

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Connecticut
Urology
Society

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Raul Pino, M.D.
Commissioner of Public Health
Capitol Avenue
PO BOX 340308
Hartford, CT

Dear Commissioner Pino:
It is with significant concern that I write regarding substitute House Bill number 5534 special act No.16-3, an act concerning the committee on the Practice of Naturopathy. I also personally testified about this before the Public Health Committee hearing.

As the current President of the Connecticut Urology Society, I represent the majority of the urologists practicing in the state of Connecticut. Our specialty training includes four years of medical school, followed by one year of general surgery and four years of urology residency. For urologists in my generation (age 40 and above), the training was in fact a total of 6 years.

During this time, we are trained to be diagnosticians and surgeons. We spend all of our time in direct patient contact sometimes up to 100 hours per week. We are trained to use hundreds of systemic medications for an array of urologic diseases, including malignancies. We understand the pharmacology of antibiotics and their potential dangerous interaction with blood thinners such as Coumadin. Without appropriate testing and assessments of sensitivities, the overuse or misuse of antibiotics can be a giant pitfall leading to the development of multi-drug resistant organisms. We feel comfortable in treating the overactive bladder with anticholinergics and now beta agonists which can have deadly interactions with some anti-arrythmics by causing QT prolongation. We are trained in the use of systemic and intravesical chemotherapy and immunotherapy for management of bladder and prostate cancer, learning to manage the side effects and potential long term complications. This knowledge again is gained over a five year period of direct patient care supervised by pharmacists, other specialists and our own mentors.

It is extremely difficult for me to understand how a naturopath could have the training and experience necessary to safely manage these medications. They do not possess the rigorous training and knowledge that prescribing so many of these drugs require. Allowing naturopaths to have the responsibility of prescribing these medications would significantly expand their scope of practice and have the potential of causing significant harm to patients. The landscape of pharmaceuticals changes frequently and requires continuous, ongoing education and exposure to specialists in all fields of medicine. I am afraid that this is not the case for naturopaths and I strongly oppose their ability to prescribe medication.

I would be happy to speak to you in person. Please contact me if you have any further questions.

Sincerely yours,
Marlene A Murphy-Setzko, M.D.
President – CT Urology Society

RECEIVED
MAY 26 2016
Department of Public Health
Office of the Commissioner

CONNECTICUT COLLEGE OF EMERGENCY PHYSICIANS

A Chapter of the AMERICAN COLLEGE OF EMERGENCY PHYSICIANS

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Raul Pino, M.D., M.P.H.
Commissioner
Connecticut Department of Public Health
P.O. Box 340308
Hartford, CT 06134-0308

Re: Prescriptive Authority for Naturopaths

Dear Commissioner Pino,

Paracelsus, a 16th century Swiss German physician and founder of toxicology, is credited with the adage "*sola dosis facit venenum*": the dose makes the poison. Long before pharmaceutical companies, physicians noticed the amount of a substance classified a drug as a medicine. Today's licensed medical professionals understand this concept because of the rigorous training that starts in medical school and extends through residency and throughout practice.

There are enormous difference between physicians and naturopaths and just because they use the word physician does not make them equivalent. Naturopathic colleges have very non-selective admission criteria and in recent years the University of Bridgeport School of Naturopathic Medicine have accepted 100% of applicants. Compare this to the average 2-3% acceptance rate for Medical Schools. In school, the Naturopathic curricular are based heavily on historic traditions many of which have been debunked or shown equivalency to placebo. Although medical treatments have changed over the centuries, the philosophy of testing medications for effectiveness and safety is the cornerstone to the decision to prescribe. Some in the public are already confused about the services provided by the two groups and policy makers should not make rules that further blur the lines.

Naturopathic educators continue to insist that a 2 semester course in pharmacology is all that is needed to prescribe synthetic or non-natural medications, ignoring the fact that medical students, APRN's and even PA's spend the bulk of their time studying scientific disciplines that relate ultimately to prescriptive authority. Medical students have 2 years of clinical activity where they learn to prescribe under the supervision of attending physicians and then continue through internship, residency and in many cases fellowships all designed as hands on clinical training that is includes a heavy emphasis on prescribing medications. Naturopathic schools have virtually no clinical exposure, and none that relates to the prescription of legend drugs. Naturopathic training ends after graduation from naturopathic school. There are no residencies that train naturopaths in how to prescribe medications.

Allowing Naturopaths to prescribe could further confuse the public to the role of the Naturopath. Under the current system patients are aware that they are being treated by ether a physician, a nurse or a physician's assistant. In fact, prescribing medication is antithetical to naturopathic philosophical doctrine. If patients mistakenly use a naturopath as a comprehensive physician, they will be exposed to other concerning practices like opposition to vaccines. Society has seen the detrimental effects of large portions of society foregoing vaccines.

Emergency physicians care for 1.75 million visits every year. Connecticut's emergency physicians are the safety net for society and care for patients 24 hours per day, 7 days per week. Many of these visits relate to the use of medicine including overdoses, known side effects, allergic reactions and drug-to-drug interactions. Taking a simple pharmacology course is insufficient training to understand all of the complexities associated with the authority to prescribe. If policy makers and the government allow Naturopaths prescribing authority, society will be at risk. Hopefully, Connecticut will not make a decision that could endanger the public.

CCEP would like to request that a member of our organization serve on the committee that may be established under HB 5534 Special Act 16-3 AAC a Committee on the Practice of Naturopathy.

Sincerely,

Hynes Birmingham, MD, MBA, FACEP
President

CONNECTICUT NURSES' ASSOCIATION

May 27, 2016

CT Department of Public Health
Brie Wolf
410 Capitol Avenue
POBox 340308
Hartford, CT 06134

Dear Ms. Wolfe

The Connecticut Nurses' Association (CNA) Board of Directors and Government Relations Committee respectfully request to be included on the committee to consider the education, examination of naturopaths and the development of a naturopathic formulary of prescription drugs.

The Connecticut Nurses' Association is the unified voice for Registered Nurses across the state, understands the interdisciplinary care team that may interface with licensed naturopaths, the Nurse Practice Act, scope of practice and implications on public health.

We look forward to hearing from you and working together to support health in our state.

Respectfully,

Kimberly Sandor
Executive Director

Stephanie Knutson
President

Mary Jane Williams
Chair of Government Relations

American College of Surgeons
Inspiring Quality:
Highest Standards, Better Outcomes

Connecticut Chapter
of the American College of Surgeons
Professional Association, Inc.

27 May 2016

Raul Pino, M.D., M.P.H.
Commissioner
Department of Public Health
P.O. Box 340308
Hartford, CT 06134

Dear Dr. Pino,

On behalf of the over 500 surgeons and over 200 surgical residents represented by the Connecticut Chapter of the American College of Surgeons I am expressing our deep concern with regard to ***Substitute House Bill No. 5534 Special Act No. 16-3 AN ACT CONCERNING A COMMITTEE ON THE PRACTICE OF NATUROPATHY***. We stand firmly opposed to this proposal for the following reasons:

1. Naturopaths were granted a Scope Expansion Committee hearing 3 years ago that determined that graduates of naturopathic colleges had insufficient education and training to prescribe prescription drugs.

2. Naturopaths receive two semesters of pharmacology as part of their basic medical science curriculum. That has been held up by the proponents of naturopathic prescriptive authority as exactly equivalent to what a physician receives and more than sufficient to safely prescribe any and all medications including controlled substances.

   Although naturopathic students learn basic examination techniques they have extremely limited exposure to patients and <u>none that includes the use of prescription medicines</u>. There are no clinical rotations in a naturopathic medical school, unlike in medical school where the greater part of the last two years are occupied in intense contact with patients in clinical settings using prescription medications under supervision. Additionally physicians possess 3 to 10 years of postgraduate training, which is a critical adjunct to learning how to use prescription medications.

3. The philosophical underpinning of naturopathic medicine is fundamentally at odds with modern medical practice. Naturopathic medicine is based on the core belief that the human body can heal illness without external or synthetic agents and it embraces old and outdated medical traditions many of which have no scientific basis or proven effectiveness. Allopathic medicine, on the other hand, is based on the belief that understanding chemistry and physiology allows physicians to interact effectively to alter the disease process and shift patients toward healthier lives. Naturopathic medical colleges have not reached a point where these divergent philosophies can be brought together in any kind of harmonious relationship.

4. The proposed bill submitted by the naturopaths called for a separate class of naturopaths with prescriptive authority called "Advanced Care Naturopaths", which would be confusing to the public.

5. The naturopaths have not demonstrated that the expansion of scope to include prescriptive authority would impact positively on access to quality care. What is clear is that the granting of such authority would create a class of prescribing provider with insufficient education and training that would to a large degree be indistinguishable from other providers with more extensive education and training.

6. The granting of prescriptive authority may embolden the naturopaths to pursue other scope expansion initiatives including wound repair, which was in their 2013 scope expansion request. Their training in wound repair would consist of watching videos and suturing plastic dummies. This one issue may be tangential to the scope expansion requested in 2016, but it is particularly relevant to our organization and others that represents surgeons.

The Connecticut Chapter is at the forefront of improving patient safety and quality in the state. In 2011 we formed the Connecticut Surgical Quality Collaborative to lead these endeavors. That entity was recently incorporated as its own entity, has been recognized nationally for it work, and has received meaningful grant funding. We believe that expanding the scope of naturopaths to include prescriptive authority would potentially place patients at risk as the prescribers lack the appropriate training and education that those who currently have prescriptive authority possess.

Please do not hesitate to contact me if you have any further questions.

Sincerely,

Michael Deren, MD, FACS
President

Connecticut Advanced Practice Registered Nurse Society

Department of Public Health

Regarding:
Substitute House Bill No. 5534
Special Act No. 16-3
AN ACT CONCERNING A COMMITTEE ON THE PRACTICE OF NATUROPATHY.

May 30, 2016
The Connecticut Advanced Practice Registered Nurse Society is writing to the Connecticut Department of Public Health regarding the ACT CONCERNING A COMMITTEE ON THE PRACTICE OF NATUROPATHY. This act allows for the establishment of a committee to address the prescription formulary for naturopaths, a change to scope of practice. As healthcare providers in the state of Connecticut, this act would potentially have major implications for CT patients, including APRN patients. The CTAPRN Society has testified and been outspoken regarding use of drugs in CT. and would like to be part of any discussion regarding the prescribing and dispensing of prescription drugs by a profession seeking a change of scope of practice to become prescribers. We are supportive of the profession of Naturopathy but are concerned and have questions. As CT prescribers, we believe this would be an opportunity to contribute in an informed manner if such a committee is formed. Thank you for your consideration.

Christina Morrissey DNP NP-C
Co-Chair of the Health Policy Committee for CTAPRN Society
Morrissey.Christina@yahoo.com
(860)753-0293

The Connecticut Society of Eye Physicians M.D.

P.O. Box 854, Litchfield, CT 06759 Tel (860)567-3787 Fax (860)567-3591

May 30, 2016

Raul Pino, M.D., M.P.H.
Commissioner
Department of Public Health
P.O. Box 340308
Hartford, CT 06134

Dear Dr. Pino:

I am writing on behalf of the Connecticut Society of Eye Physicians (CSEP), the ophthalmologists' organization representing over 300 eye MDs statewide. We are writing in response to Special Act 16-3 An Act Concerning a Committee on the Practice of Naturopathy. We do not feel that, in a time of severe budget constraints, a committee to rehash what was already done by a Scope Review Committee just three years ago is a productive use of taxpayer funds. That committee spent many hours reviewing Naturopathic training and listening to their rebuttals and arguments, and concluded that they do not have the training requisite to the responsibility of prescribing legend drugs. Nothing has changed in the interim.

In the event that circumstances require convening another committee to look at this issue as outlined in SA 16-3, the Connecticut Society of Eye Physicians requests to be included on the committee as representatives of a health care profession (ophthalmology) that may be affected by a change to allow persons licensed to practice naturopathy to prescribe, dispense or administer prescription drugs (cf sec 1, (a) 2 of SA 16-3). Naturopaths have stated repeatedly during testimony for this legislation and during the Scope of Practice Review Committee meetings that they intend to use this authority to prescribe treatment for glaucoma and other eye conditions. This claim is troubling to say the least. Glaucoma is a complex disease. Proper management requires years of training and sophisticated equipment. Modern glaucoma treatment involves far more than simply monitoring intraocular pressure (itself a learned skill requiring consistent, accurate measurement using equipment not found in a general practitioner's office). The standard of care also requires assessment of corneal thickness, monitoring of visual fields using standardized equipment and protocols, and imaging of the optic nerve. Even my fellow MDs who do not practice ophthalmology do not have the hubris to claim they can properly manage this disease. That NDs do not recognize their limitations here is worrisome. A physician that does not know what they do not know is dangerous. Improper management of glaucoma can

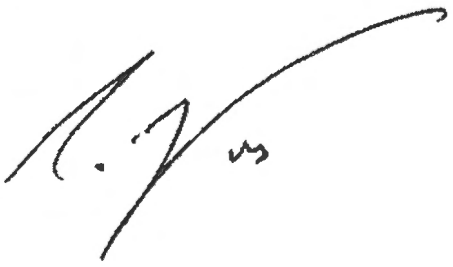
lead to blindness and all of its associated morbidity and social cost. And this is just one field of concern.

Naturopathic training contains very limited exposure to proper use of prescription medications, and virtually no practical experience in their management. It affords only passing mention of glaucoma and its proper management, and no experience at all in treating this chronic disease over time. Hoping NDs will incorporate better training if they gain the authority to prescribe is putting the cart before the horse. In almost any other field of endeavor, proof of capability must be demonstrated before privileges are given. Even Little League Baseball has tryouts.

Allowing this change would adversely impact the eye health of Connecticut's residents and place them at risk of receiving substandard care, with potentially blinding consequences. The effects could be calamitous for patients and their families. Patients are confused already by the vast array of providers for their care. They already have trouble determining if they are receiving quality care. The state cannot rely on public education and caveat emptor alone to protect them. Adding another provider with limited training but unlimited authority will only create bigger problems.

Finally, while not specifically an eye-related problem, nothing in this bill would restrict NDs from prescribing controlled substances. The diversion of even properly prescribed opioids is an epidemic problem resulting in deaths every day. The DEA recognized that a larger pool of prescribers is directly linked to more diversion, irrespective of the number of fraudulent prescribers. That is why they reclassified several medications recently. Adding more providers with authority to prescribe will only increase the problem.

Sincerely,



Steven Thornquist, MD
Legislative Co-Chair
Connecticut Society of Eye Physicians

Connecticut Coalition of Advanced Practice Nurses

American College of Nurse-Midwives (ACNM), Region I, Chapter 2
Connecticut Advanced Practice Registered Nurses Society (CTAPRNS)
Connecticut Association of Nurse Anesthetists (CANA)
Connecticut Nurses' Association (CNA)
Connecticut Chapter of the American Psychiatric Nurses Association (APNA-CT)
National Association of Pediatric Nurse Practitioners (NAPNAP), Connecticut Chapter
New England Chapter of the Gerontological Advanced Practice Nurses Association (NEGAPNA)
The Northwest Nurse Practitioner Group

May 31, 2016

To: Connecticut Department of Public Health

Re: Special Act No. 16-3: AN ACT CONCERNING A COMMITTEE ON THE PRACTICE OF NATUROPATHY.

As Chair of the Coalition of Advanced Practice Nurses, representing the above organizations, I am writing to request participation to discuss establishment of a committee to explore prescription formulary for the CT Naturopaths. As this is a change in their scope of practice and APRNS are prescribers, this matter should be given high priority given the recent issues surrounding prescribing medications. Naturopaths provide excellent care to the residents of Connecticut. Collaboration with our colleagues is essential to provide the best care to the residents of Connecticut. APRNS are deeply concerned and vocal about the current issues surrounding prescribing drugs and would welcome an opportunity to participate in these discussions. Having been through the Scope of Practice Review process, we welcome an opportunity to discuss this issue further if a committee were formed.

Sincerely,

Lynn Rapsilber

Lynn Rapsilber DNP ANP-BC APRN FAANP
Chair: Coalition of Advanced Practice Nurses
lrapsilber@optonline.net

Connecticut State Medical Society
FOUNDED IN 1792

127 Washington Avenue, East Building, 3rd Floor, North Haven, CT 06473-1715
Phone (203) 865-0587 Fax (203) 865-4997 www.csms.org

May 31, 2016

Raul Pino, M.D., M.P.H.
Commissioner
Department of Public Health
P.O. Box 340308
Hartford, CT 06134

Re: Impact Statement of the Connecticut State Medical Society Relevant to Special Act 16-3: An Act Concerning A Committee on the Practice of Naturopathy

Dear Commissioner Pino,

Special Act 16-3 An Act Concerning a Committee on the Practice of Naturopathy began its life as HB 5534 An Act Concerning the Practice of naturopathy, a bill that contained language establishing the concept of "advanced naturopathic care" based exclusively on the ability of naturopaths to prescribe, dispense and administer legend drugs; everything else in the definition already fell within the scope of practice of an ordinary naturopath. In the process of creating this vehicle for scope expansion they also created a contradiction in terms that lies at the core of our objections. The safe and effective prescribing, dispensing and administering of legend drugs is fundamentally dependent upon understanding and respecting human physiology, biochemistry and pharmacology; science based medicine, the realm of allopathic medicine whereas naturopathy derives its philosophy mostly from ancient teachings and historic precedent and not from evidence based studies. The advancement in "advanced naturopathic care" comes not from the expansion or development of naturopathic concepts, but from borrowing of foreign and previously rejected allopathic processes without embracing the underlying philosophy.

The Connecticut State Medical Society, and its constituent organizations along with a number of specialty societies and other health care specialties have opposed the expansion of scope by naturopaths into prescriptive authority since their first efforts more than three years ago. In 2013 the naturopaths were granted a scope expansion committee hearing process that determined that graduates of naturopathic colleges had insufficient education and training to prescribe legend drugs. The committee process highlighted many of the deficiencies in naturopathic education and training including a significant emphasis on didactic, lecture based learning and the absence of meaningful opportunities for the practical application of skill. Although naturopathic students take a course in pharmacology, as do medical students, they have no opportunity to apply their knowledge in the clinical setting under the supervision of faculty.

Unlike medical schools, naturopathic colleges are not connected with hospitals and other medical institutions where they would have access to patients. The faculty of naturopathic schools is almost entirely part time with few if any having any experience prescribing legend medications. Reports in the media have highlighted the necessity of naturopathic students having to learn their diagnostic skills almost entirely by practicing on each other. This is far from ideal. Medical students, on the other hand, begin with a strong foundation in basic medical science, but spend more than half of their medical school experience in clinical settings, getting the same sort of "hands-on" experience

that the apprentice electrician gets in the field under the supervision of an experienced, licensed professional. The training a physician receives with regard to prescriptive authority amounts to

8,000 to 10,000 hours beyond the basic pharmacology course, time spent in clinical rotations in medical school, internship, residency training and fellowships. The value of this exposure and experience cannot be underestimated.

Medical schools are highly selective institutions. The average medical school accepts only 2-3% applicants whereas the acceptance rates for most naturopathic schools are close to 100%. Students competing for a spot in a medical school have to do well in all of their classwork and especially in rigorous science and math pre-medical subjects. They begin their medical school careers with a solid understanding of the scientific method and its application to care. Pharmacology is taught, not as a mostly irrelevant aside, but as the foundation for an understanding of pharmacokinetics and its application to the use of legend medications.

The naturopaths assert that a two-semester course in pharmacology along with passing a test in pharmacology should be the only prerequisite for prescriptive authority, and yet we do not authorize our pharmacists to prescribe, dispense or administer any legend drug other than naloxone, despite undergoing a far more rigorous education and training in pharmacology. Physicians do not learn how to prescribe in a pharmacology class. They learn how to prescribe in their clinical rotations in thousands of hours of education and training in medical school, internship, residency and for many if not most, fellowships too.

These deficiencies have been made clear to the leadership of the naturopaths in Connecticut and to Vice Provost of the Health Sciences Division of the University of Bridgeport, David Brady, ND. They have chosen not to address them.

Much has been said about the necessity of this particular scope expansion to support the University of Bridgeport, but too little has been said about the impact it might have on the health and well-being of the citizens of Connecticut. Is there any evidence that patients are clamoring for this expansion of scope? Is there any evidence that access to health care will be substantially improved if naturopaths have prescriptive authority? The best we have heard is only that patients will be spared the necessity of going to two doctors, but is that so bad? Under the present statutes all patients who go to a naturopath are perfectly aware that they cannot obtain prescription medications from a naturopathic physician. But should things change, patients will assume that a naturopathic physician, a doctor with ND behind his or her name, has exactly the same education and training as a medical doctor with an MD or DO, and that is not honest, transparent or true, and neither is it safe.

During the scope committee hearings we grappled with many concepts including limited formularies and attitudes about vaccination, issues that merit discussion even now. Initially the naturopaths insisted on full prescriptive authority, including even controlled substances, but after sensing significant resistance they came back with a much smaller panel of classes. This new restricted formulary still included oxytocics, abortifacients and glaucoma medications. We found it extremely difficult to understand why naturopaths would want to use either of the former, and even one of their chief panel members, a licensed pharmacist and naturopath could not explain why these classes were selected for inclusion. Those of us on the committee who are ophthalmologists immediately recognized the absurdity of insisting upon glaucoma medications for the simple reason that the diagnosis and management of glaucoma extends well beyond simple pressure measurement such that it is neither practical nor safe for anyone but an eye specialist to perform this function. Even the most highly trained naturopaths on the committee did not know enough about glaucoma to

defend their stance. One thing that became immediately clear from our committee discussions was the enormous difficulty posed by creating a narrow formulary. Even some of the safest and most commonly used medications pose risks that can put lives at risk.

More troubling are naturopathic attitudes toward vaccination. Many naturopaths are negatively disposed toward vaccinations either because they have bought into disproven theories about autism or because they believe, despite the absence of evidence, that certain metals contained in some vaccines are toxic to the human body. It is not unusual for a naturopath to counsel patients about vaccination in a risk-benefit analysis that plays to the risks while understating the benefits. Who among us has seen a case of polio? And yet we are increasingly seeing outbreaks and mini-epidemics of measles and pertussis that are generated solely because our herd immunity is declining as a consequence of liberal attitudes about non-compliance with mandatory vaccinations.

There is little if any evidence that naturopathic education and has changed appreciably since 2013. Naturopathic training has not changed at all since it is all but non-existent. A naturopath can practice in Connecticut with a degree only and without the rigorous testing and extensive postgraduate experience that is the most important part of a physician's training and that has become the established standard for excellence. The decision to grant scope expansion should be based first and foremost upon the need and safety of the citizens of this state and not on the needs of a local educational institution or the desires of any one group of providers We hope and trust that safety and quality of care remain the paramount concern in any determination or recommendation by the Department of Public Health. To do otherwise would return us to the pre-Flexner era when any physician could claim competence and patients were at the mercy of un-measurable ability and experience. We respectfully request representation on any committee so formed by the Commissioner of Public Health pursuant to Special Act No. 16-3.

Sincerely,

Matthew C. Katz
Executive Vice President/CEO

David K. Emmel, MD
Chair, Legislative Committee

CONNECTICUT ACADEMY OF
FAMILY PHYSICIANS
CARING FOR CONNECTICUT'S FAMILIES

Commissioner Raul Pino, M.D., M.P.H
Department of Public Health
410 Capitol Avenue
P. O. Box 340308
Hartford, CT 06134

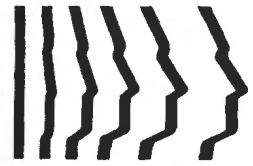
On behalf of over 400 Family Physicians who are members of the Connecticut Academy of Family Physicians (CAFP) we are submitting these comments regarding whether the naturopaths can or should be granted certain prescriptive authority

The CAFP opposes this expansion for services by Naturopathic physicians due to the impact it would have on providing quality of care to the people of Connecticut. Although they have extensive training in using botanical medicines, education in pharmacology of prescription medications is extremely limited - just 4 credits are required at the University of Bridgeport. In addition, 90-95% of naturopaths do not go on to residency training where MD's and DO's gain extensive knowledge of prescribing in clinical practice. Current problems with the over use of antibiotics and narcotics can only worsen the challenges that we already have by adding more prescribers to the system who have far less experience.
If a scope of practice review committee is created, we request that a representative of the CAFP be allowed to participate.

Very truly yours,

Mark Schuman
Executive Director

One Regency Drive • P.O. Box 30 • Bloomfield, CT 06002
Telephone (860) 243-3977 • (800) 600-CAFP in CT only • *FAX* (860) 286-0787 • *Web Page* www.ctafp.org



The Connecticut Society of

Plastic Surgeons, Inc.

May 31, 2016

Raul Pino, M.D.
Commissioner of Public Health
410 Capitol Avenue
PO BOX 340308
Hartford, CT 06134

Dear Commisioner Pino:

I am writing to you as President of the Connecticut Society of Plastic Surgeons, Inc. regarding House Bill No. 5534 Special Act No. 16-3 An Act Concerning A Committee On The Practice of Naturopathy.

Changes to the general statute that allow persons licensed to practice naturopathy to prescribe, dispense or administer prescription drugs are concerning. In reviewing the curriculum of naturopathic school programs, there appears to be no consistent education regarding current prescription medications. In fact, one of the tenets of naturopathy has always been an approach to healing without prescription medications.

Unlike allopathic and osteopathic physicians, the overwhelming majority of naturopathic practitioners do not go on to residency programs. This is a critical component of medical education where physicians spend an additional 12,000 hours on post doctoral training, sometimes even more with fellowship training.

With the current lack of required post doctoral training for naturopathic providers, there is no way for naturopaths to have first hand knowledge of prescriptive medications and their potential interactions and side effects in the clinical setting upon leaving the school setting. This lack of practical education needs to be fully addressed as it may lead to unnecessary harm to patients.

Physicians who currently have prescriptive authority are concerned about the scope of practice expansion for naturopathic providers without clear indications of prior education, testing of prescription medication knowledge prior to obtaining prescriptive authority or defined continuing medical education. In addition, it would be significantly outside of the scope of practice of naturopathic providers to have full access to prescriptive authority of all medications as allopathic and osteopathic physicians have received additional education after completing school. For all of the reasons outlined above, a limited naturopathic formulary needs to be developed and carefully monitored.

CSPS would also like to request that a member of our organization serve on the committee that may be established under HB 5534, Special Act 16-3, AAC A Committee on the Practice of Naturopathy.

Please do not hesitate to contact me with any further questions or to discuss this matter in further detail.

Sincerely,

Orlando DeLucia, MD
President
CSPS, Inc.

American Academy of Pediatrics
HEZEKIAH BEARDSLEY CONNECTICUT CHAPTER

HEZEKIAH BEARDSLEY CONNECTICUT CHAPTER

104 HUNGERFORD STREET • HARTFORD, CT 06106 • TEL. (860) 525-9738 • FAX (860) 727-9863

May 31, 2016

Raul Pino, M.D., M.P.H.
Commissioner Department of Public Health
410 Capitol Avenue
P.O. Box 340308
Hartford, CT 06134

Dear Commissioner Pino,

I am writing today on behalf of our members, the nearly 1000 pediatricians in the state of Connecticut who are the clinicians most educated in pediatric health care and have the depth and breadth of knowledge, skills, and experience to diagnose and deliver optimal care to children.

I am expressing our deep concern with regard to Substitute House Bill No. 5534 Special Act No. 16-3 AN ACT CONCERNING A COMMITTEE ON THE PRACTICE OF NATUROPATHY.

The American Academy of Pediatrics (AAP) advocates that every child receive high-quality, accessible, family-centered, continuous, coordinated, comprehensive care in a medical home. To this end, optimal pediatric care is best delivered in a team-based approach that is led by a primary physician, ideally a pediatrician, who assumes responsibility for managing the patient's care. All professionals who provide pediatric care must hold to the highest standards of education and training and continually demonstrate their skills and competencies.

In recent years, the health care market has seen a significant increase in the number of non-physician clinicians who seek to care for children. Professional associations for psychologists, pharmacists, massage therapists, physical therapists, occupational therapists, optometrists, acupuncturists, naturopaths, homeopaths, and chiropractors have actively sought expanded scopes of practice in the care of children. In an ever growing and more complicated health care delivery system, patients and families need to know what services these clinicians are licensed and trained to provide and understand the differences in education and skills among them. In that light, I am attaching a chart (see below) that shows the level of training a pediatrician needs in order to be competent in their scope of practice. Often, a specialist needs seven over more years of specialized education, including 12-14,000 hours of clinical patient hours.

https://www.aap.org/en-us/advocacy-and-policy/state-advocacy/PublishingImages/Pediatric%20Education%20and%20Training%20State%20Advocacy%20Infographic.jpg

Knowing that scope of practice legislation falls under the jurisdiction of individual states, state legislatures are therefore the loci of deliberations on these issues. The competing political agendas and perspectives

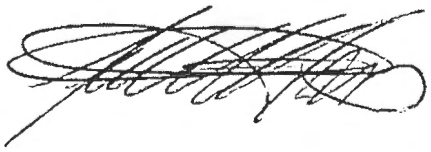
expressed during these deliberations often generate highly charged debates. To bring a uniformity of approach and an essential level of civility to this discourse, the AAP endorses the 2005 recommendations of the Federation of State Medical Boards regarding the approach to scope of practice legislation.[16] A portion of the Federation of State Medical Boards statement follows: "Changing or creating a new scope of practice for a health profession necessitates establishment of a legitimate need for the change, along with a systematic review of the impact of the proposed change on public health, safety, and welfare. Patient safety and public protection must be the primary objectives in making decisions on scope of practice. It is important for boards and legislatures to recognize that there are often significant differences in the prerequisites, the scope, and the duration of education provided to other health care practitioners when compared with that provided to physicians. Policy makers must ensure that all practitioners are prepared, by virtue of education and training, to provide the services authorized in their scope of practice in a safe, effective, and economical manner."

Our direct concerns related to naturopaths having the ability to prescribe, dispense or administer prescription drugs given that they generally believe that only natural substances are necessary. Pediatricians are trained for hundreds of hours on prescription medications and the implications with children from birth until adulthood. Pediatricians and allopathic physicians in general have extensive training in pharmacology as well as toxicology and prescribe medications with a keen awareness of the effects as well as the side effects of the drugs they prescribe. This is a key difference between pediatricians and naturopaths.

Additionally, there is great disagreement between pediatricians and naturopaths regarding vaccinations. The AAP believes in the importance and life saving need to vaccinate children and young adults against preventable diseases. We believe that naturopaths do not.

Thank you for your time and attention, and I would be very pleased to answer any questions you may have.

Yours truly,



Anton Alerte, MD
President

Appendix B

Committee Membership

Committee on the Practice of Naturopathy
(Established pursuant to Special Act 16-3)

Organization	Representative(s)
American College of Surgeons Professional Association, Inc.	Brendan Campbell, MD, MPH, F ACS
Connecticut Academy of Family Physicians	Frank Crociata, DO Dom Casablanca, MD
Connecticut APRN Society	Penny McEvoy, DNP, APRN, ANP-BC
Connecticut Coalition of APRNs	Donna Sanchez, CRNA Lynn Rapsilber, DNP, APRN-BC, FAANP
Connecticut Naturopathic Physicians Association	Rick Liva, RPh, ND Daniel Seitz, JD, EdD Richard Malik, ND
Connecticut Nurses Association	Stephanie Knutson, MSN, RN Thomas Regan, MD
Connecticut State Medical Society	David Emmel, MD Kenneth Ferrucci, MPA
Connecticut Department of Consumer Protection, Drug Control Division	Rodrick Marriott, RPh
University of Bridgeport	Marcia Prenguber, ND, Dean Jose Mahfoud, MD, ND, Professor David Brady, ND, Vice Provost

Appendix C

Tennessee & South Carolina Naturopathy Laws

2015 Tennessee Code
Title 63 - Professions Of The Healing Arts
Chapter 6 - Medicine and Surgery
Part 2 - General Provisions
§63-6-205 - Practice of naturopathy.

Universal Citation: TN Code § 63-6-205 (2015)

(a) It is unlawful for any person to practice naturopathy in this state.

(b) "Naturopathy" means nature cure or health by natural methods and is defined as the prevention, diagnosis and treatment of human injuries, ailments and disease by the use of such physical forces as air, light, water, vibration, heat, electricity, hydrotherapy, psychotherapy, dietetics or massage and the administration of botanical and biological drugs.

(c) (1) In no event shall naturopathy mean the sale of herbs or natural health information exchanges provided as a service so long as:

(A) The sale or provision of information exchanges is not conducted for the purpose of the prevention, diagnosis or treatment of any physical ailment or physical injury to or deformity of another; and

(B) In any instance involving natural health information exchanges, the seller obtains a signed acknowledgement from the buyer that the seller is neither a licensed practitioner of the healing arts in this state, nor meets the recognized qualification criteria that would allow the provision of any form of diagnosis, treatment recommendation or medical care in this state. For the purposes of meeting the requirements of this section, the seller shall keep the signed acknowledgement from the buyer on file for a period of three (3) years.

(2) [Deleted by 2012 amendment.]

(d) A violation of this section is a Class B misdemeanor.

(e) This section does not apply to persons who comply with the regulatory laws of the state with respect to the practice of the various healing arts.

http://law.justia.com/codes/tennessee/2015/title-63/chapter-6/part-2/section-63-6-205/

South Carolina Code of Laws
Unannotated

Title 40 - Professions and Occupations

CHAPTER 31

Naturopathy

SECTION 40-31-10. Practice unlawful.
It shall be unlawful for any person whether heretofore licensed or not under the laws of this or any other State to practice naturopathy in this State.

HISTORY: 1962 Code Section 56-901; 1956 (49) 1624.

SECTION 40-31-20. Penalties.
Any person violating the provisions of this chapter shall, upon conviction, be guilty of a misdemeanor and be fined not exceeding five hundred dollars or be imprisoned for a period of not exceeding one year, or both, in the discretion of the court.

HISTORY: 1962 Code Section 56-902; 1956 (49) 1624.

Appendix D

Federation of Naturopathic Medicine Regulatory Authorities (FNMRA): *Naturopathic Regulatory Authority General Information Links*

Naturopathic Regulatory Authority General Information Links

US Regulatory Authority Home Page	Contact Information	Statutes and Rules	Verification of License or Discipline Record	Continuing Ed Requirements	Formulary List or Prescriptive Authority
Alaska	contact	Statutes and Regulations	License Search	no online information available	no prescriptive authority
Arizona	contact	Statues and Rules	License Search	Continuing Education	prescriptive authority
California	contact	Laws and Regulations	License Search	Continuing Education	modified prescriptive authority
Connecticut	contact	Statutes	License Search	Continuing Education	no prescriptive authority
Colorado	contact	Laws, Rules and Policies	License Search	Laws, Rules and Policies	no prescriptive authority
District of Columbia	contact	Municipal Regulations	License Search	Continuing Education	no prescriptive authority
Hawaii	contact	Statutes and Rules	License Search	no online information available	Formulary list
Idaho	Has ND licensing laws but no licensing board	Licensure in Idaho			
Kansas	contact	Administrative Regulations	License Search	Continuing Education	modified prescriptive authority
Maine	contact	Laws and Rules	License Search and Verification	Continuing Education	modified prescriptive authority
Maryland	FAQ about Maryland licensure laws	House Bill 402	License will be required 3/1/2016		
Minnesota	contact	Statutes	License Search	Continuing	no prescriptive authority

				Education	
Montana	contact	Rules	License Search	Continuing Education	Formulary List
New Hampshire	contact	Laws & Rules	no online information available	Continuing Education	Formulary List
North Dakota	FAQs for practicing in North Dakota	Laws	List of licensed NDs	rules still being developed	rules still being developed
Oregon	contact	Laws and Rules	License Verification	Continuing Education	Formulary List
Puerto Rico	no online information available				
Utah	contact	Statutes and Rules	License Verification	Continuing Education	Formulary List
Vermont	contact	Statutes and Rules	License Search	Continuing Education	Prescriptive authority
Washington	contact	Laws	License Verification	Continuing Education	Prescriptive authority
US Virgin Islands	Has ND licensing laws but no licensing board	VI Code, title 27, chapter 4			
Canadian Regulatory Authority Home Page	**Contact Information**	**Laws and Regulations**	**Verification of License or Discipline Record**	**Continuing Ed Requirements**	**Formulary List or Prescriptive Authority**
British Columbia	contact	Laws and Regulations	Licensed Search	Continuing Education	Prescriptive Authority
Alberta	contact	Naturopaths Profession Regulation	Search for Registered Members	no online information available	no prescriptive authority
Manitoba	contact	Naturopathic Act & Regulations	List of Active Registrants	Continuing Education	no prescriptive authority
Ontario	contact	Naturopathy Act & Regulations	Registered ND list	Continuing Education	prescriptive authority granted after passing Prescribing exam
Saskatchewan	contact	Naturopathy Act	Registered ND list	Continuing Education	no prescriptive authority

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Appendix E

The Journal of Alternative and Complementary Medicine:
Evidence-Based Medicine and Naturopathy

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 12, Number 3, 2006, pp. 323–328

PERSPECTIVES

Evidence-Based Medicine and Naturopathy

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ABSTRACT

Evidence-based medicine (EBM) has been advocated as a new paradigm in orthodox medicine and as a methodology for natural medicines, which are often accused of lacking an adequate scientific basis. This paper presents the voices of tradition-sensitive naturopathic practitioners in response to what they perceive as an ideologic assault by EBM advocates on the validity and integrity of natural medicine practice. Those natural medicine practices, which have tradition-based paradigms articulating vitalistic and holistic principles, may have significant problems in relating to the idea of EBM as developed in biomedical contexts. The paper questions the appropriateness of imposing a methodology that appears to minimize or bypass the philosophic and methodological foundations of natural medicine, and that itself seems primarily driven by political considerations.

INTRODUCTION

This paper has developed as a response to the emergence of evidence-based medicine (EBM) as a "new paradigm" in orthodox medicine[1] and a "new" rationale for health policy workers.[2] The authors' position is intended to reflect the logic of different naturopathic modalities in showing how the idea of EBM is problematic for naturopathy and other disciplines and practices that deploy "evidence" in their texts and professional lives. EBM assumes a hierarchy of knowledge and method, and is an implicit, if not explicit, critique of nonorthodox systems of health and healing. For instance from a pro-EBM position, it has been suggested that the evidence accepted by naturopathic practitioners is less valid and less reliable than "science-based" evidence.*,[3] This is the kind of unresearched dogma that has stimulated the writing of this paper.

Evidence and evidence-based practice needs to be understood as context dependent, and bounded by philosophic assumptions. The authors argue that the premises of EBM as developed by Sackett and his medical fellows are often inapplicable to these other modalities. EBM does have a role to play in complementary and alternative medicine (CAM), for example, but, as part of the mix of evidence, and not as a gold standard of clinical practice and research.† That is, natural scientific and medical reasoning are relevant and sometimes part of CAM and allied modalities, but they do not necessarily represent the dominant or preferred logic of these practitioners.

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*Rhetoric about the dangers of nonorthodox medicine has been so abundant in scientific medical journals, the media, and science-dominated tertiary institutions, such that bashing the nonorthodox has virtually become common sense for medical doctors and professional scientists. See, for example, Sackett et al., and Ernst.[3]

†As Singer and others have pointed out, CAM is a biomedical construction that tends to presuppose and validate the idea that CAM should converge toward the logic of biomedical and scientific orthodoxy. (Singer J, Fisher K. Appropriateness and resistance: The impact of the mainstreaming of traditional herbalism, forthcoming.)

The authors argue that a hierarchy of knowledge that privileges the randomized controlled trial (RCT), "scientific objectivity," statistically based "truths," and other canards, runs counter to most naturopathic ideologies and practice; and that demands from doctors, scientists, and policy makers for more hard evidence in the mix will contribute only tangentially to a further understanding of these medicines.

The present concern is with the potential for EBM rhetoric and institutional pressures to make naturopathy more submissive to medical dominance and widely coerce nonorthodox systems of health and healing to the mainstream, and to some extent to be co-opted by biomedical orthodoxy.[4,5]

The authors do not claim to represent all CAM and naturopathic practitioners, because this is a paradigmatically diverse group, but to the extent that these practitioners embrace holism and vitalism as core beliefs and practices, these views may be seen to resonate with what the authors contend is a more traditional standpoint. This perspective does not reject science, evidence, or empirical research, which will become more apparent in the following. Rather, the authors simply contend that these more traditionally based beliefs and practices are often marginalized and excluded by opponents and fellow practitioners keen to mainstream and/or scientize.‡

CLASSICAL EBM

The ideas of William Sackett are considered seminal in the current literature dedicated to EBM, as any web search will show. Sackett et al.[1] have defined EBM at some length, which is reproduced below for the insights this definition brings to the understanding of the epistemologic and institutional power relations presupposed as "normal."

> The practice of EBM means integrating clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgement that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patient's predicaments, rights and preferences in making clinical decisions about their care. By best available clinical evidence we mean clinically relevant research often from the basic sciences of medicine but especially from patient centred clinical research into the accuracy and precision of diagnostic tests (including the clinical examination) the power of prognostic markers, and the efficacy and safety of therapeutic rehabilitative regimens. External clinical evidence both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious and safer. (pp. 71–72)

Closer reading of this text reveals a number of dualisms/dichotomies in the reasoning. These dualisms line up under the difference between clinical expertise and clinical evidence, and reveal something of the institutional basis and power relations expressed in the idea of EBM. "External," "basic" scientific research, "tests," "markers" and the logic of the laboratory are contrasted with the "internal," subjective, individualistic practices and diagnoses of clinicians in the privacy of the clinic. This kind of dualistic logic is problematic for naturopaths, namely herbalists and hom[oe]opaths, in this study. It also reifies a public/private dichotomy that subtly reinforces the legitimacy and logic of state-controlled bureaucracy.

This kind of dichotomizing logic also buttresses the idea that there is a legitimate hierarchy of knowledge and method with the RCT as the gold standard and the clinician's notes, observations, and judgments right down there in status with ethnography, sociology, and anecdote.[6] As shown in this paper, there are practitioners of naturopathic modalities who do not subscribe to this hierarchy at all; they tend to see this as a form of nonholistic reductionism. The more insidious effect of this scientistic approach to evidence is that other naturopathic (and alternative) practitioners may simply assume that their craft is actually incompatible with "legitimate" science and medicine, and that they are just silly or nonscientific. Rather, this paper suggests that the general incompatibility results not from a failure of reason or logic, but to differences in cosmology and methodology that stem from the naturopath's genuine commitment to holistic health and the idea of participation in complex systems. This line of analysis speaks to the idea of paradigmatic difference and the logical inability of orthodox medicine or science in correcting, or coopting, healing modalities that are based in traditional approaches to health and healing.

EBM AS A HEGEMONIC CULTURAL MOVEMENT

Given that EBM involves elites, institutions, notions of progress, and much funding, it might be considered a hegemonic cultural movement generated as a continuation of the ascendency of medical dominance.§ In the United Kingdom, EBM has been identified by medical powerbrokers as a paradigm shift in medicine, and applied as a rationale for pub-

‡As discussed in Evans' forthcoming Ph.D. dissertation (Southern Cross University, 2006).

§Evan Willis and other sociologists of medicine have defined medical dominance to be constituted through hegemonic cultural practices.[7]

lic policy making, or in effect, the further marginalization of competing approaches to health. This cultural movement has registered as an explosion of institutions dedicated to the teaching, researching, and proselytizing of EBM.‖ There are dedicated journals, postgraduate courses and conferences, databases, and Web resources hosted by a plethora of centers and groups.¶

In the United Kingdom, EBM has been an integral part of the process of changing the organization of the health system. EBM prioritizes quantifiable data and quantitative research. This evidence, in conjunction with the statistical deployment of databases, has been able to provide meta levels of analysis and has particularly empowered statisticians, epidemiologists, and other quantitative analysts in the determination of health policy and infrastructure, as Charlton and Miles point out.[2] The impact of EBM in Australia and the United States does not appear so overwhelming, but there is one major institutional driver that has been identified as controlling in these countries, the insurance industry.[4] Although the detailed process may vary from country to country, the broad project is the same as it has been for centuries: Attack the medical competition; show no intellectual tolerance; and only take those prisoners who can be converted.

Of course, the general idea of evidence in medicine does not automatically entail the RCT, but it should be noted that alternative or traditional views that are not grounded in evidence from RCTs tend to be dismissed or marginalized as less valid. Sometimes this may be legitimate, but the purpose of this paper is to challenge the idea that the RCT is, or should be, the gold standard for CAM and naturopathy. One can only hope to begin this discussion in a short paper, but the general position is, nonetheless, that naturopathic research can proceed using evidence that is scientifically valid (i.e., empirically testable) without necessarily negating assumptions of holism or vitalism. This philosophical view cannot be argued in this short paper beyond asserting that naturopathy needs to continue to legitimize a variety of methodologies and epistemologies as part of its eclectic nature. Empiric evidence remains critically important, but science and the proponents of EBM need to be further educated about the wisdom of tradition. Of course, this does not exclude the converse either. The authors seek to promote discourse, not dogma.

TYPIFYING THE PROBLEMS NATUROPATHIC PRACTITIONERS CONFRONT

The contributing authors of this paper and other colleagues constituted themselves as a small focus group that might explore the philosophic, methodologic, and professional dilemmas that EBM raises for naturopathic modalities.#

Members of the working group were asked to consider what problems EBM raised for them as naturopathic professionals. The individual responses, as presented in the following, are most revealing. In the responses of the homeopath and two herbalists, the extent of the paradigm divide between EBM and their concerns is profound. Both modalities use evidence but in a holistic and vitalistic context.

The reflections of these naturopaths on the working logic of their modalities (their clinical logic) appears more complex than that of the RCT (the gold standard in EBM) and a generally reductive approach to the question of evidence. The authors suspect that most clinicians, both medically orthodox and naturopathic, would share misgivings about the possible "tyranny of EBM." This is actually Sackett's own phrase for the overenthusiasm for EBM. Although the individual responses presented in the following do not constitute a survey of practitioners as one might perform in a more extended analysis of these fields, they are typical, based on the authors' professional experience, related research, and the existing curricula of college and university courses. As the summary-analyses that which accompany each statement attempt to show, there is a strong consensus that EBM is antithetical to holistic and vitalistic philosophies of health.** Other shared concerns also arise.

AN HERBALIST'S RESPONSE TO EBM

My concerns regarding the adoption of EBM as a basis for medical decision making relate (a) to the underlying aims of, and values reflected within, our medical system, and (b) its applicability to CAM.

Values. EBM is held to contribute to "better" health outcomes and "more effective" medicine. However

‖In 2003 a Web site in the UK was found to list the following indicators: seven postgraduate courses, 33 journals with an EBM focus, 12 databases with an EBM focus, and a whopping 77 EBM "health web resorts which are Centres, Units and Collaborations" (e.g., The Cochrane Collaboration), among other activities and organizations. Accessed December 8, 2005: http://www.herts.ac.uk/lis/subjects/health/ebm.htm

¶Charlton and Miles provide more detail about conditions arising in the United Kingdom.

#In Australia, naturopaths are typically trained in a number of modalities, usually herbal medicine, nutrition, homeopathy and tactile therapies (massage). Within clinical practice, practitioners may specialize in area(s) of interest. Practitioners may vary in the extent to which they embrace science and medicine as fundamental in their beliefs and practices.

**The authors know of no reliable quantitative data about these differences, but the forthcoming theses of Evans and Howden (Southern Cross University, 2006) do begin to quantify these matters.

discussion is curiously absent regarding the values behind such statements, and questions such as "how should better health outcomes be measured?" and "what would a better health system look like?" have not been part of this debate.

For example to what extent are longevity, or the "saving of lives" markers of medical "success"? Given finite resources, is a society "healthier" when the bulk of its population is over 50, or over 80? Is it a sign of health when 90% of very premature babies survive but require more medical interventions for the rest of their lives?

Equations between "better medicine" and "more EBM" do not include the environmental impact of particular interventions. If such considerations were included in discussions of "best practice," a preferred treatment may be a medicinal plant that is 30% less effective but 90% less environmentally demanding than a pharmaceutical. However if these considerations are not included, the preferred treatment may be a drug which is 30% more effective and 90% more environmentally demanding.

CAM. Concern from herbalists and naturopaths in Australia (and elsewhere) regarding the application of EBM to CAM has focussed primarily on methodological issues, especially hierarchies of evidence, and the difficulties of applying of RCTs within disciplines where a multi-interventionist and individualistic approach to patient treatment is the norm. It is not only that treatment within the naturopathic disciplines involves multiple interventions, but also that practitioners consider multiple indicators of patient distress and improvement.

These treatments are complex, and the systems they seek to change are similarly complex. RCTs are a valuable source of information: it is their preferencing over other types of evidence which is problematic. The practical reality is that most RCT's are carried out by companies attempting to amass sufficient data to fulfil regulatory requirements for introducing a new product onto the market. Such trials aim to assess the safety and efficacy of particular products to alleviate particular symptoms or diseases. They contribute only marginally to the individualised prescriptions and advice which makes up the bulk of clinical herbal practice.

Summary

This account argues that:

1. EBM lacks concern for community health.
2. EBM does not account for ecologic considerations; and
3. Because herbal medicine is holistic and health oriented, it opposes complex interventions and interactions in naturopathic practice to the reductive process of isolating single factors and simple cause–effect relationships.

A HOMEOPATH'S RESPONSE TO EBM

The meaning of the word "evidence" changes according to who is allowed to define it.

The "evidence" of EBM is largely that which arises from the Random Controlled Trial (RCT). It involves levels of significance of the chance of removal of individual symptoms (in past cases) and bears no relevance to future cases except in terms of the "probability" of "success" or "failure." It is incapable of predicting "success" (or failure) in any one individual case.

The "evidence" of homeopathy is twofold and is specific to the individual case.

- On the one hand we have the "evidence" of the remedy as collected in "provings"—the symptoms produced by feeding carefully controlled doses of a substance to "healthy" human beings
- On the other hand we have the "evidence" collected from the patient—an holistic picture of the totality of symptoms being experienced by the patient, constructed in a way that is readily comparable with the evidence of the provings.

It is the philosophy of homeopathy—that "like cures like" (*similia similibus curentur*)—which links these two pieces of evidence. This philosophy states that a match of the "major" symptoms of the remedy with the "major" symptoms of the patient will assist in the movement toward "cure."

Disease, according to EBM, is characterized by a collection of (largely unrelated) symptoms, the mere removal of which is then said to constitute "cure" (or at least "success" in an RCT).

Homeopathy, on the other hand, is based on an Hippocratic, humorally based model of the human being—consisting of earth, water, air and fire (body, mind, soul, and spirit). The homeopath is therefore interested in all aspects of the human being in-so-far as they "point" to the nature of the *dis*-ease.

In homeopathy "success" is the improvement of "well-being" and "quality of life" resulting from the matching of the totality of symptoms of the patient with the totality of symptoms of the remedy. This will normally (although not necessarily) also involve the removal (or at least the easing) of the symptom picture. The symptoms are not the disease—they point to the nature of the disease. *Dis*-ease, within this model, is a necessary means to growth and human evolution, and longevity is a possible consequence rather than an aim.

Summary

In this practitioner's view:

1. Statistically based inferences about the likelihood of outcomes for typical cases are of little use in the treatment of individual cases. The homeopath follows patient symptoms over a length of time and the analysis of patterns of change requires holistic logic and practice. That is, in individual cases it is not possible to isolate symptoms and causes from the whole person. Knowledge from RCTs would be of little use in therapeutic practice.
2. The kind of evidence involved in homeopathy derives from controlled processes that have been largely validated through continued observation and assessment and documented since the time of Samuel Hahnemann, (M.D.) at least. The kind of data generated in this historical process could not be replaced by data from RCTs.
3. The logic of the RCT is alien to hom[oe]opathy as shown by the difference in their desired outcomes.

A NATUROPATH'S RESPONSE TO EBM

Naturopathy, a Western nonbiomedical ethnomedicine is based on holistic and vitalistic principles[8] whereas biomedicine, the prevailing ethnomedicine is based on scientific reductionist principles.[9,10] Given such extensive difference it is inappropriate to superimpose reductionist methodologies that are paradigmatically incongruent with the holistic practice of naturopathy.

The notion of "the whole being greater than the sum of the parts" epitomises the philosophical differences between "traditional naturopathy" and scientific medicine.[11] Traditional naturopathy does not easily fit into a scientific research model. For example, three patients presenting with migraine as their primary health concern are likely to receive three very different herbal formulas that take into account the unique nuances of the individual. As EB methodology gives primacy to RCTs which is based on limiting as many variables as possible, application is methodologically incongruent to traditional herbal/naturopathic treatment. It is of course possible to apply EB methodology to a named active isolated plant constituent or to a specific nutrient. However, traditional naturopathy is base on the understanding that a plant's efficacy is based on the synergy of the whole plant rather than a so called "active constituent." RCTs simply cannot cope methodologically with the holistic nature of naturopathic medicine.

By imposing EBM, naturopathy is not legitimated according to its own paradigmatic definitions, but rather, is evaluated according to the parameters set by the scientific model resulting in the marginalization and corruption of "traditional naturopathic knowledge." This is exemplified in the practice of "scientific herbal medicine" (phytomedicine) in which only herbs subjected to and validated by RCTs are legitimated as effective medicines. Such herbs are then symptomatically prescribed to treat specific disease states, rather than applying a whole person/whole plant approach. The knowledge base of traditional naturopathy is taken out of context and inappropriately manipulated to fit a scientific paradigm.[6] As a result, traditional knowledge and practice is dismissed, devalued and in real danger of becoming extinct!

Summary

According to this practitioner:

1. Naturopathy is based on holistic and vitalistic principles.
2. Biomedicine is based on reductionism and is paradigmatically incongruent with naturopathy.
3. EBM marginalizes and corrupts traditional naturopathic knowledge.

A NATUROPATHIC EDUCATOR'S RESPONSE TO EBM

EBM represents a style of thinking that appears to exclude the possibility of a truly holistic approach to health care. The hierarchy of evidence includes, in theory, a range of approaches that encompasses different treatment strategies and types of authority. The reality is quite different, with the RCT dominating the validation of knowledge and empowering a specific branch of health care to continue its domination. The approach rests on a completely unquestioned assumption about the superiority of Western based biomedicine. The concept that there might be other ways of looking at health is not even raised it is so remote to the theoreticians who advocate the use of EBM. Vitalism lies at the heart of natural medicine, a deep respect for the body's self-healing capacity and a commitment to working with that innate force. Vital force! How does the RCT cope with that! Where does preventative medicine fit in? What about traditional practices?

Untested, blanket acceptance of EBM education has serious ramifications for CAM. When the educational direction changes, there is the potential to create a whole new style of thinking in the next generation of practitioners. If the structures of EBM are taken into the classroom and given as untested authority of the integrity of CAM, then somehow CAM has surrendered its authority to an external measure, without so much as a whimper. Upcoming practitioners will

teach, as they have been taught. If they are not given a deep understanding of what holism and vitalism means, rather only the small range of science-based versions of CAM as validated by EBM, then the profession will change and holism as a concept will become diluted.

Summary

In this educator's opinion:

1. EBM is antithetical to holistic and vitalistic approaches to health care; and
2. There is danger that EBM will be accepted uncritically in educational institutions.

CONCLUSIONS

The word "evidence" recently has gained a new weight in medical discourse and institutional life, but in Australia so far EBM has mainly impacted only rhetorically on naturopathy. EBM has been touted as a "new paradigm" and as a corrective for outdated, bad or unscientific practices. Although it may be true that some medical and health practices are not supported by a weight of evidence and that this can lead to harm, it does not follow that doctors, scientists, or any bureaucrats should have a monopoly on the meaning and deployment of evidence.

As discussed, the core assumptions and institutional focus of EBM is largely antipathetic to those naturopathic modalities that emphasize vitalism and holism in their foundations. This critical issue of course refers to the broader question of naturopathy's survival within a culture that is socially, politically, and economically dominated by biomedicine. The RCT and other empirical modes of health research are undoubtedly valuable additions to health-related stocks of knowledge, but in the context of both the institutionalization of naturopathy and the basic comprehension of naturopathic modalities, it is emphasized that naturopathy needs to be understood as having and requiring firm foundations in traditional and nonorthodox modalities of health and healing first and foremost. These philosophies are the baseline of the naturopathic approach and need to be respected and preserved when there is any move by external forces to create an integrative shift in healthcare practice.

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Appendix F

Bastyr University: *Naturopathic Doctors Adopt Evidence-Based Medicine, Study Finds*

Thursday, August 8, 2013

Naturopathic Doctors Adopt Evidence-Based Medicine, Study Finds

Researchers describe a cultural shift toward balancing clinical evidence, judgment and patient values.

Clinical training taught researcher Joshua Goldenberg, ND, that medicine is both a science and an art.

Naturopathic doctors (NDs) increasingly embrace evidence-based medicine as part of their practice, according to a study by Bastyr University researchers published in the *International Journal of Naturopathic Medicine*.

The study asked naturopathic leaders about their attitudes toward evidence-based medicine (EBM), the philosophy that medical practice should be guided by the best available research data, balanced with a doctor's judgment and a patient's values. Those interviewed described a "rapid cultural shift" among NDs toward "cautious embrace" of evidence-based medicine, the authors wrote.

"I was glad to see the results," says co-author Jane Guiltinan, ND, dean of Bastyr's School of Naturopathic Medicine. "I came to naturopathic medicine from a conventional medical background and believe that, for naturopathic medicine to evolve and become more effective, the field needs to bridge the worlds of science and naturopathic philosophy. The study suggests that's happening."

It's a significant finding for a discipline sometimes seen in tension with

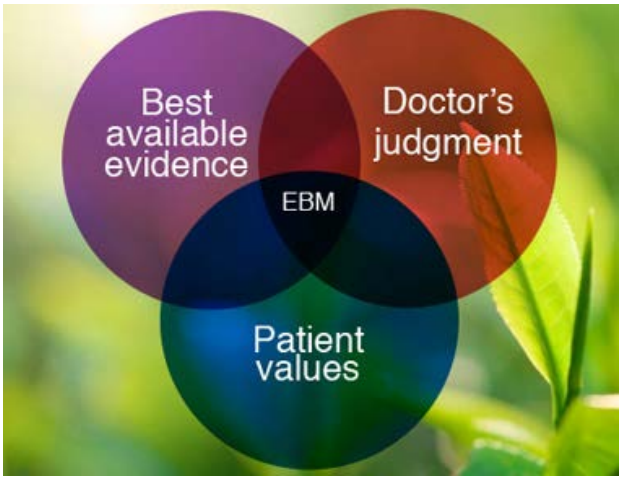
scientific conventions. Naturopathic medicine rests on the philosophy of *vis medicatrix naturae* — the healing power of nature. While naturopaths have conducted and used clinical research for years, they stress that there are things conventional science cannot measure, such as the body's natural ability to heal. The findings suggest the profession is growing more comfortable integrating science and nature, says lead author Joshua Goldenberg, ND ('13).

"For me, the big message is not that there are different camps among naturopaths, but that this culture is changing rapidly," says Dr. Goldenberg, a recent graduate of Bastyr University's Doctor of Naturopathic Medicine program. "That's very exciting."

"Research is Self-Reflection"

The research team, funded by the Bastyr Center for Student Research, interviewed 15 naturopathic physicians and research leaders by phone and in person. The team found that much depended on how respondents defined evidence-based medicine. The more comprehensive they understood it to be, the more they trusted it. (Dr. Guiltinan describes evidence-based medicine as "scientific evidence, clinical judgment, and patient values, all weighted equally.")

Once NDs understand that evidence-based medicine has room for a doctor's judgment and a patient's values, they become much more accepting, Dr. Goldenberg says.



Evidence-based medicine triad.

"When we really probed the people who had negative views about evidence-based medicine, they understood the definition was, 'Patient comes in with X and you always give them Y,'" he says. "No one really means that. That's the fear, but it's certainly not the intention of the founders of EBM."

The study found multiple reasons for the attitude shift, including the influence of leaders in the naturopathic world and a desire for credibility in conventional medicine. The growth of funding and institutions for naturopathic research was another key reason.

Some respondents gave poignant reasons for changing, such as working with AIDS patients.

“I'm going to float the idea that what substantially changed the attitude of 'We don’t have anything to prove, we can cure any disease,' was the AIDS epidemic," wrote one participant. "Any ND worth their salt was trying to help people who are HIV-positive and had developed AIDS. And I think everybody honest just realized we didn’t have any effective therapy.”

“Research is self-reflection,” wrote another. “We have to reflect on ourselves. Not everything we’re going to do is going to be perfect, and if you’re not willing to examine yourself, do you really deserve to be a doctor?”

The Art of Medicine

Dr. Goldenberg grew interested in naturopathic attitudes after his journey working in conventional science and discovering that healing requires more than science. He came to Bastyr after working as a molecular ecologist and

passing up conventional medical schools (read the story of his epiphany). During his Bastyr studies, he discovered that the scientific dimension of medicine and the *vis*, or vitalistic dimension, are not exclusive — they aid each other. Balancing them became important as he began clinical training.

“When I first fell in love with the idea of EBM, I wasn't working in a clinical setting yet," he says. “To be in clinic, with real patients, you learn medicine is very artful and beautiful, but it's really a mess sometimes. You try to get everything better and do the best for your patient, but it's not this clean-cut cookbook where the patient comes in with X and you give them Y. That just doesn't happen in real life, and it wouldn't be good medicine."

He also learned that much conventional medicine relies on sparse evidence that is often later called into question. For example, medical doctors commonly use selective serotonin reuptake inhibitor drugs to treat depression. But a meta-analysis found they may be no more effective than a placebo for all but the most extremely ill.

To Dr. Goldenberg, that suggests medicine must always involve a doctor’s judgment, a patient’s values and an element of mystery.

Two Patients, Two Approaches

Dr. Guiltinan also comes from a scientific background, studying medical technology as an undergraduate. As a faculty supervisor at Bastyr Center for Natural Health, the University's Seattle teaching clinic, she offered two stories that illustrate how the naturopathic field has changed — and how it remains distinct from conventional medicine.

Co-author Jane Guiltinan, ND, has called on the naturopathic profession to embrace evidence-based medicine.

1. A woman recently visited Bastyr Center after a stroke had sent her to the emergency room. ER doctors put her on pharmaceutical drugs for high blood pressure and cholesterol, and she needed help reducing the risk of another stroke.

At Bastyr Center, she met with a team of naturopathic medicine students who reviewed the evidence supporting her medications, along with their side effects and risks. They also considered herbal alternatives for blood pressure such as hawthorn berry, garlic and lime leaves. Because of the woman's high risk of another heart incident, they suggested she continue taking her medications, while also working to lose weight and lower cholesterol through dietary changes.

Their supervisor — Dr. Guiltinan — confirmed it was a responsible plan for a high-risk patient.

"In the past, students might have argued with me about that," she said. "But they reached this conclusion in their own independent research for this case."

2. That same day, another patient visited Bastyr Center looking for a second opinion on hormone-replacement therapy, which she had been using for three years for menopausal symptoms. Student clinicians reviewed the clinical evidence and suggested she taper off the hormone treatment, because it brings elevated risks after several years. After reviewing the plan with Dr. Guiltinan, they helped the patient make the transition with naturopathic methods of adrenal support, such as Siberian ginseng, ashwagandha and organic soy.

Those two examples provide a small picture of the path NDs can forge by integrating the best of their medicine with the most successful elements of

conventional medicine, Dr. Guiltinan says. She wrote an editorial accompanying the attitudes study calling for NDs to embrace evidence-based medicine.

“It is the right thing to do for our patients,” she writes. “They deserve therapies that have been validated. The time to scrutinize what we believe and what we do with patients in a systematic way is here.”

Learn more about Bastyr's Doctor of Naturopathic Medicine program and research studies.

RELATED

Bringing Healing to Families in Need

Through a partnership with the nonprofit charter school EJE Academy, naturopathic clinicians at Bastyr University California are offering free health care to students and their families in an underserved region of San Diego

>

Bastyr University
14500 Juanita Drive N.E.
Kenmore, WA 98028-4966

(425) 602-3000
(425) 823-6222 (fax)

Seattle Clinic Website

Bastyr University California
4106 Sorrento Valley Blvd.
San Diego, CA 92121-1407

(858) 246-9700
(858) 246-9710 (fax)

San Diego Clinic Website

Appendix G

University of Bridgeport College of Naturopathic Medicine

vs.

MD Medical School Curriculum

Medical Education Hours Comparison
U. of Bridgeport College of Naturopathic Medicine Vs. MD Medical School Curriculum

Pharmacology is taught throughout the curriculum in both conventional medical and naturopathic medical training.

University of Bridgeport College of Naturopathic Medicine (UBCNM) Curriculum
Two courses are dedicated to pharmacology and drug therapeutics totaling 72 hours. Another 86 hours of pharmacology and drug therapeutics is taught in cardiology, gynecology, endocrinology, pediatrics, rheumatology, EENT, neurology, gastroenterology, urology/proctology, oncology, dermatology, minor office procedures, emergency medicine, environmental medicine, obstetrics, geriatrics, clinical physical laboratory diagnosis I and II, and immunology. 158 hours of pharmacology and drug therapeutics is taught in total. Total Instructional hours at UBCNM are 4515 hours, comprising 765 hours of basic sciences; 2358 hours of clinical sciences; and 1392 hours of clinical practice.

Conventional Medical School Programs
At Yale, UConn, and Quinnipiac University Schools of Medicine, pharmacology is part of a block format curriculum, and these schools do not identify hours specifically dedicated to pharmacology instruction. A commonly cited figure for total pharmacology instruction at conventional medical schools is 120 hours.Total Instructional hours at most conventional medical school programs ranges from 4300 to 5100 hours.

States That License Naturopathic Doctors and States That Have Drug Prescribing Authority

State	Drug Authority	State	Drug Authority
Alaska	No	Maryland	No
*Arizona	Yes (Large Rx Authority)	Minnesota	No
*California	Yes (Significant Rx Authority)	Montana	Yes (Significant Rx Authority)
Colorado	No	New Hampshire	Yes (Significant Rx Authority)
*Connecticut	No	North Dakota	No
Hawaii	Yes (Large Rx Authority)	*Oregon	Yes (Large Drug Authority)
Kansas	No	Utah	Yes (Significant Rx Authority)
Maine	Yes (Small Rx Authority)	Vermont	Yes (Large Drug Authority)
		*Washington	Yes (Large Drug Authority)

*States that have Naturopathic Medical Schools

Safety and Malpractice Record**
The safety records of NDs in states with licensure are typically much better than those of MDs and DOs in these states. In 2006, the California Bureau of Naturopathic Medicine contacted the licensing agencies in states that allow NDs to prescribe. None of the states reported any patient harm or disciplinary action due to ND prescribing, nor were there any civil actions against NDs for prescribing.The Bureau also contacted the NCMIC Insurance Company, which insures many NDs in all licensing states, as well as all the naturopathic medical schools. In a letter dated June 7, 2006, NCMIC stated: “In the five years that NCMIC has been insuring Naturopathic Physicians and the colleges, we have never opened a claim against a Naturopathic Physician involving prescription medications.”

The California Bureau contacted Jury Verdicts Northwest (JVN) to see if there were any civil actions filed against licensed NDs. JVN covers both Oregon and Washington, the two states with the greatest number of NDs and the longest histories of licensure (since 1919 and 1927, respectively). JVN found no cases against NDs for prescription negligence, and added that, “for that matter our database contained no cases against naturopathic doctors at all.”

The safety record of naturopathic physicians regarding pharmacologic substances is well demonstrated in the northwest where NDs have broad prescriptive authority. Jury Verdicts Northwest, a legal database which records court cases in Washington and Oregon, the area of the country with the largest number of naturopathic physicians, shows no judgments for malpractice against NDs since the database was started in 1983 through 2010.
**Vermont Office of Professional Regulation Study on Prescriptive Authority for Naturopathic Physicians February 2013.

Appendix H

Naturopathic Medicine Data and Facts Sheet

Safety

Disciplinary Actions and Malpractice claims

As cited by Dr. Sean Heerey in his article: The Value of Naturopathic Medicine in New York-Part V: Safety:

"Malpractice claims against CAM practitioners occur less frequently and typically involved less severe injury than claims against Conventional Physicians (Cohen, 1996, Studdert, et. al., 1998)."

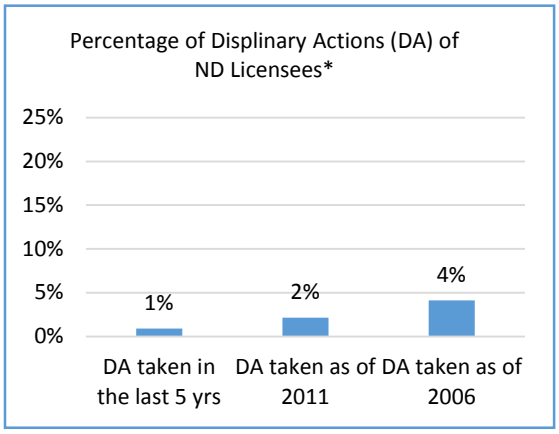
As an example, "Jury Verdicts Northwest with civil court records in states where 55% of naturopathic doctors practice, reported that their records show ***zero cases paid against naturopathic doctors and only 17 filed in 20 years***."

The following table shows that there were only 17 ND malpractice claims filed from 1990 to 2010, compared to the 1 million claims filed against MDs and DOs in one year alone (i.e., 2009).

The figure below shows the low percentage of disciplinary actions taken of ND license holders approximately a 10-year period.

	Year(s)	U.S.
MD/DO Malpractice Claims Paid	2009	107,391
MD/DO Malpractice Claims, Estimated Total Filed	2009	1 million
MD/DO Malpractice Claims, Total Paid	2009	$34.7 billion
ND Malpractice Claims, Total Filed	1990-2010	17

http://www.nyanp.org/the-value-of-naturopathic-medicine-in-new-york-part-v-safety/



*Licensees from: AK, CT, HI. ME, MN, MT, NH, ND, OR, UT, and VT.

Licensure/Registration & Prescriptive Authority

Currently, 17 states, the District of Columbia, and the United States territories of Puerto Rico and the United States Virgin Islands have licensing or regulation laws for naturopathic doctors. Of these 20 regulatory entities, 10 or 50% grant either prescriptive or modified prescriptive authority or a formulary list. The following tables shows states/jurisdictions that have ND licensing laws, ND prescriptive authority, and the examinations that are required for licensing.

States/Jurisdictions the have ND licensing laws.	Prescriptive Authority	NPLEX Examinations Required for Licensure/Registration				Other Required Exams
		Part I – Biomedical Science	Part II			
			Core Clinical Science	Clinical Elective Minor Surgery	Clinical Elective Acupuncture	
1. Alaska		X	X			
2. Arizona	Prescriptive authority	X	X	X	X	
3. California	Modified prescriptive authority	X	X			
4. Colorado		X	X			
5. Connecticut		X	X			
6. District of Columbia		X	X			
7. Hawaii	Formulary list	X	X	X		
8. Kansas	Modified prescriptive authority	X	X		X	
9. Maine	Modified prescriptive authority	X	X	X		
10. Maryland		X	X			
11. Minnesota		X	X			
12. Montana	Formulary list	X	X	X		
13. New Hampshire	Formulary list	X	X			
14. North Dakota		X	X			
15. Oregon	Formulary list	X	X	X		
16. Utah		X	X	X		
17. Vermont	Prescriptive authority	X	X			ND Pharmacological Exam
18. Washington	Prescriptive authority	X	X	X		
19. Puerto Rico		X	X			
20. Virgin Islands						
Canadian Provinces:						
1. Alberta		X	X	1	1	
2. British Columbia	Prescriptive authority	X	X	X		
3. Manitoba		X	X			
4. Ontario	Prescriptive authority	X	X		X	Ontario Prescribing and Therapeutics Examination
5. Saskatchewan		X	X		X	

[1] Required only if planning to use these modalities in practice.

Comparison of Types & Number of Malpractice Allegations by Type of Practitioner

The data presented in the following table show that licensed Naturopaths comprise a very small percentage (i.e., 0.009%) of practitioners who are associated with malpractice allegations.

Malpractice Allegation Group by Practitioners Field of License Cross-tabulation From the NPDB Public Use Data File*									
Malpractice Allegation Group	**Practitioners' Field of License**								**Total**
	Allopathic Physician (MD)	**Physician Resident (MD)**	**Osteopathic Physician (DO)**	**Osteopathic Physician Resident (DO)**	**Advanced Nurse Practitioner [3/5/02 - 9/9/02]**	**Homeo -path**	**Naturo -path**	**Physician Assistant**	
Diagnosis Related	100980	583	8356	122	0	1	4	1283	111329
Anesthesia Related	9295	88	456	8	1	0	0	11	9859
Surgery Related	85074	423	3993	72	1	0	0	99	89662
Medication Related	16469	138	1422	16	0	1	5	221	18272
IV & Blood Products Related	901	66	50	1	0	0	1	5	1024
Obstetrics Related	25172	390	1426	40	0	0	1	12	27041
Treatment Related	55957	459	4246	68	2	4	14	634	61384
Monitoring Related	5836	84	411	9	0	0	1	57	6398
Equipment/Product Related	1404	13	87	0	0	0	3	8	1515
Other Miscellaneous	5366	53	290	19	0	0	2	70	5800
Behavioral Health Related	473	7	27	0	0	0	0	3	510
Total Number	**306927**	**2304**	**20764**	**355**	**4**	**6**	**31**	**2403**	**332794**
Total Percentage	**92.227%**	**0.692%**	**6.239%**	**0.107%**	**0.001%**	**0.002%**	**0.009%**	**0.722%**	**100%**

*Data aggregated from the "public use data file" from the National Practitioner Data Bank (NPDB), U.S. Department of Health and Human Services (Last Update August 2016).

Cost Effectiveness

There are an array of studies that demonstrate the cost effectiveness of ND practice, particularly in the area of preventive medicine. The following highlight some of the findings from the studies.

- "Corporate health management programs associated with prevention and wellness showed a 26% reduction in health care costs and a$6 returned for every $1 invested"(Lafferty, W.E., et. al., 2010).

- "Median per-visit expenditures were $39.00 for CAM care and $74.40 for conventional outpatient care in Washington. The total expenditures per enrollee were $2,589, of which only $75 (2.9%) was spent on CAM"(Lafferty, W.E., et. al., 2010).

- "The Diabetes Prevention Trial demonstrated that the prevention of type 2 diabetes by diet and lifestyle therapies was **more cost effective than pharmaceutical therapy** in high-risk patients. For each quality-adjusted life years (QALY) saved, a lifestyle modification program costs $8,800 while metformin therapy costs $29,000. Additionally, the lifestyle modification program was shown to be **cost-effective in all adults**, while metformin was not cost-effective after age 65" (Herman, W.H., et. al., 2005).

- As cited by Dr. Sean Heerey in his article: The Value of Naturopathic Medicine in New York-Part V: Safety:
  "848 employees for the Vermont Automobile Dealers Association were examined and advised by Naturopathic Doctors (NDs) for one year. The organization saved $1.5 million in direct and indirect medical costs the first year; that is $1800 per employee" (*Vermont Automobile Dealer's Association and Green Mountain Wellness Solutions).*

Curriculum

Accreditation

Council on Naturopathic Medical Education (CNME) is the federally-recognized programmatic accreditor for naturopathic medical schools, with educating NDs to meet the comprehensive standards and competencies to prepare them for practice in any state, including those with modern scopes of practice and broad prescriptive authority.

Comparison of ND & MD Curriculum

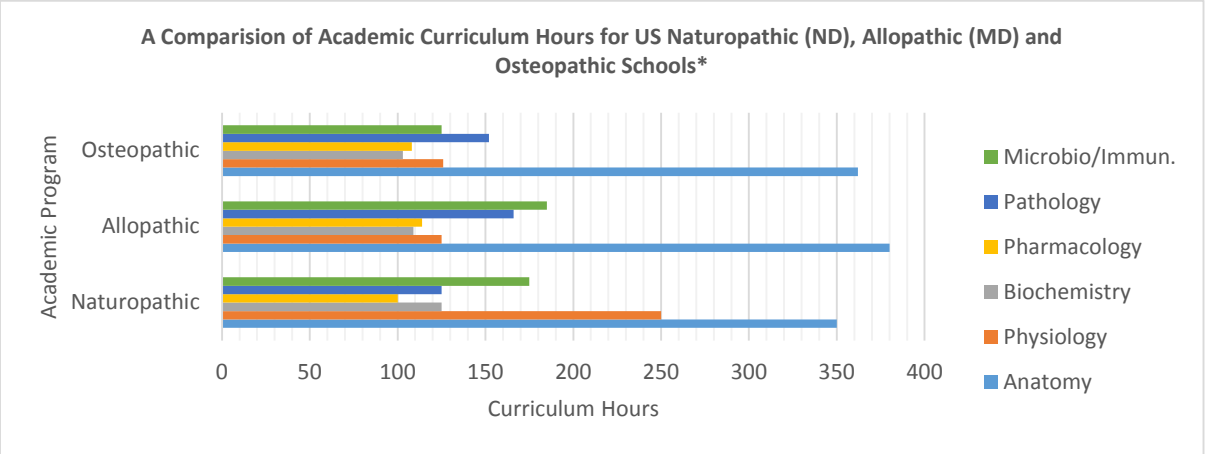
The 2013 comprehensive report entitled "*Naturopathy in Vermont*: *Evaluating Education Differences and the Role of Naturopathic Doctors (NDs) as Primary Care Providers*" conducted by the Nelson A. Rockefeller Center-Policy Research Shop at Dartmouth College and presented to the Vermont State Government Operations Committee includes a comparison of ND and MD curricula. As shown in the table below, the number of credits for the ND program exceeds the number of credits of the MD program.

Number of Credits			
	ND (Bastyr)	**MD (Washington)**	**Difference (ND-MD)**
1st & 2nd years	154.5	124	+30.5
3rd & 4th years	161.0	164	-3.0
Total Credits	315.5	288	+27.5

A comparison of academic curriculum hours for ND, MD and Osteopathic schools by subject as indicated in the following table shows that, overall, ND schools has the highest number of curriculum hours compared to MD and Osteopathic schools.

Comparison of academic curriculum hours for US Naturopathic (ND), Allopathic (MD) and Osteopathic Schools*			
Subject	Profession		
	Naturopathic	Allopathic	Osteopathic
Anatomy	350	380	362
Physiology	250	125	126
Biochemistry	125	109	103
Pharmacology	100	114	108
Pathology	125	166	152
Microbio/Immun.	175	185	125
Total	1125	1079	976

*Jensen (1997)



*Jensen (1997)

Pharmacology Competency Assurance – Additional Steps

The ND profession has taken the additional step and proposed successful completion an additional robust capstone clinical pharmacology course and examination, with a curriculum designed and taught by an independent college of pharmacy, as an additional requirement to attain prescriptive authority for the ND in Connecticut.

References

Cohen, M.H. (1996). Malpractice and vicarious liability for providers of complementary & alternative medicine. *Benders Health Care Law Mon*, Jun, 3-13.

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Appendix I

Massachusetts College of Pharmacy and Health Sciences,
Clinical Pharmacology Review for Naturopathic Physicians

PPB 850: Clinical Pharmacology Review for Naturopathic Physicians

This three-credit course in clinical pharmacology review was designed for naturopathic physicians in preparation for obtaining prescriptive authority as defined by their state's law.

At the conclusion of this course, students will be able to:

- Describe fundamental pharmacologic principles including dose-response relationships, drug-receptor binding, drug metabolism and elimination, and the basic pharmacokinetic principles.
- Describe the effects of drugs used in the treatment of autonomic, cardiovascular, renal, hematological, endocrine, respiratory, musculoskeletal, and central nervous system disorders.
- Select appropriate antimicrobial drug treatment based on knowledge of the various types of infections.
- Analyze the similarities and differences between these drugs with specific reference to their mechanisms of action, therapeutic indications, principle adverse effects, major drug interactions, and specialized delivery systems, when appropriate.
- Apply the principles of chemistry, biochemistry, pharmacology, physiology, and pathophysiology to the individualization of drug selection and analysis of clinical case studies.
- Describe relevant dietary and nutritional considerations needed to augment treatment.

MCPHS ONLINE
Massachusetts College of Pharmacy and Health Sciences

To enroll in PPB 850:

- Visit http://online.mcphs.edu/register
- Navigate to PPB 850 in the alphabetical course listing and click “Add”
- Once the course has been added to your shopping cart, you can view it at the top of the page
- Click “Continue to User Info”
- Complete all required fields and then select “Continue to Payment”
- Verify that the course section and title are accurate. PPB 850 is a graduate level course, so tuition is $900/credit. Your shopping cart should total $2700.
- Enter your credit card number and click “Complete Registration”
- You will be registered for the course and should receive a username and password from the University within 4-5 business days.

Have more questions if this course is right for you?

Questions about PPB 850 may be directed to Lana Dvorkin at lana.dvorkincamiel@mcphs.edu or Phung On at phung.on1@mcphs.edu.

If you are having difficulty with registration for the course, or the section is closed, please call MCPHS Online at 508.373.5890 or email online@mcphs.edu.

MCPHS ONLINE
MASSACHUSETTS COLLEGE *of* PHARMACY *and* HEALTH SCIENCES

MASSACHUSETTS COLLEGE OF PHARMACY & HEALTH SCIENCES
MCPHS UNIVERSITY ONLINE
CLINICAL PHARMACOLOGY REVIEW
FOR NATUROPATHIC PHYSICIANS

1. Catalog Information

a. Course number:	TBD
b. Course Title:	Clinical Pharmacology Review for Naturopathic Physicians
c. Lecture Hours per Week:	3
d. Laboratory Hours per Week:	0
e. Recitation Hours per Week:	0
f. Self-instruction Hours per Week:	0
g. Experiential Hours per Week:	0
h. Credit Hours per Semester:	3
i. Prerequisites and Co-requisites:	Graduation from a CNME Naturopathic Program

j. Instructor(s) bearing primary responsibility as Course Coordinator:

Lana Dvorkin Camiel, PharmD
MCPHS University, Boston
Office: W311 Phone: (617) 732-2915
Email: lana.dvorkin@mcphs.edu
Office Hours: TBA

k. Semester and Frequency Offered: Fall (annually)

2. Catalog Description

Emphasizes the basic principles of pharmacology, pharmacokinetics, pharmacodynamics, and dose-response relationships along with an in-depth consideration of drugs affecting the autonomic,cardiovascular,renal, hematological, endocrine,respiratory, musculoskeletaland central nervous systems.Provides an in-depth study of agents used to treat disorders associated with these organ systems, as well as agents used for the treatment of infectious diseases.

3. Other Information

a. Programfor which course is intended:	Naturopathic Physicians
b. Elective or required:	Required
c. Department name:	MCPHS Online, MCPHS University, Boston

4. Course Goals and Objectives and Instructional Strategies

a. Goals and Objectives:

MASSACHUSETTS COLLEGE OF PHARMACY & HEALTH SCIENCES
MCPHS UNIVERSITY ONLINE
CLINICAL PHARMACOLOGY REVIEW
FOR NATUROPATHIC PHYSICIANS

Clinical Pharmacology for Naturopathic Physicians addresses the dynamic aspects of drug action and the concepts relating to drugdisposition. Particular emphasis is placed on a drug's mechanism of action, its therapeutic indications, and its principle adverse effects. The class handouts and notes are meant to supplement the relevant chapter topics in the textbook.Upon successful completion of this course, thestudent will be able to:

1. Describe fundamental pharmacologic principles including dose-response relationships, drug-receptor binding, drug metabolism and elimination, and the basic pharmacokinetic principles.
2. Describe the effects of drugs used in the treatment of autonomic, cardiovascular, renal, hematological, endocrine, respiratory, musculoskeletaland central nervous system disorders.
3. Select appropriate antimicrobial drug treatment based on knowledge of the various types of infections.
4. Analyze the similarities and differences between these drugs with specific reference to their mechanisms of action, therapeutic indications, principle adverse effects, major drug interactions, and specialized delivery systems, when appropriate.
5. Apply the principles of chemistry, biochemistry, pharmacology, physiology, and pathophysiology to the individualization of drug selection and analysis of clinical case studies.
6. Describe relevant dietary and nutritional considerations needed to augment drug treatment.

b. Instructional Strategies:

Online lectures, case discussions, and reading assignments will be employed.

5. **Assessment Techniques**

Examinations will consist primarily of multiple choice questions designed to assess the student's core knowledge of basic and clinical pharmacology and the ability to extrapolate this knowledge to clinical case situations. Exams will generally be cumulative.

6. **Examinations and Grading Methods**

Weekly module quizzes	25%
Three, one-hour examinations:	50%
Final examination (cumulative):	25%

Passing grade is a 75.

a. There will be no make-up exams without prior approval by the course coordinator. If a make-up exam is approved, the format of the exam may be different from the original.

b. In the event of an official school cancellation on a scheduled exam date, the exam will be given on the next scheduled class meetingunless otherwise notified.

MASSACHUSETTS COLLEGE OF PHARMACY & HEALTH SCIENCES
MCPHS UNIVERSITY ONLINE
CLINICAL PHARMACOLOGY REVIEW
FOR NATUROPATHIC PHYSICIANS

Students must abide by the Academic Policies and Procedures set forth in the MCPHS College Catalog. *Important information regarding Excused Absence Approval, Disability Support Services for students, Academic Honesty and Plagiarism and other academic policies is set forth in the Academic Policies and Procedures section of the MCPHS Catalog.* https://my.mcphs.edu/CollegeCatalog. Students must read, understand, and comply with all of these policies and procedures.

7. **Resources**

Required Text: Katzung, B.G. ed., Basic and Clinical Pharmacology, 12th edition, Lange Medical Books / McGraw-Hill, New York, N.Y. 2012. (**Available through online library resources**).

8. **Course Outline**

Highlighted in yellow – comes from 2015 CT ND Prescriptive Authority Drug Classes & Exclusions (see last page)

Highlighted in blue included in course instruction

Week	Topic	Instructor
1	**Course Introduction** Receptors, Pharmacodynamics, Signal Transduction, Pharmacokinetics, Drug Metabolism, Pharmacogenetics	TBA
2, 3	**Central Nervous System** Central nervous system drugs Autonomic drugs Smooth muscle relaxants Anesthetics, local Intro to CNS Pharmacology & Neurotransmission Neurodegenerative Diseases Autonomic Receptors, Cholinergic Agents, Anti-Cholinergic Agents Anxiolytics, Anti-Epileptics, Antidepressants, Mood Stabilizers, Parkinson's Disease and Movement Disorders, Skeletal Muscle Relaxants, Neuromuscular Blockers, General Anesthetics, Local Anesthetics	TBA
	Exam 1	

4	**Pain Control** Anti-Gout Agents Analgesics, antipyretics, Anti-inflammatory agents NSAIDs and Non-opioid Analgesics, DMARDs, and Gout	TBA
5,6	**Cardiovascular System** Cardiovascular drugs Electrolytic, caloric and water balance Blood formation and coagulation, derivatives Adrenergic Agonists, Adrenergic Antagonists, Calcium Channels Blockers, ACE-Is & ARBs, Cardiac Glycosides/Inotropes & Direct Vasodilators, Intro to Renal, Diuretics, Cholesterol Lowering Agents, Hematopoietics, Thrombolytics	TBA
	Exam 2	

7	**Endocrine System** Hormones Contraceptives Pituitary and Hypothalamic Hormones, Thyroid and Anti-Thyroid, Adrenocorticosteroids and Adrenocortical Antagonists, Agents that Affect Bone Mineral Homeostasis, Anti-Diabetic Agents, Gonadal Hormones	TBA
8, 9	**Infectious Diseases** Anti-infective agents, Antiprotozoal, Antileprotic, Antibiotic, antiviral, agents Serums, toxoids, vaccines Immunosuppressive and Immunomodulation agents *Beta*-Lactams & Macrolides, Sulfonamides &Antimycobacterials, Quinolones, Aminoglycosides, Misc. Antimicrobial Agents, Antifungals &Antiprotozoals, Antivirals	TBA
	Exam 3	

10	**Respiratory System** Antihistamines Bronchodilators Expectorants and cough preparations Mast cell stabilizers	TBA

11	**Gastrointestinal System and Nutrition** Gastrointestinal drugs Enzymes Vitamins, Minerals, Trace Minerals, Amino Acids, Lipids	TBA
12	**Eyes, Ears, Nose, Throat and Dermatology** Ophthalmic, Otic and Nasal ointments, solutions, suspensions, preparations Antiperspirants Skin and mucous membrane preparations	TBA
13	**Clinical Toxicology** Alcohol deterrents Diagnostic agents, aids and Function Test agents Heavy metal antagonists/Chelating agents	TBA
	Final Exam	

2015 CT ND Prescriptive Authority Drug Classes & Exclusions

Summary: A Connecticut licensed naturopathic physician will be able to legally prescribe any legend drug or controlled substance with the following exclusions:

EXCLUDED ITEMS

1. Intracardiac, intraosseous, intrathecal, intravitreal medications.
2. Controlled substances exclusions;
    a. All Schedule I;
    b. Schedule II - cocaine, methamphetamine, methadone
    c. Schedule III ketamine.
3. Other Exclusions: Antineoplastic (anti-cancer) agents classified as legend drugs, Barbituates, Typical and Atypical Anti-psychotics, General Anesthetics, Gold Compounds, Antiarrythmia drugs, Isotretinoin, Roentgenographic agents, Radiopharmaceuticals, Radioisotopes, Abortifacients, Oxytocin, all Glaucoma drugs.

INCLUDED DRUG CATEGORIES

The included drugs under these categories are established and listed in the American Hospital Formulary Service published by the American Society of Hospital Pharmacists.

Antihistamines
Anti-infective agents, Antiprotozoal, Antileprotic, Antibiotic, antiviral, agents
Anti-Gout Agents
Autonomic drugs
Blood formation and coagulation, derivatives
Cardiovascular drugs
Central nervous system drugs
Analgesics, antipyretics, Anti-inflammatory agents
Contraceptives
Diagnostic agents, aids and Function Test agents
Electrolytic, caloric and water balance
Enzymes
Expectorants and cough preparations
Ophthalmic, Otic and Nasal ointments, solutions, suspensions, preparations
Gastrointestinal drugs
Heavy metal antagonists/Chelating agents
Hormones
Anesthetics, local
Serums, toxoids, vaccines
Antiperspirants
Skin and mucous membrane preparations
Smooth muscle relaxants
Vitamins, Minerals, Trace Minerals, Amino Acids, Lipids
Alcohol deterrents
Bronchodilators
Immunosuppressive and Immunomodulation agents
Mast cell stabilizers

New drug categories created in the future.

Appendix J

American Association of Naturopathic Physicians (AANP)
Guidance Regarding Naturopathic Practice and Care

American Association of Naturopathic Physicians (AANP) Guidance Regarding Naturopathic Practice and Care

Approved by AANP's House of Delegates August 4, 2015

Introduction –This guidance document describes established practices, models, and criteria by which a naturopathic doctor/physician (ND) undertakes evaluation, consultation and/or management of an individual patient. This document is offered as general guidance for NDs and practice consistent with its provisions, while encouraged, is voluntary. This guidance is intended to apply to general practice, but may not be applicable in all clinical circumstances or jurisdictions. NDs must use their independent judgment to apply the guidance to their practice in accordance with the applicable laws, regulations, and ordinances of their jurisdictions.

Naturopathic medicine - A distinct system of primary health care - an art, science, philosophy and practice of diagnosis, treatment and prevention of illness. Naturopathic medicine is distinguished by the principles which underlie and determine its practice. These principles are based upon the objective observation of the nature of health and disease, and are continually re-examined in the light of scientific advances. Methods used are consistent with these principles and are chosen upon the basis of patient individuality. Naturopathic physicians are primary health care practitioners, whose diverse techniques include modern and traditional, scientific and empirical methods. (AANP Position Paper, Definition of Naturopathic Medicine. 1989, 2000, 2011)

Doctors of Naturopathic Medicine – NDs diagnose, treat, and help prevent diseases using a system of practice that is based on the natural healing capacity of individuals. NDs may use physiological, psychological or mechanical methods. NDs may also use natural medicines, prescription or legend drugs, foods, herbs, or other natural remedies. (US Dept. of Labor, 2009)

State Licensing and Health Insurance – NDs practice in some states as licensed "Naturopathic Physicians" or licensed "Naturopathic Doctors," while other states do not require licensing but limit the scope of healthcare services that can be provided to the client. Variations in health insurance coverage may also affect healthcare choices on a state-by-state basis. The variations in state laws include differences in the ability to prescribe prescription medications. These variations in scope and insurance must be considered in evaluating ND practice and care in different states. (AANP Position Paper, Definition of Naturopathic Medicine. 1989, 2000, 2011)

Intention and Purpose - The intentions and purposes for developing Guidance Regarding Naturopathic Care and Practice are to:

- Provide a foundation for the practice of naturopathic medicine in licensed and unlicensed states for the purpose of protecting and improving the health of the public.
- Provide assurance of uniform agreement within the profession on the competencies of naturopathic practice.
- Inform the public of the role naturopathic care has in maintaining public safety and appropriate patient care.
- Provide guidance to state practice and licensing boards in order to evaluate professional actions.
- Provide an overview of practice in order to facilitate collaboration with other medical professions.
- Provide structure to accommodate ongoing advances in naturopathic medical progress and practice innovation.

Guidance Regarding Naturopathic Care and Practice –An ND makes a good faith effort to abide by this guidance, to the extent possible under the law, by undertaking the following actions:

1. <u>Professionalism:</u>

- **Facilitates and Documents Informed Consent.** An ND provides patients/clients with information necessary to make informed choices about their healthcare, including procedures, prescribed medications and natural substances. This information and discussion allows for patient/client questions and include the likely benefits and potential harm of avoiding alternative medical or surgical care options, as applicable, to the extent of the ND's knowledge and training. This discussion may emphasize that the patient/client has the freedom to pursue other treatment, or medical care from other health care professionals. In the event that a patient is unable to make autonomous decisions, consent may be given by a designated proxy (i.e., parent, spouse, next of kin, medical power of attorney, etc.). The informed consent process will also disclose any conflicts of interest.

- **Maintains Accurate and Secure Patient Records.** An ND maintains a record, documenting evaluation, consultation and/or management services provided to each patient in a manner consistent with federal and local regulations. Records are legible, accurate, complete, and include only abbreviations and symbols that are commonly used and understood by medical professionals, or provide a legend. For the purposes of patient/client evaluation, diagnosis, and optimizing clinical care, data may be collected from: the person affected; that person's designee, e.g., family member or medical power of attorney; or records from other health care providers. The medical records for a patient encounter include an active assessment, as a final, working or differential diagnosis. Plans for reaching a final diagnosis may be included for differential diagnoses, as applicable.

- **Pursues Continued Education and Training.** An ND makes his/her best effort to remain current with medical knowledge, including advancements in naturopathic medicine, through accredited continued medical education.

2. <u>Patient Management:</u>

- **Provides Primary Care or Specialized Care According to Training and/or Limitations in Scope.** An ND is trained as a provider of primary care services. For the purposes of this guidance, "primary care" may include: first contact for acute/emergency triage; care for the entire spectrum of age and health; health promotion and prevention services; evaluation and management of acute and chronic disease, including long-term continuing care; assessment of patients' social determinants of health; designee for signing birth/death certificates and advanced directives as permitted by law; co-management and/or consultation with other care providers as necessary in order to maintain and improve patients' health. However, an ND may choose to focus or limit their practice to certain methods, modalities, patient populations or areas of practice. If an ND specializes or limits their practice (i.e., methods, modalities, patient populations or areas of practice) he/she: discloses the nature of the practice limitations to the public, patients, and colleagues when relevant; and makes appropriate referrals if requested by a patient, and/or as indicated by medical risk, disease severity or lack of response to treatment.

- **Provides Beneficent Treatment(s).** An ND develops and documents a management and ongoing monitoring plan with each patient intended to provide health improvement, disease prevention and/or treatment, with its rationale based on accepted knowledge and practices. The plan is: clear in its goals in the context of the patient's condition and health status; logical in sequence and duration; consistent with naturopathic education; compatible with other therapies the patient may be undergoing; and modifiable based on new information and/or knowledge. Experimental approaches may be offered with appropriate informed consent and/or when the patient/client refuses treatments with established efficacy; when standard treatments have failed; are not available; or are not well tolerated by the patient. All treatments are based on naturopathic principles and training, in that they may:
    - Promote self-healing;
    - Remove the cause of conditions when known and possible;
    - Promote health and prevent disease when possible;
    - Provide the greatest chance of patient benefit while providing the lowest risk of patient harm;
    - Be individualized;

- Address multiple determinants of health and disease; and/or
- Include attempts at patient education and empowerment, i.e., encourage self-efficacy.

- **Discloses Prognosis and Evaluate Treatment Progress**. When possible an ND:
  - Provides each patient/client with information on their diagnosis and/or health prognosis;
  - Re-evaluates the effectiveness of treatment plans in a timely manner;
  - Modifies unsuccessful plans promptly;
  - Provides or offers a referral to other appropriate health care providers in the absence of timely progress;
  - Discusses perceived and actual barriers to risk reduction and/or treatment progress with the patient, including poor patient adherence, and the continuation of unhealthful practices by the patient.

- **Provides Patients with Additional Health Resources upon Discharge.** If a patient/client consistently ignores the ND's healthcare advice and/or persistently makes choices that may be harmful to themselves, the ND may discharge the patient from his or her practice. The reason for discharge is documented in the patient's records. Any refusal by the ND to further participate in the patient's health care including further evaluation, consultation and/or management is communicated by written notice to the patient. Referral options to other appropriately trained health care providers are provided to the patient upon termination of care when possible, to be pursued at the discretion of the patient.

3. <u>Medical Assessment and Diagnosis:</u>

- **Employ a Valid Diagnostic Process.** When establishing and reporting a patient/client diagnosis or assessment, an ND utilizes accurate and clinically relevant information, and use accepted criteria, which may include: the patient/client's medical and symptom-specific history; physical examination; past medical records; and diagnostic testing, including laboratory testing, imaging, and/or diagnostic procedures. Diagnostic criteria employed are consistent with the established health care disciplines and philosophies in which the ND has been trained. Combinations of diagnostic approaches from multiple disciplines may be employed (e.g., allopathic plus naturopathic, homeopathic plus naturopathic, etc.). The diagnostic process includes the necessary evaluation, or referral for evaluation, of potentially life-threatening conditions as indicated by the person's history, examination and available diagnostic testing. Plans for re-evaluation of working diagnoses based on responses to treatment and/or the availability of new diagnostic information are documented; similarly, plans for reaching a final diagnosis are also documented for ongoing differential diagnostic plans.

4. <u>Communication and Collaboration:</u>

- **Provide Patient-Centered Care.** An ND respects the autonomy, values and choices of his/her patients/clients regarding their preferences for: preventive measures; participation in health screening schedules, health maintenance, health promotion and disease care; and recommended examinations, imaging, laboratory testing, clinical procedures, diagnostic and treatment options. Patients/clients have control of continuation of care decisions; requests for alternate opinions and/or referral; and the composition of their health care team. Variations in permitted scope of practice and health insurance can negatively affect the patient/client/doctor relationship and may limit the role of the ND in facilitating appropriate evaluation, consultation and/or treatments.

5. <u>Systems-based Practice:</u>

- **Contribute to the Greater Health Care Community and the Public Health.** An ND is aware of and considers health policy guidance released by local and regional public health agencies, and attempts to meet the following professional responsibilities:
  - Serves as a consultation resource for other medical professionals.

- Reports diseases as required by federal, state and/or local law(s).
- Stays current with public health updates issued by the U.S. Centers for Disease Control and Prevention and State and County/City Departments of Health.
- Disseminates information in support of public health and the benefits/risks of preventive agents and screenings
- Participates actively in public health surveillance.

Note: Guidance cannot account for individual variation among patients and is not intended to supplant professional judgment with respect to particular patients or special clinical situations. AANP considers practice consistent with this guidance to be voluntary, with the ultimate determination regarding application to be made by the ND in the light of each patient's individual circumstances. While AANP makes every effort to present accurate and reliable information, the information provided in these guidelines is "as is" without any warranty of accuracy, reliability, or otherwise, either express or implied. Neither AANP nor its officers, directors, members, employees, or agents will be liable for any loss, damage, or claim with respect to any liabilities, including direct, special, indirect, or consequential damages, incurred in connection with this guidance or reliance on the information presented.

Any questions about this document or its intended use may be directed to communications@naturopathic.org.

Appendix K

Draft Proposed Formularies. Connecticut Naturopathic Prescriptive Authority Drug Classes & Exclusions

(proposal submitted to CT DPH by Rick Liva, ND, 7/25/16)

CT ND Prescriptive Authority Drug Classes & Exclusions

Summary: A Connecticut licensed naturopathic physician will be able to legally prescribe any legend drug or controlled substance with the following exclusions:

EXCLUDED ITEMS

1. Intracardiac, intraosseous, intrathecal, intravitreal medications.
2. Controlled - Schedule I agents, cocaine, methamphetamine, methadone, ketamine.
3. Antineoplastic (anti-cancer) agents classified as legend drugs.
4. Typical and Atypical Anti-psychotics, Barbituates (stand alone only, in combination with other drugs allowed, example Fiorinal)
5. General Anesthetics, Gold Compounds, Antiarrythmia drugs, Isotretinoin
6. Roentgenographic agents, Radiopharmaceuticals, Radioisotopes
7. Oxytocics, All Glaucoma drugs, Bone Resorption Inhibitors
8. Antithrombotic Agents (anticoagulants), Hematopoietic Agents, Hemorrheologic Agents, Antihemorrhagic Agents, Complement Inhibitors
9. Biologic Response Modifiers, Disease Modifying Antirheumatic Drugs (DMARs),
10. Immuno Suppressive Agents (excluded are; antithymocyte globulin (equine), antithymocyte globulin (rabbit), basiliximab, belatacept, belimumab, cyclosporine, mycophenolate, sirolimus, tacrolimus)
11. Other Miscellaneous Agents (excluded are; abobotulinumtoxin A, botulinum toxin, canakinumab, cinacalcet, dalfamridine, incobotulinumtoxinA, lanreotide, miglustate, nitisinone, octreotide, onabotulinumtoxinA, rilonacept, rimabotulinumtoxinA, sapropterin)

INCLUDED DRUG CATEGORIES

Naturopathic physicians would have to authority to prescribe and use any drug in these categories except where specifically excluded (see exclusion list). Naturopathic physicians would have to authority to prescribe and use any Over The Counter (non-prescription) drugs or preparations in any available form.

ANTIHISTAMINE DRUGS – self explanatory

ANTI-INFECTIVE AGENTS, Examples: Antiprotozoal, Antileprotic, Antibiotic, antiviral agents - self explanatory

AUTONOMIC DRUGS
Examples
(a) Parasympathomimetic Agents (examples, agents for dementia and Alzheimer's disease)
(b) Anticholinergic Agents (example is scopolamine patch for nausea and dizziness)
(c) Sympathomimetic (Adrenergic) Agents (examples, phenylephrine for nasal congestion, agents for asthma)
Skeletal muscle relaxants
Miscellaneous – Nicotine agents for smoking cessation

BLOOD FORMATION
Examples
(a) Antianemia Drugs
(A) Iron Preparations

CARDIOVASCULAR DRUGS (examples: meds for blood pressure, cholesterol lowering, vasodilating drugs)

CENTRAL NERVOUS SYSTEM DRUGS
ANALGESICS, ANTIPYRETIC, ANTI-INFLAMMATORY DRUGS - self explanatory
Examples
(a) Analgesics and Antipyretics
(b) Opiate Antagonists, Agonists and partial agonists
(c) Anticonvulsants
(d) Psychotherapeutic Agents (NO typical or atyplical antipsychotic agents per exclusion above) Antidepressants, sedatives, anti-migraine agents, anti-parkinson agents

CONTRACEPTIVES - self explanatory

DIAGNOSTIC AGENTS, AIDS AND FUNCTION TEST AGENTS
Examples: Cortrosyn for Pituitary Function, D-Xylose for Intestinal absorption, Mumps skin test antigen, Tuberculin PPD test,

ELECTROLYTIC, CALORIC AND WATER BALANCE
Examples
(a) Acidifying Agents
(b) Alkalinizing Agents
(c) Ammonia Detoxicants
(d) Fluid Replacements Preparations
(e) Ion-Removing Agents
(f) Caloric Agents
(g) Diuretics
(h) Irrigation Solutions
(i) Uric acid eliminating or managing agents

ENZYMES - self explanatory

RESPIRATORY TRACT AGENTS
Examples: Expectorants and cough preparations, antihistamines, bronchodilators, anti-inflammatory agents, etc - self explanatory

OPHTHALMIC, OTIC AND NASAL PREPARATIONS – Examples: ointments, solutions, suspensions, preparations – anti allergy, anti infective, anti-inflammatory drugs, NO GLAUCOMA DRUGS

GASTROINTESTINAL DRUGS
Examples
(a) Antacids and Adsorbents
(b) Antidiarrhea Agents
(c) Antigas Agents
(d) Cathartics and Laxatives
(e) Cholelitholytic Agents
(f) Emetics
(g) Antiemetics
(h) Antiulcer Agents and Acid Suppressants
(i) Prokinetic Agents (enhances gastrointestinal motility)
(j) Anti-inflammatory Agents (k) Drugs for IBS, colitis, ulcers

HEAVY METAL ANTAGONISTS/CHELATING AGENTS - self explanatory

HORMONES & SYNTHETIC SUBSTITUTES – Examples: male and female hormone replacement, anti-diabetic agents, etc - self explanatory

ANESTHETICS, LOCAL - self explanatory

SERUMS, TOXOIDS, VACCINES - self explanatory

SKIN AND MUCOUS MEMBRANE PREPARATIONS – Examples: anti-infective agents, anti-inflammatory, anti-acne agents, etc

SMOOTH MUSCLE RELAXANTS - Examples: Gastrointestinal, urinary and respiratory, self explanatory

NUTRIENTS BY INJECTION: EXAMPLES: VITAMINS, MINERALS, TRACE MINERALS, AMINO ACIDS, LIPIDS, PHOSPHOLIPIDS, FATTY ACIDS, ALPHA LIPOIC ACID, GLUTATHIONE, ETC.

HOMEOPATHIC PREPARATIONS - self explanatory

MISC THERAPEUTIC AGENTS
ALCOHOL DETERRENTS - self explanatory
ANTI-GOUT DRUGS - self explanatory
ANTIDOTES - self explanatory
5 ALPHA REDUCTASE INHIBITORS
BETAINE
SULFASALAZINE

Included going forward all new AHFS (American Hospital Formulary Service) drug categories created in the future and new drugs added to allowed categories.

(proposal submitted to CT DPH by Rick Liva, ND, 9/6/2016)

CT ND Prescriptive Authority Drug Classes & Exclusions

Summary: A Connecticut licensed naturopathic physician will be able to legally prescribe any legend drug or controlled substance with the following exclusions:

EXCLUDED ITEMS

1. Intracardiac, intraosseous, intrathecal, intravitreal medications. NO intravenous anti-infective agents.
2. Controlled Substances: - cocaine, methamphetamine, ketamine; NO injectable schedule drugs
3. Antineoplastic (anti-cancer) agents classified as legend drugs.
4. Typical and Atypical Anti-psychotics, Barbituates (stand alone only, in combination with other drugs allowed, example Fiorinal)
5. General Anesthetics, Gold Compounds, Antiarrythmia drugs, Isotretinoin
6. Roentgenographic agents, Radiopharmaceuticals, Radioisotopes
7. Oxytocics, All Glaucoma drugs, Bone Resorption Inhibitors
8. Antithrombotic Agents (anticoagulants), Hematopoietic Agents, Hemorrheologic Agents, Antihemorrhagic Agents, Complement Inhibitors
9. Biologic Response Modifiers, Disease Modifying Antirheumatic Drugs (DMARs),
10. Immuno Suppressive Agents (excluded are; antithymocyte globulin (equine), antithymocyte globulin (rabbit), basiliximab, belatacept, belimumab, cyclosporine, mycophenolate, sirolimus, tacrolimus)
11. Other Miscellaneous Agents (excluded are; abobotulinumtoxin A, botulinum toxin, canakinumab, cinacalcet, dalfamridine, incobotulinumtoxinA, lanreotide, miglustate, nitisinone, octreotide, onabotulinumtoxinA, rilonacept, rimabotulinumtoxinA, sapropterin), Digoxin Immune FAB, Glucarpidase, Galsulfase, Ovulation Stimulants, Uterine Active Agents, Agents for Hypertensive Emergencies, Agents for Patent Ductus Arteriosus, Agents for Pheochromocytosis, Dobutamine, Dopamine, Isoproterenol HCL, Norepinephrine Bitartrate, Midodrine HCL, Lung Surfactants, Ophthalmic Alpha Adrenergic Agonists, Ophthalmic Beta-Adrenergic Blocking Agents, Ophthalmic Prostaglandin Analogues, Ophthalmic Carbonic Anhydrase Inhibitors, Succinylcholine Chloride, Nitrous Oxide, Propofol

INCLUDED DRUG CATEGORIES

Naturopathic physicians would have to authority to prescribe and use any drug in these categories except where specifically excluded (see exclusion list). Naturopathic physicians would have to authority to prescribe and use any Over The Counter (non-prescription) drugs or preparations in any available form.

ANTIHISTAMINE DRUGS – self explanatory

ANTI-INFECTIVE AGENTS, Examples: Antifungal, Antiprotozoal, Antileprotic, Antibiotic, antiviral agents - self explanatory

AUTONOMIC DRUGS

Examples

(a) Parasympathomimetic Agents (examples, agents for dementia and Alzheimer's disease)

(b) Anticholinergic Agents (example is scopolamine patch for nausea and dizziness)

(c) Sympathomimetic (Adrenergic) Agents (examples, phenylephrine for nasal congestion, agents for asthma)

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ANALGESICS, ANTIPYRETIC, ANTI-INFLAMMATORY DRUGS - self explanatory
Examples
(a) Analgesics and Antipyretics
(b) Opiate Antagonists, Agonists and partial agonists
(c) Anticonvulsants
(d) Psychotherapeutic Agents (NO typical or atyplical antipsychotic agents per exclusion above) Antidepressants, sedatives, anti-migraine agents, anti-parkinson agents

CONTRACEPTIVES - self explanatory

DIAGNOSTIC AGENTS, AIDS AND FUNCTION TEST AGENTS
Examples: Cortrosyn for Pituitary Function, D-Xylose for Intestinal absorption, Mumps skin test antigen, Tuberculin PPD test, Allergen Patch Tests, etc.

ELECTROLYTIC, CALORIC AND WATER BALANCE
Examples
(a) Acidifying Agents
(b) Alkalinizing Agents
(c) Ammonia Detoxicants
(d) Fluid Replacements Preparations
(e) Ion-Removing Agents
(f) Caloric Agents
(g) Diuretics
(h) Irrigation Solutions
(i) Uric acid eliminating or managing agents

ENZYMES - self explanatory (injectable enzyme preparations excluded)

RESPIRATORY TRACT AGENTS
Examples: Expectorants and cough preparations, antihistamines, bronchodilators, anti-inflammatory agents, etc - self explanatory

OPHTHALMIC, OTIC AND NASAL PREPARATIONS – Examples: ointments, solutions, suspensions, preparations – anti allergy, anti infective, anti-inflammatory drugs, NO GLAUCOMA DRUGS

GASTROINTESTINAL DRUGS
Examples
(a) Antacids and Adsorbents
(b) Antidiarrhea Agents
(c) Antigas Agents
(d) Cathartics and Laxatives
(e) Cholelitholytic Agents
(f) Emetics

(g) Antiemetics

(h) Antiulcer Agents and Acid Suppressants
(i) Prokinetic Agents (enhances gastrointestinal motility)
(j) Anti-inflammatory Agents (k) Drugs for IBS, colitis, ulcers

HEAVY METAL ANTAGONISTS/CHELATING AGENTS - self explanatory

HORMONES & SYNTHETIC SUBSTITUTES – Examples: male and female hormone replacement, anti-diabetic agents, etc - self explanatory

ANESTHETICS, LOCAL - self explanatory

SERUMS, TOXOIDS, VACCINES - self explanatory

SKIN AND MUCOUS MEMBRANE PREPARATIONS – Examples: anti-infective agents, anti-inflammatory, anti-acne agents (excluds ISOTRETINOIN), etc

SMOOTH MUSCLE RELAXANTS - Examples: Gastrointestinal, urinary and respiratory, self explanatory

NUTRIENTS BY INJECTION: EXAMPLES: VITAMINS, MINERALS, TRACE MINERALS, AMINO ACIDS, GLYCYRRHIZA, LIPIDS, PHOSPHOLIPIDS, FATTY ACIDS, ALPHA LIPOIC ACID, GLUTATHIONE, Sterile Water, Saline Fluids, Dextrose in Water, Sodium Bicarbonate, HCL, ETC.

HOMEOPATHIC PREPARATIONS - self explanatory

MISC THERAPEUTIC AGENTS
ALCOHOL DETERRENTS - self explanatory
ANTI-GOUT DRUGS - self explanatory
ANTIDOTES - self explanatory
5 ALPHA REDUCTASE INHIBITORS
BETAINE
SULFASALAZINE

Included going forward all new AHFS (American Hospital Formulary Service) drug categories created in the future and new drugs added to allowed categories.

Appendix L

Never Only Opioids: *The Imperative for Early Integration of Non-Pharmacological Approaches and Practitioners in the Treatment of Patients with Pain*

PAINS PROJECT

TRANSFORMING THE WAY PAIN IS PERCEIVED, JUDGED AND TREATED

POLICY BRIEF

NEVER *ONLY* OPIOIDS:

THE IMPERATIVE FOR EARLY INTEGRATION OF NON-PHARMACOLOGICAL APPROACHES AND PRACTITIONERS IN THE TREATMENT OF PATIENTS WITH PAIN.

Fall 2014 — Issue 5

POLICY **BRIEF**

NEVER ONLY OPIOIDS: THE IMPERATIVE FOR EARLY INTEGRATION OF NON-PHARMACOLOGICAL APPROACHES AND PRACTITIONERS IN THE TREATMENT OF PATIENTS WITH PAIN.

INTRODUCTION: The Imperative for Non-Pharmacological Approaches and Practitioners in Pain Treatment

Former U.S. Army Surgeon General Eric Schoomaker, MD, PhD, has characterized the military's advanced engagement of complementary and integrative approaches and practitioners as "the imperative for integrative medicine in the military."[1] This urgency came even as integrative practices are already embedded in military medicine. By 2012, 120 military facilities offered 275 complementary and alternative medicine programs producing 213,515 visits for active duty military members.[2]

Shortly thereafter, the director of the National Institutes of Health's National Center for Complementary and Alternative Medicine, Josephine Briggs, MD, announced an NIH working group involving Schoomaker on integrative pain strategies for the military, declaring that "opioids alone cannot be the answer."[3]

The perception of an "imperative" for using non-pharmacological strategies in the military begs a major policy question. Is there an imperative for integrative health and medicine for treatment of pain in the civilian population?

In 2010 with the passage of the Patient Protection and Affordable Care Act (ACA), Congress recognized the impact of complementary and alternative medicine (CAM) -- a term that includes meditation, acupuncture, chiropractic care and naturopathic treatment, among other things. While CAM is mentioned in various parts of the ACA, two sections specifically call attention to this integrative, bio-psychosocial approach. Section 2706 requires that insurance companies "shall not discriminate" against any health provider with a state-recognized license. Section 5101 includes licensed complementary and alternative medicine providers and integrative health practitioners in its definition of health professionals in the "health care workforce."

> "This is a unique, historic moment to capitalize on what we know works to effectively treat pain. It marks the beginning of a cultural shift in how health care is practiced in the military."[4]
>
> — Former Army Surgeon General Lt. Gen. Eric B. Schoomaker, MD, PhD, 2009

There is a distinct need for balance in the twin public health crises of prescription drug abuse and inadequately-treated chronic pain. The Institute of Medicine has declared pain a major public health challenge.[7] Simultaneously, deaths related to prescription medications soared 400% in women and 265% in men in a decade.[8] Every year, prescription opioids contribute to 17,000 deaths; NSAIDs and acetaminophen send another 80,000 people to the ER;[9] and NSAID use is associated with increased risk of GI bleeds, impaired renal function, and cardiovascular death. Opioids have become problematic street drugs among our youth.[10] Immeasurable personal costs of chronic pain are linked to $300 billion in additional health care costs and $335 billion in lost productivity.[11] Multiple non-pharmacological approaches, methods and practitioners with evidence to support their inclusion should be considered important tools in addressing these public health challenges.

Ellen: A Patient's Story

Ellen* is a 46-year old, college-educated African American female with a history of severe migraines beginning at age 22. She is married with one child and runs a part-time consulting business, working from home. She suffers migraines lasting several days, three-to-four times a month, and her work schedule varies with the frequency and severity of her headaches.

Ellen was seen at a pain management center in the past year, where she was offered medication and a facilitated support group. She has had medications, including opioids, prescribed, but she tries to avoid these unless absolutely necessary. She doesn't like the side effects and cannot perform her work as effectively. Chronic pain has negatively affected her relationships with her family. While she used to enjoy dancing with her husband and working in her garden, with her headaches she seldom feels she can now.

When she can, Ellen attends the support group for people living with chronic pain. After hearing a success story about an integrative approach to managing fibromyalgia pain, Ellen decided to investigate non-pharmacological options. She began getting a massage twice a month for three months. She felt noticeably more relaxed and aware of how she was sitting at the computer after the first month. Her massage therapist recommended yoga or Pilates for self-care between sessions. She chose yoga, took a series of classes, and practiced postures at home, especially when she noticed feeling stressed.

After reading about mindfulness, Ellen began morning walks and used this time to practice deep breathing and being fully present. She already avoided certain foods as headache triggers, and talked with a nutritional consultant about an anti-inflammatory diet. With her family's support, they all began eating more vegetables, fruit and fish, less processed foods, sugar and artificial sweeteners, and eliminated soda.

After three months, Ellen had fewer, less severe migraines, and noticed her stress sooner. She more often managed her headaches with OTC medications, and only occasionally used prescription medication. She spent more time in the garden, her mood improved, and she was able to work more productively and engage more positively with her family. She continues to add to her repertoire of self-care strategies, gets a massage about once a month, practices yoga and mindfulness, attends her support group, and eats more healthfully.

Ellen had the personal resources and determination to investigate her options, explore, and make positive changes. Every patient living with chronic pain should have education about, and access to, non-pharmacological treatment options and knowledgeable practitioners who can guide them in creating an individualized plan of care that includes complementary, integrative, and self-care options.

* Ellen's story is a composite of several real individuals who participated in a University of Virginia study of people living successfully with chronic pain: http://www.medicine.virginia.edu/community-service/centers/wisdom/home.

Indeed, we have an imperative to immediately engage in a thorough exploration of how to implement non-pharmacological approaches to improve pain treatment. The time is right. Values-based changes in payment and team-based methods in the delivery of care support engagement. The current evidence base, advanced practices and the military can guide us. This policy brief outlines the issues and opportunities and recommends solutions.

Evidence to Support Optimal Integrative Treatment

Research into non-pharmacological care is vastly underfunded on the federal level compared to industry funding for drugs and high cost procedures. Despite this disparity, present evidence is more than sufficient to support integration of these strategies and providers in multiple settings.

> "Ideally, most patients with severe persistent pain would obtain pain care from an interdisciplinary team."
>
> — IOM Blueprint

Most current health care is not based on optimal evidence, and research typically takes one to two decades to be implemented in practice.[5] The medical director of the University of Pittsburgh Medical Center shared a sobering perspective when he said that "only about a quarter of what we do has strong evidence, and we only do that about half the time."[6]

Our tangled relationship to evidence is particularly problematic in optimal treatment of people with pain. We have agents, such as analgesics, with multiple studies showing they suppress pain symptoms. At the same time, new evidence is growing that prolonged use of these agents can worsen these very symptoms and poses substantial risks.[7,8] These risks may be exacerbated by the concept of neuroplasticity, the functional, chemical and anatomical changes in the nervous system that can take place in response to pain. This concept of neuroplasticity highlights the importance of psychological factors in the central processing of pain and provides an explanation for how non-pharmacological approaches may work to reduce the intensity of the pain experience.

Non-pharmacological approaches pose no such risk, and there is substantial evidence to support their use. In fact, the evidence base for non-pharmacological approaches to pain management was sufficient 15 years ago for the Joint Commission's 2000 mandate on pain to include "non-pharmacological approaches."[9] Evidence has grown considerably since then. The American College of Physicians and American Pain Society includes multiple non-pharmacological practices in their low back pain guidelines.[10] The NIH has published information on evidence levels for diverse complementary and integrative interventions.[11] *Pain Medicine* devoted a recent issue to the evidence for patient engagement.[12]

While the military is building non-pharmacologic approaches and practitioners into multiple practices,[13] few civilian settings have implemented practices that include significant opportunities to break the analgesic-pain cycle. Present evidence is more than sufficient to support early use of non-pharmacological strategies, including complementary and integrative care, in real-world settings.

Widening the Circle of the Integrative Pain Workforce

The Institute of Medicine concludes that "ideally, most patients with severe persistent pain would obtain pain care from an interdisciplinary team."

The report singles out "psychologists or other mental health professionals, rehabilitation specialists, and/or complementary and alternative medicine [CAM] therapists)." Yet the report also notes that primary care doesn't customarily include these specialists.

Care providers and patient-created teams in specialized pain centers frequently include integrative practitioners and/or therapies. The growth of these licensed fields is tied to consumer interest in non-pharmacological approaches. Pain-related conditions are the dominant force in growing consumer use of chiropractic, acupuncture and Oriental medicine, naturopathic medicine, and massage therapy. Together, these total over 380,000 licensed practitioners. An estimated 3,000

medical doctors and 1,000 nurses have been educated to competency-based standards in integrative or holistic medicine. Pain was viewed as the most effective treatment area in a survey of health system integrative medicine centers.[21]

These practitioners are already part of the nation's workforce and provide services to many who live with chronic pain. They are also formally included in an as yet unfunded portion of the Affordable Care Act, Section 5101, the National Health Care Workforce Commission. In this patient-centered era, policy on research and practice should proactively include integrative health practitioners.

"Non-Discrimination in Health Care" Fosters Non-Pharmacological Options

Lack of reimbursement is a major barrier to the optimal inclusion of non-pharmacological approaches in the treatment of people with pain. Licensed practitioners with skills in non-pharmacological or integrative approaches are often not covered providers. Patient choice, practitioner referrals, and health system employment are constrained.

Depending on interpretation and implementation, Section 2706 of the Affordable Care Act, "Non-Discrimination in Health Care," may move us toward lowering this barrier. The section was included in response to requests from a consortium of 13 organizations of licensed and certified integrative health professionals with expertise in treating people with pain conditions, the Integrative Healthcare Policy Consortium, and also by the American Chiropractic Association.

Section 2706 is the subject of considerable debate nationally and in the states. The AMA House of Delegates resolved to overturn it. The national Blue Cross Blue Shield Association and some other insurers have responded affirmatively. Many insurance commissioners are disregarding it. Three federal agencies including the Department of Health and Human Services essentially dismissed the section. However, the U.S. Senate Appropriations Committee has twice told these agencies their actions violate Congressional intent.

Some Resources for Evidence on Non-Pharmacological Approaches

Guidelines

Pain Management Standards (Joint Commission on Accreditation of Healthcare Organizations, 2000)

Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline (American College of Physicians and the American Pain Society, 2007)

Other Resources

Chronic Pain and Complementary Health Approaches: What You Need to Know (NIH National Center for Complementary and Alternative Medicine)

Are Self-Care Complementary and Integrative Therapies Effective for Management of Chronic Pain? A Rapid Evidence Assessment of the Literature and Recommendations from the Field. (Pain Medicine, 2014)

Clinical Update: A Holistic Model of Care (International Association for the Study of Pain, 2014)

Clinicians' and Educators' Desk Reference on the Licensed Complementary and Alternative Healthcare Professions (Second Edition, 2013)

Clinical Update: Chronic Pain Management – Measurement-based Step-Care Solutions (International Association for the Study of Pain, 2012)

> "Overall, CAM users had lower average expenditures than nonusers ($3,797 versus $4,153). Their outpatient expenses were higher, but offset by lower expenses for inpatient care and imaging. People who had the heaviest disease burdens accounted for the highest levels of savings, an average of $1,420."[22]
>
> — IOM Blueprint

Since 1996, Washington State has been an experiment for coverage of licensed complementary and alternative medicine practitioners. The law that forced inclusion has been compared to Section 2706. Research has found lower average costs from covered users of these practitioners compared to non-users.[23]

Maturation of Licensed Integrative Health Professions

Profession	Accrediting Agency Established	US Dept. of Education Recognition	Recognized Schools or Programs	National Exam Created	State Regulation	Total Licensed Practitioners
Acupuncture and Oriental medicine	1982	1990	61	1982	44	28,000
Chiropractic	1971	1974	15	1963	50	72,000
Massage therapy	1982	2002	88*	1994	48	280,000
Naturopathic medicine	1978	1987	7	1986	18	5,500

* Only includes those schools accredited through the specialized accrediting agency for massage therapy, the Commission on Massage Therapy Accreditation. Source: Updated from the Clinicians and Educators Desk Reference on the Licensed Complementary and Alternative Healthcare Professions. Academic Consortium for Complementary and Alternative Care (2013)

Notably, patients with the heaviest disease burdens accounted for the most significant savings.

Yet application and implementation that follows Congressional intent will stimulate opportunities for wider implementation and support patient choice.

> "The Joint Commission would significantly increase health system exploration of non-pharmacological treatment by beginning to score non-pharmacological approaches in pain treatment."

Roles for Accreditors and Certification Agencies

Under-implementation of non-pharmacological approaches results from multiple cultural, economic, educational and systemic barriers. The military has an advantage in engaging course corrections. Leaders can quickly marshal forces. For instance, when the Veteran's Administration decided its practitioners should be knowledgeable about integrative options, they quickly created an online course. Attendance was mandated. Awareness spread. Culture shifted.

Mandating courses to promote public health is not uncommon. There are many examples of requiring continuing education on a particular subject for licensure or recertification such as for HIV, ethics, cultural competency, and CPR.

Authoritative responses to pressing imperatives are powered by accreditation agencies for academic institutions and for hospitals and outpatient settings. Certification organizations for health professionals can similarly prompt practice shifts.

In a patient-centered era, mandated requirements can bridge the chasm between biomedical approaches, i.e., prescription pain medications, nerve blocks, surgeries and other interventional approaches, and the bio-psychosocial approaches promoted by complementary and alternative medicine. Bridging this chasm can help change the way pain is perceived, judged and treated.

Non-Pharmacological Approaches

Physical modalities

- ❑ Acupuncture
- ❑ Chiropractic and Osteopathic manipulation
- ❑ Massage therapy, hydrotherapy, and aromatherapy
- ❑ Physical therapy
- ❑ Trigger point therapy
- ❑ Occupational therapy

Relaxation and Mind/Body therapies

- ❑ Meditation, guided imagery, Reiki, music therapy
- ❑ Psychological therapies

Movement-based therapies

❑ Yoga, dance, exercise, aquatic therapy
❑ Tai chi and qi gong
❑ Movement education and postural awareness such as Alexander Technique, Feldenkrais, Egoscue Method, and Trager

Creative Arts Therapies

❑ Art, drama, dance, music and poetry therapy

Nutritional counseling

❑ Dietary changes and weight loss
❑ Learning to shop for and prepare healthy meals
❑ Identifying food sensitivities that cause inflammation

Strategies for Self-Care

❑ Learning to cope with the emotional and social consequences of pain
❑ Topical pain relievers (non-pharmacological)
❑ Participation in support groups and social support generally
❑ Mindfulness, meditation, guided imagery and contemplative practices
❑ Self-massage and partner massage
❑ Exercise
❑ Spending time in nature and engaging in other pleasurable or personally meaningful activities

Because licensed complementary, integrative and mental health practitioners are often trained in multiple non-pharmacological modalities, their inclusion into team-based care is an efficient method for increasing patient access to non-pharmacological approaches.

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PAINS' mission is to transform the way pain is perceived, judged and treated.

"Never Only Opioids"
is the 5th in a series of briefs profiling policy issues important to improving chronic pain care.

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This policy brief is a product of the Pain Action Alliance to Implement a National Strategy (PAINS) in collaboration with the Academic Consortium for Complementary and Alternative Health Care (ACCAHC) and the Center for Practical Bioethics. ACCAHC participation was funded by an unrestricted grant from the NCMIC Foundation.

Funded by US Cancer Pain Relief Fund

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Appendix M

Current Use of Chelation in American Health Care

J. Med. Toxicol. (2013) 9:303–307
DOI 10.1007/s13181-013-0347-2

PROCEEDINGS

Current Use of Chelation in American Health Care

Paul M. Wax

Published online: 12 October 2013

Abstract The National Center for Health Statistics estimates that more than 100,000 Americans receive chelation each year, although far fewer than 1 % of these cases are managed by medical toxicologists. Unfortunately, fatalities have been reported after inappropriate chelation use. There are currently 11 FDA-approved chelators available by prescription although chelation products may also be obtained through compounding pharmacies and directly over the internet. Promotion of chelation training is prominent on some alternative and complementary medicine websites.

Keywords Chelation therapy · Heavy metal poisoning · Inappropriate chelation practices · FDA-approved chelators · Chelation training

Background

The word *chelate* comes from the Greek word referring to a claw. Scientifically, a chelate refers to a ligand binding to a central metal atom at two or more points. Chelation therapy involves the administration of a chelating agent. Chelation therapy is a controversial and divisive topic because many practitioners encouraging such therapy eschew traditional science. The National Center for Complementary and Alternative Medicine (NCCAM) was founded within the National Institutes of Health (NIH) in 1992 to investigate and evaluate promising unconventional medical practices. The NCCAM newsletter from September 2010 states that "chelation has been scientifically proven to rid the body of excess toxic metals" [1]. It should be emphasized that evidence that chelation can remove metals does not mean that it is indicated for treatment whenever a "high" measurement is identified. Clinical evidence of symptoms consistent with excess exposure should be sought, and efforts should be made to reduce any ongoing exposure to clinically significant sources. Importantly, chelation therapy may affect many different elements not only resulting in enhanced elimination of toxic metals such as lead and arsenic, but also potentially increasing elimination of essential trace metals such as chromium, cobalt, copper, and iron that are needed for normal physiologic function. Chelators have the potential of causing harm because of what they may do to these essential metals. Evidence that chelation improves outcome is scarce, and such data, or lack thereof, is addressed elsewhere in this issue [2, 3].

In 2005, Agency for Toxic Substances and Disease Registry (ATSDR) scientists, John Risher and Sherlita Amler, published a paper in neurotoxicology about the inappropriate use of chelating agents in the diagnosis and treatment of putative mercury poisoning [4]. The report stated that each year ATSDR receives dozens of calls from individuals who have been chelated with either dimercaptopropanesulfonic acid (DMPS) or dimercaptosuccinic acid (DMSA) prior to the collection of any urine samples, and who have been subsequently diagnosed with mercury poisoning. The paper states that it is unfortunately all too common for practitioners to make a diagnosis of mercury intoxication and begin treatment without performing an adequate clinical workup. The American College of Medical Toxicology (ACMT) organized a symposium, supported by a Cooperative Agreement with ATSDR, to provide guidance for properly assessing these patients [5].

This paper will provide a review of currently available chelating agents and their indications, describe the various ways chelators are obtained, and discuss the frequency of use of these chelators and the types of health-care providers who are involved with chelation therapy. To provide a proper context for these objectives, three cases of inappropriate chelation practices that have come to the attention of medical toxicologists and public health organizations will be presented.

Previously presented at the conference "Use & Misuse of Metal Chelation Therapy" held on February 29, 2012, at the Centers for Disease Control, Atlanta, GA. This conference was jointly sponsored by the American College of Medical Toxicology and the Medical Toxicology Foundation with support from the Agency for Toxic Substances and Disease Registry.

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Inappropriate Chelation Practices: Case Examples

The first case is a health consultation that was performed by ATSDR several years ago involving the Higgins Farm National Priorities List site [6]. The case involved a family who was currently using a private well adjoining the Higgins Farm. ATSDR was asked to assist in the interpretation of environmental and medical test results that were previously obtained and evaluate the potential impact of contaminants from the Higgins Farm on the family. Apparently, two children had developed neurological impairments. One of them, who was 5 1/2 years old, previously had been diagnosed with attention deficit hyperactivity disorder and was undergoing chelation therapy for metal exposures. In these cases, heavy metal testing was performed after a chelator was administered. The spot mercury in the 5 1/2-year-old after DMSA was 10 μg/g creatinine; the spot mercury level in one of the adults after DMPS was 21 μg/g creatinine. Although these levels were used to justify treatment, interpreting such postchelation levels is very problematic. Typical reference ranges are based on measurements performed prior to any chelation treatment. Moreover, in this case no source of mercury could be located, suggesting that there may not have been any mercury exposure in the first place.

The second case involved a 43-year-old female who visited a medical toxicologist for a second opinion after her naturopath had diagnosed her with heavy metal poisoning. She had a history of chronic fatigue, difficulty concentrating, inability to get out of bed or talk, and was too fatigued to write a letter. She went to several "regular doctors," including a psychiatrist and a dermatologist, but they were unable to relieve her symptoms. Out of frustration, she sought treatment from a naturopath who she had seen for about a year. This naturopath ordered a urine heavy metal screen to be collected both before and after the administration of DMPS. The urine mercury levels were 1 and 18 μg/g creatinine, respectively. She was started on a course of chelation based on this "positive" response to the chelation challenge. However, the patient never had any symptoms of mercury toxicity, nor did she have any known exposure to mercury.

The third case was published in the Morbidity and Mortality Weekly Report (MMWR) in 2006 [7]. This case involved a 53-year-old female who was treated with 700 mg of ethylenediaminetetraacetic acid (EDTA) administered intravenously over 10 to 15 min in a naturopathic practitioner's clinic. The EDTA was intended to remove heavy metals from her body, but 10 to 15 min after she received this treatment, she suddenly became unconscious and had a cardiac arrest. During the resuscitation, she was given calcium gluconate and calcium chloride intravenously. Despite that treatment, her ionized calcium remained critically low at 3.8 mg/dL (normal, 4.5–5.3 mg/dL), and she died. This tragic case, along with two other deaths from EDTA described in the same MMWR report, brought needed attention to the inappropriate use of chelation therapy and its dangers.

Currently Available Chelating Agents

Currently, there are 11 FDA-approved chelators on the market (see Table 1) [8]. British Anti-Lewisite, also known as BAL or dimercaprol, is a dithiol chelator that was first developed by Peters in 1945 [9]. It is only available by prescription. It is formulated with peanut oil and can only be administered parenterally by deep intramuscular injection. It is approved for treatment of arsenic, gold, and mercury poisoning. It is also approved for the treatment of acute lead poisoning when given concomitantly with edetate calcium disodium. BAL use is associated with many adverse effects, including elevated blood pressure, painful injections, and potential for sterile abscess formation, as well as being contraindicated in those with peanut allergy, but it is an effective chelator and can be used in the treatment of arsenic and mercury poisoning and in certain cases of lead poisoning.

EDTA, another of the early chelators, was first synthesized in the 1930s and has both non-medicinal as well as medicinal uses. Among its many nonpharmaceutical uses, EDTA is used extensively in the paper industry. It is found in some laundry detergents and is used in water treatment facilities and the food and beverage industry.

There are two different types of EDTA that have been formulated for pharmaceutical use—EDTA complexed with calcium and EDTA without calcium. The formulation with calcium is known as edetate calcium disodium, also known as disodium versenate. The formulation without calcium is edetate disodium, no calcium in its name. One can easily be confused between these types of EDTA, but the difference is critically important, as the formulation with calcium will not bind calcium, while the one without calcium will bind calcium.

Table 1 FDA-approved chelators

Dimercaprol (BAL)
Edetate calcium disodium (calcium EDTA)
Succimer (DMSA)
Penicillamine
Trientine hydrochloride
Deferoxamine mesylate
Deferiprone
Deferasirox
Pentetate calcium trisodium (Ca-DTPA)
Pentetate zinc trisodium (Ca-DTPA)
Prussian blue (Radiogardase)

Edetate calcium disodium was first approved in 1953. It is available by prescription and is approved for the treatment of lead poisoning. It is only administered parenterally, and in recent years there have been periodic shortages of the drug. Currently, there are no oral formulations of calcium disodium EDTA that are FDA approved. Adverse reactions associated with the use of edetate calcium disodium include acute renal failure, mild increase in hepatic transaminases, hypotension, cardiac arrhythmias, and allergic reactions.

Edetate disodium was also approved in the 1950s and was used predominantly in the treatment of hypercalcemia. As mentioned above, a 2006 MMWR report noted that three patients died after receiving disodium EDTA from the effects of severe hypocalcemia. In part because of these tragic deaths, disodium EDTA was withdrawn from the market in 2008. It is no longer FDA approved and is no longer available through traditional routes.

The most commonly prescribed chelator today is succimer, also known as Chemet or by its chemical acronym, DMSA. This is a prescription drug available in an oral formulation only; it is approved for use in the treatment of lead poisoning in pediatric patients with blood lead levels >45 μg/dL. While generally safe, DMSA has been associated with mild elevations in hepatic transaminases and allergic reactions. As discussed elsewhere in this issue, DMSA is also used in the treatment of mercury and arsenic poisonings although these are not FDA-approved indications [10].

Penicillamine is another chelator. Unlike the others discussed above, penicillamine is a unithiol possessing only one thiol group. It is an oral chelator and is available by prescription only. It is approved for the treatment of Wilson's disease, which is a chronic copper storage disease, cystinuria, and refractory rheumatoid arthritis. It has also been used to treat lead poisoning, but that use has been off-label. Serious hematological and renal adverse reactions have been associated with penicillamine including leukopenia, thrombocytopenia, aplastic anemia, proteinuria, hematuria, and nephrotic syndrome.

There are several FDA-approved iron chelators. Deferoxamine, originally approved in the 1960s, is an intravenous chelator that is approved for the treatment of acute iron poisoning and chronic iron overload due to transfusion-dependent anemia (such as thalassemia) in the setting of numerous blood transfusions. Adverse reactions associated with deferoxamine use include hypotension, hypersensitivity reactions, ARDS, renal failure, and susceptibility to *Yersinia* infections. Deferasirox and deferiprone are two oral iron chelators, recently introduced to the USA that are also approved for chronic iron overload.

Prussian blue, which can be used in the treatment of thallium and cesium poisoning, was FDA approved in 2003. In 2004 the FDA approved calcium DTPA and zinc DTPA to enhance the elimination of various radioactive nuclides including plutonium, americium, or curium.

There is also one chelator that is sometimes used in the USA that is not FDA approved, DMPS. This chelator is structurally related to DMSA or Chemet and is available both intravenously and orally. It is currently not FDA approved, but it can be obtained through some compounding pharmacies. It has been used in the treatment of mercury and arsenic poisonings and some other less common heavy metal poisonings.

Alternate Sources of Chelating Agents

Depending on the specific product, chelators are available by prescription, through compounding pharmacies, and at times sold directly over the internet. Any licensed medical provider can prescribe a chelator, including naturopaths and other types of alternative medicine physicians.

Compounding pharmacies customize preparations of medicine that are not otherwise commercially available. A physician or veterinarian or other prescribing practitioner writes a prescription for a customized preparation, and a licensed pharmacist at a compounding pharmacy prepares the prescription, utilizing active pharmaceutical ingredients. This process has been subject to ongoing legal and regulatory debates because compounding pharmacists essentially design their own customized pharmaceutical product. The question of whether this is a new compound that should be subject to FDA scrutiny remains controversial. Questions arise about the safety of some of these compounded pharmaceuticals because they are not currently subject to the stringent safeguards of FDA-approved products (see Fig. 1). Recently, a large outbreak of fungal meningitis resulting in more than 60 deaths was attributed to a preservative-free methylprednisolone acetate (MPA) preparation that was produced by a compounding center in New England [11]. This outbreak resulted in renewed calls for greater FDA regulation of compounding pharmacies [12].

The Federal Register from January 1999 provided a list of drugs that were nominated for inclusion on the bulk drug list that may be used in compounded products. One of these drugs was DMPS. The Federal Register states that "DMPS appears to be relatively nontoxic, and serious adverse affects associated with its use has not been commonly reported" [13]. This conclusion may understate the potential problems with DMPS, as DMPS has been associated with Stevens–Johnson syndrome [14].

One can also obtain a chelator without a prescription. Searching for "DMSA" on amazon.com yields results for not only DMSA but also calcium disodium EDTA [15]. Some of these DMSA products are described as "guaranteed pharmaceutical grade." One of the DMSA preparations available through Amazon is Captomer-250, which is 250 mg of DMSA. This formulation is considerably stronger than prescription

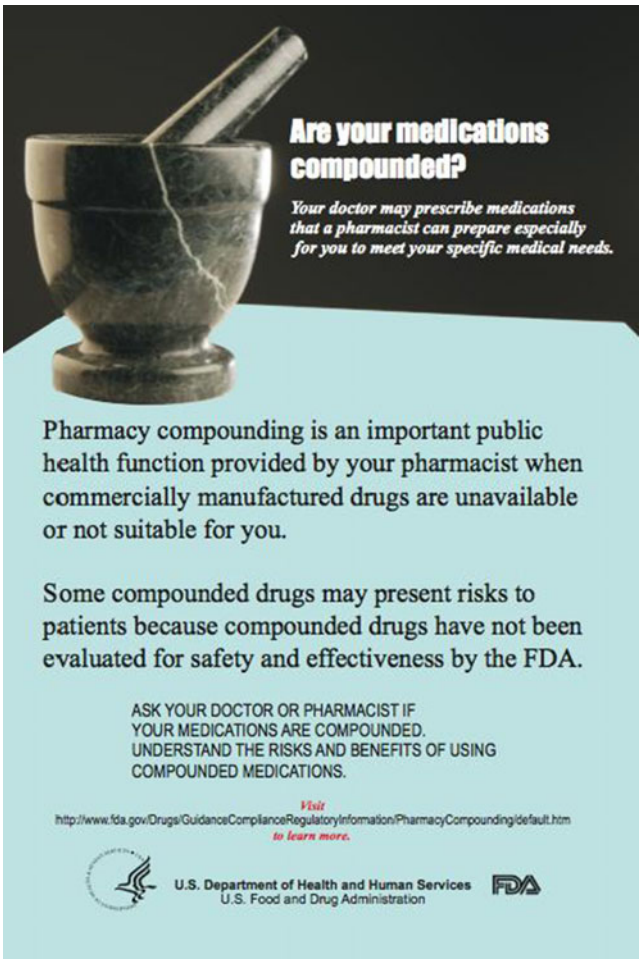

Fig. 1 FDA advertisement about compounding pharmaceuticals

DMSA, which is 100 mg per capsule, potentially leading to dosing errors.

Extent of Use of Chelating Agents

According to a 2008 National Health Statistic Report published by the National Center for Health Statistics, approximately 66,000 adults received some sort of chelation in 2002, and in 2007 the number was 111,000 adults [16]. In 2007, it was estimated that 72,000 children received chelation, for a total of 183,000 adults and children.

Comparing these data to national poison center data reveals markedly different numbers. The National Poison Data System (NPDS) collects data on antidote usage reported to poison centers. Strikingly, in 2007, only 466 cases involving the use of chelators were reported to poison centers, compared to 183,000 chelation cases estimated in the National Health Statistic Report cited above [17]. In a registry of 17,500 patients cared for by medical toxicologists across the USA between 2010 and 2012 in both the inpatient and outpatient settings, only 66 patients received chelation therapy [18]. These discrepancies suggest that not only treatment philosophy, but the nature of reporting, differs greatly across medical practitioners regarding the diagnosis of metal poisoning. Moreover, in many instances, chelators may have been administered to chelate mercury in children with autism spectrum disorders, chelate calcium in adults with atherosclerotic plaques and coronary or peripheral artery disease, or even chelate lead in some children with modest elevations in lead levels to treat ADHD. Unfortunately, data on chelator use by indication is not available. While data on which type of health-care practitioners most commonly prescribe chelation treatments is also not easily obtainable, poison center and medical toxicology registry data suggest only a small fraction of these treatments are prescribed by medical toxicologists.

According to the NIH, complementary and alternative medicine refers to "the array of health care approaches with a history of use or origins outside of mainstream medicine" [19]. They include a broad range of practices and beliefs such as acupuncture, chiropractor care, and also chelation. It is estimated that nearly 40 % of Americans use alternative medicine therapies on a regular basis [19]. This accounts for hundreds of millions of visits and over $20 billion spent on alternative therapies on a yearly basis, according to a 2005 Institute of Medicine report [20].

Several professional societies whose focus seems to be on complementary, alternative, and integrative medicine appear to have a keen interest in chelation training based on information provided on their websites [21, 22]. The American College for the Advancement of Medicine (ACAM) website states that "whether you're new to detoxification education or are a seasoned practitioner, ACAM's rigorous training will enhance your practice treatment options and improve health outcomes" [21]. The American Board of Clinical Metal Toxicology (ABCMT) offers board certification in clinical metal toxicology. Certification by the ABCMT requires the applicant to pass a written and oral examination and to be "responsible for the administration of two thousand intravenous infusions for the treatment of heavy metal toxicity" [22].

Conclusion

In summary, at this time there are almost a dozen FDA-approved chelators. While these are typically dispensed by prescription, chelators may also be available through compounding pharmacies and directly over the internet. National Health Statistics data suggest that more than 100,000 Americans may receive chelation each year, although far fewer than 1 % of these cases are managed by medical toxicologists. Finally, chelation therapy appears to be prominently promoted by some of the alternative and complementary medicine societies, raising concern about the validity of

both diagnosis and treatment of heavy metal poisoning in the USA.

Conflict of Interest The ACMT/ATSDR Cooperative Agreement provided grant funds to Dr. Wax and/or to ACMT for support of the chelation conference, for speaker honorarium, for travel reimbursement, and for editorial assistance.

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ATSDR Disclaimer

This publication was supported by the cooperative agreement award number 1U61TS000117-04 from the Agency for Toxic Substances and Disease Registry (ATSDR). Its contents are the responsibility of the authors and do not necessarily represent the official views of the Agency for Toxic Substances and Disease Registry (ATSDR).

Appendix N

Letter Regarding Chelation Therapy & Heavy Metal Toxicity

Christian D. Andresen, Section Chief
Practitioner Licensing and Investigations
Connecticut Department of Public Health
410 Capitol Avenue
Hartford, CT 06134

August 27, 2016

Dear Mr. Andresen,

I am a physician licensed to practice medicine in the state of Connecticut. I am board certified in Emergency Medicine, Medical Toxicology, and Undersea and Hyperbaric Medicine. I completed my Medical Toxicology fellowship at the University of Connecticut Health Center in 2006. I worked as a Medical Toxicologist at Hartford Hospital from 2006 through 2015, and was the director of a Medical Toxicology clinic at Hartford Hospital. I am currently employed at MedStar Georgetown University Hospital in Washington, DC, and practice Emergency Medicine, Hyperbaric Medicine, and Medical Toxicology.

Medical Toxicology involves the diagnosis, treatment, and prevention of both accidental and intentional poisonings in humans. As a Medical Toxicologist, I have had the opportunity to evaluate many patients for potential heavy metal toxicity, generally related to arsenic, mercury, and lead. Some of these patients have been come to me after being evaluated by naturopathic practitioners, after those practitioners performed provoked metal testing which reportedly revealed abnormal results. Some of these patients have also previously undergone chelation therapy for supposed metal toxicity.

While heavy metal poisoning is a legitimate diagnosis, it is rarely encountered in clinical practice. In ten years of clinical practice as a Medical Toxicologist, I can count on one hand the number of patients I have chelated for true heavy metal poisoning. The toxicity of metals depends on multiple factors including the state of the metal (inorganic, organic, or elemental) and the route of exposure. For example, there are numerous websites that delineate the "toxicity" of mercury dental amalgams, and recommend that people with mercury fillings have them removed and/or receive chelation in order to "treat" the toxic effects of this metal. However, mercury dental amalgams are composed of elemental mercury. Elemental mercury, unlike inorganic and organic mercury, is not toxic when ingested orally. Thus, even if a person with mercury dental amalgams swallowed an entire filling, the subsequent toxicity would be essentially zero. Elemental mercury is toxic when inhaled, and can lead to neurologic dysfunction. There is actually more harm in having mercury dental amalgams removed than in keeping them intact in a patient's mouth, as the act of amalgam removal involves vaporization which can lead to inhalation by the patient and dental staff. I have encountered several patients whose naturopathic practitioners have advised them to have their mercury fillings removed; some of them have gone through the trouble of actually having the fillings removed. This is reprehensible, as their fillings were entirely nontoxic to begin with and there was no medical indication to have the amalgams removed at all.

Unfortunately, the naturopathic practitioners did not understand that the chemical composition and route of exposure affects the potential toxicity of metals. These naturopathic providers' lack of adequate medical knowledge resulted in their patients receiving an unnecessary procedure that, unfortunately and paradoxically, may have resulted in increased risk for heavy metal toxicity.

The diagnosis of heavy metal poisoning is also a specialized process that requires specific knowledge about the tissue distribution and clearance of metals from the body. Arsenic is renally excreted, and the gold standard for detecting arsenic poisoning in humans is the 24-hour urinary arsenic level. Certain types of arsenic (elemental and organic) are nontoxic to humans when ingested orally. An elevated 24-hour urinary arsenic level usually is secondary to ingestion of seafood, which contains organic (but nontoxic) arsenic. Testing a patient for potential arsenic toxicity involves either asking the patient to abstain from eating fish for a period of time before the testing, or requesting that the testing laboratory speciate the results into inorganic (toxic) and organic (nontoxic) forms. I have treated many patients, some of whom were referred by naturopathic practitioners, who had elevated urinary arsenic levels and who requested that I prescribe them chelation therapy to "detoxify" their bodies from arsenic. Upon careful evaluation, I determined that all of these patients had elevations in their urinary arsenic levels secondary to seafood that was ingested around the time of the testing. None of these patients required chelation therapy.

While Medical Toxicologists are aware of the complexities of heavy metals and how this affects the evaluation and diagnosis of patients who present with potential heavy metal poisoning, most other medical specialties are unaware of these factors. Naturopathic practitioners have even less knowledge and experience concerning heavy metals, and in my experience are most often unaware of the important issues surrounding the diagnosis and treatment of heavy metal poisoning. On numerous occasions, I have cared for patients who were advised by their naturopathic practitioners that they were suffering from heavy metal toxicity and required treatment with chelation therapy. I have always found that these patients were incorrectly diagnosed, and did not actually have a significant body burden of heavy metals. Additionally, many naturopathic practitioners prefer to use provoked urinary testing to assay for heavy metals. Provoked urinary testing involves the administration of a chelator to a patient prior to the inception of testing. Chelation (derived from the Greek word "chele", or "claw") involves the administration of a drug to bind a particular toxin and form a stable, excretable complex. After a chelator is administered to a patient, the patient's urinary levels of heavy metals will uniformly become elevated, as the chelator removes even physiologic levels of non-toxic metals from the body. The presence of heavy metals in a chelator provoked urinary specimen does not equate with the presence of heavy metal toxicity, as many of the metals drawn out of the body by the chelator are not associated with significant toxicity. However, there are laboratories and practitioners who feed on patients' fears of heavy metal poisoning, that recommend or provide provoked chelation testing and then recommend chelation "supplements" to "detoxify" the body after the diagnosis of chelator-provoked heavy metal poisoning is made. In my Medical Toxicology practice, I have encountered multiple patients who have been

treated by naturopathic practitioners for heavy metal "poisoning" after undergoing provoked chelation urinary testing. Their provoked urinary heavy metal testing results are elevated, and the patients are terrified that they are suffering the effects of heavy metal toxicity. However, the patients (and likely many of the naturopathic practitioners) are unaware that the "toxic metal" reference ranges provided by the testing laboratories are inaccurate, as they are always reference ranges for non-provoked urine tests, so they cannot even be applied to the provoked urine testing patients! Some of these patients have spent significant amounts of money to purchase the recommended detoxification supplements and chelation therapy after receiving these inaccurate results; none of these medications are covered by commercial health insurance. I generally retest these patients for heavy metals under standard non-provoked conditions, and I have never diagnosed legitimate heavy metal toxicity in any of these patients, as their non-provoked urinary testing is always negative.

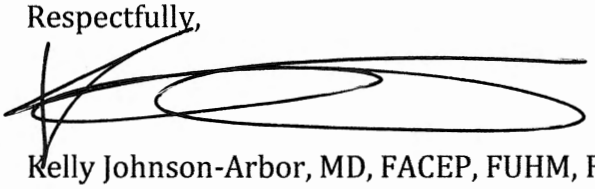
Chelation therapy is another realm of medicine that requires specific education and training for appropriate and safe administration. Because true heavy metal toxicity is an infrequently made diagnosis, chelation is rarely performed in clinical medicine. As with all medical procedures, chelation has risks associated with it. With the exception of childhood lead poisoning, many patients who require chelation are admitted to the hospital for the procedure so that proper monitoring can be performed during the treatment.

Occasionally, chelation can result in a fatal outcome, especially if the incorrect drug is administered. Calcium disodium EDTA (CaNa2EDTA) is a chelator used for the treatment of lead poisoning; it is sometimes also recommended as a treatment for atherosclerosis, although there is no scientific evidence to support its use for this condition. In 2006, the CDC published a MMWR report that described the deaths of three patients who received chelation in the form of disodium EDTA instead of calcium disodium EDTA. All three patients developed fatal hypocalcemia after the administration of disodium EDTA. In one of these cases, the administration of disodium EDTA occurred in a naturopathic practitioner's office. While the Medical Toxicology community is aware that there is a difference between calcium disodium EDTA and disodium EDTA and that there are significant risks associated with the administration of disodium EDTA, a naturopathic practitioner who has significantly less medical education and training may not be aware of these issues and may inappropriately dispense the incorrect medication to an unsuspecting patient.

As a Medical Toxicologist, I am concerned that the naturopathic practitioner population lacks the medical knowledge and training to accurately diagnose and treat heavy metal poisoning. I strongly believe that naturopathic practitioners should not be allowed to diagnose and treat heavy metal poisoning, and I worry that additional adverse events, including fatalities, will occur if naturopathic practitioners are allowed to continue treating patients for heavy metal poisoning. The diagnosis and treatment of heavy metal exposure and poisoning requires specialized knowledge regarding the chemical structures of metals, their different routes of exposure and resulting toxicities, and the correct methods of treatment. Even after the completion of two years of fellowship and ten years in clinical practice as a Medical Toxicologist, I continue to learn new insights into the

intricacies of heavy metal poisonings. Naturopathic practitioners, who did not complete specialized Medical Toxicology fellowship training and who are not board certified in the specialty, clearly lack the ability to adequately assess and treat these patients. I fully support any resolution that will prevent naturopathic practitioners from diagnosing or treating patients with suspected heavy metal toxicity.

Respectfully,



Kelly Johnson-Arbor, MD, FACEP, FUHM, FACMT

Appendix O

Letter from Medical and Nursing Committee Members

September 27, 2016

Chris Andresen, Chief
Practitioner Licensing and Investigations Section
410 Capitol Avenue, MS # 12MQA
P.O. Box 340308
Hartford, CT 06134

Dear Chris;

On behalf of all of the organizations listed below, we would like to congratulate you and the entire Department of Public Health (DPH) team for doing an excellent job running the committee meetings that explored the conditions under which Connecticut naturopaths might acquire a degree of prescriptive authority. However, we collectively feel it is important to submit this joint statement so nothing is misconstrued by our willingness to participate in the process outlined at the last meeting of the committee.

Naturopaths trained in this state, or any state, do not have sufficient education and training at this time to safely prescribe the medications they have requested. They do not have the scientific foundation, nor even the commitment to evidence-based therapy that must be the cornerstone of all practice, let alone practice that involves risk to life and limb. Whether they can at some point achieve such capability is open to question and depends to a large degree on attitudinal changes they may or may not be prepared to undertake. Our position at the end of the last meeting was that we are committed to working more closely in collaboration with the naturopaths in ways that will enhance the skills that are unique to each of our groups and constructively toward the effort to achieve a degree preparation sufficient to allow for safe prescriptive authority, but we have not endorsed a specific pathway or time scale under which this may be undertaken. We are united in this position, which we take very seriously and which we hold on behalf of the citizens of Connecticut who deserve only the very best.

Thank you again for your commitment and dedication to fulfilling he requirement of last session's legislation. We look forward to continued productive interactions with you and our naturopath colleagues.

Sincerely,

Connecticut State Medical Society
Connecticut Nurses Association
Connecticut Academy of Family Physicians
CTAPRNS
Connecticut Association of Nurse anesthetists
Connecticut Dermatologic Society
Connecticut Society of Eye Physicians
Connecticut Coalition of Advanced Practice Nurses
Connecticut Urology Society
Connecticut ENT Society

Appendix P

Naturopathy in Vermont

The Nelson A. Rockefeller Center at Dartmouth College
The Center for Public Policy and the Social Sciences
Policy Research Shop

Naturopathy in Vermont

Evaluating Education Differences and the Role of Naturopathic Doctors (NDs) as Primary Care Providers

Presented to the Vermont Senate Government Operations Committee

PRS Policy Brief 1213-07
April 23, 2013

Prepared By:

Roanna Wang '13
Eric Yang '14

This report was written by undergraduate students at Dartmouth College under the direction of professors in the Rockefeller Center. Support for the Policy Research Shop is provided by the Ford Foundation and by the Fund for the Improvement of Postsecondary Education, U.S. Department of Education.

Contact:
Nelson A. Rockefeller Center, 6082 Rockefeller Hall, Dartmouth College, Hanover, NH 03755
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EXECUTIVE SUMMARY

Vermont is currently undergoing both a shortage of primary care physicians and a reevaluation of policies in the state related to the practice of naturopathy by naturopathic doctors (NDs). This report details the policy history and current policy environment on naturopathy, identifies the areas of need for primary care, and evaluates the educational training and accreditation of naturopathic practitioners in Vermont. The six areas of concern in naturopathic education are: the undergraduate prerequisites to entering ND programs, the teaching of homeopathy, medical coursework, the lack of ND residencies, the licensing examination, and the continuing education policies.

This paper discusses options for the State of Vermont, including stricter regulations on the practice of homeopathy, providing quality ND internships and residencies, formulating an additional examination for new ND practitioners, requiring more continuing education hours, and improving the integration of NDs into existing hospital systems. The result of such policy changes may yield improved quality of care provided by NDs, broader patient access to naturopathic practices, increased alignment of ND and MD care through Blueprint for Health teams, and the drawing in of more primary care practitioners to Vermont. Properly trained naturopaths as primary care providers can contribute to reduced healthcare costs in Vermont and personalized care for patients. MDs can learn from NDs about holistic evaluations of disease while NDs can learn about modern technologies for improving the efficacy of care.

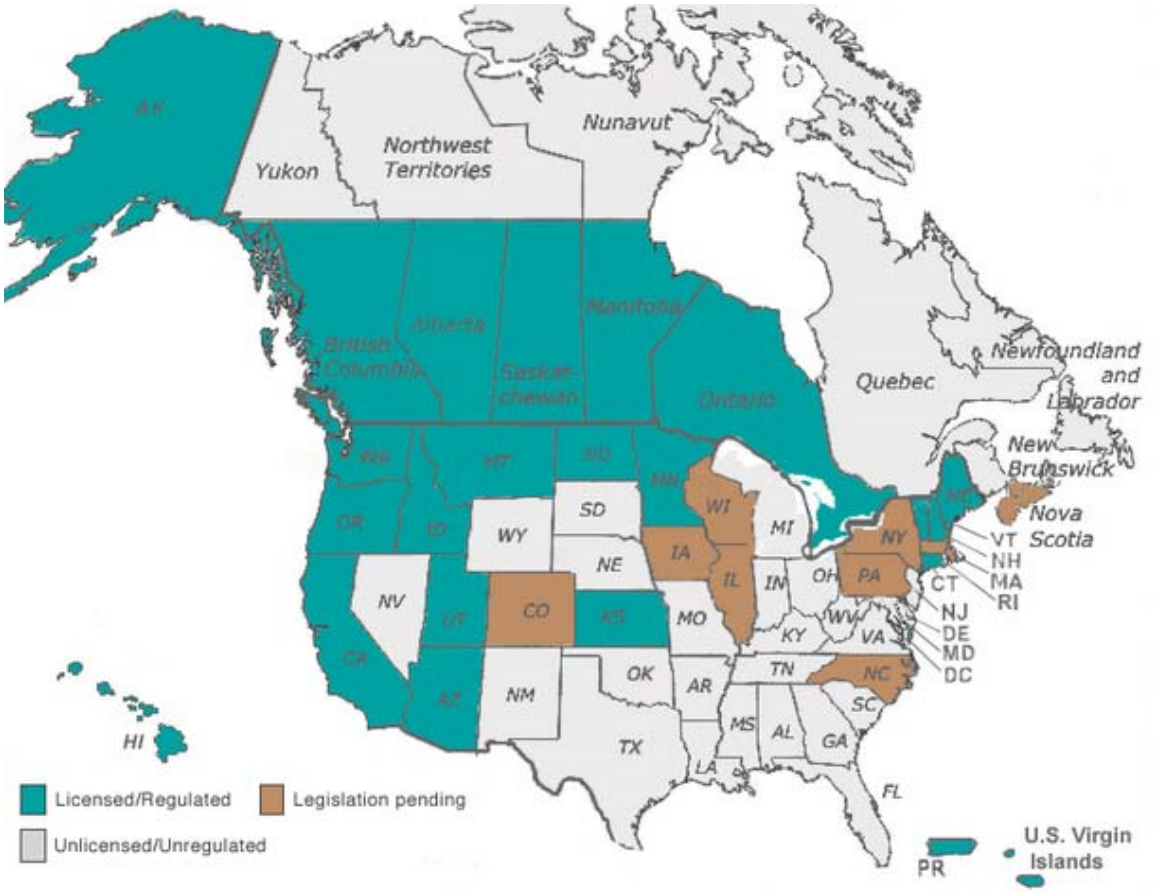
1. NATUROPATHS IN VERMONT

1.1 Background

Naturopathic medicine is a system of primary health aimed at preventing, diagnosing, and treating conditions of the human mind and body. Naturopathy favors a holistic approach with non-invasive treatment and, similar to conventional medicine, encourages minimal use of surgery and drugs. There are two types of naturopathic practitioners: traditional naturopaths and naturopathic physicians (NDs). NDs employ the principles of naturopathy within the context of conventional medical practices. NDs work with their patients to prevent and treat acute and chronic illness and disease, restore health, and establish optimal fitness by supporting the person's inherent self-healing process.[1] Modalities utilized by NDs include diet and clinical nutrition, behavioral change, hydrotherapy, homeopathy, botanical medicine, physical medicine, pharmaceuticals, and minor surgery.[2]

Naturopathic medicine is represented in the United States by the American Association of Naturopathic Physicians (AANP), which was founded in 1985 and has 2,000 student, physician, supporting, and corporate members.[3] The licensing of NDs is determined at

the state level. Currently, 16 states, the District of Columbia, and the United States territories of Puerto Rico and the United States Virgin Islands have licensing laws for NDs.[4]



Source: Association of Accredited Naturopathic Medical Colleges[5]

For licensure in these jurisdictions, NDs are required to graduate from an accredited four-year residential naturopathic medical school and pass an extensive postdoctoral board examination (NPLEX). Licensed NDs must fulfill state-mandated continuing education requirements annually, and have a specific scope of practice defined by their state's law. NDs are trained as primary care physicians, with an emphasis in natural medicine. Depending on the state, NDs may also be licensed to perform minor office procedures and surgery, administer vaccinations, and prescribe many prescriptive drugs.[6] NDs work in private practice, community health centers, universities, and private industry. They often collaborate with conventional physicians in the co-management and mutual referral of patients.

1.2 Vermont Policy History

Chapter 81 of Title 26 in the Vermont statutes details the underlying state policies concerning the practice of naturopathic medicine. Vermont defines naturopathic medicine as "a system of health care that utilizes education, natural medicines, and natural therapies to support and stimulate a patient's intrinsic self-healing processes and to prevent, diagnose, and treat human health conditions, injuries, and pain."[7] Practitioners are allowed to administer a variety of diagnostic techniques and nonprescription treatments as well as an approved set of prescription medications. As with other states, Vermont requires practitioners of naturopathic medicine to have an ND degree from a naturopathic medical college certified by the Council of Naturopathic Medical Education and the Department of Education. State licenses are granted upon completion of a Vermont-specific examination separate from the NPLEX professional accreditation exam.[8] Moreover, NDs must obtain special licenses to dispense prescription drugs or perform naturopathic childbirth. They are also prohibited from performing surgeries unrelated to naturopathic childbirth and using non-FDA-approved devices for therapeutic purposes. They are subject to the same laws about reporting disease outbreaks, births, and deaths as other physicians. NDs licensed in other states and current ND students can only practice if working in conjunction with a VT-licensed naturopathic physician. To maintain their licenses, Vermont naturopathic physicians are required to submit a renewal application every two years and complete 30 hours of continuing education during this period.[9]

The Vermont Secretary of State assigns the following responsibilities to the Office of Professional Regulation, to be carried out by a director with the support of two appointed, experienced naturopathic physicians:[10]

1. Providing licensure and application information
2. Administering licensing examinations and pharmacology examinations
3. Collecting, reviewing, accepting, revoking, and renewing licensing applications
4. Managing disciplinary measures and public complaints
5. Issuing special licenses for prescription drugs and naturopathic childbirth

The Office of Professional Regulation maintains a comprehensive set of administrative rules as well as a prescription medicine formulary for naturopaths.[11] These online documents detail the specific laws for licensure and renewals, scope of permitted care practices and prescribed drugs, and miscellaneous information and accountability protocols.

The most recent legislation affecting the practice of naturopathic medicine in Vermont was Act No. 96 (S.209), *An Act Relating to Naturopathic Physicians*, passed on May 2, 2012. The act made several amendments throughout the Vermont statutes that sought to better clarify the role of naturopathic physicians in the primary care system, primary care

being defined as "first-contact and continuing care for individuals with signs, symptoms, or health concerns, not limited by problem origin, organ system, or diagnosis."[12] First, the act mandates that health insurance plans recognize the general primary care services of naturopathic providers to be equivalent to the services provided by primary care physicians with MDs, including setting "reasonable deductibles, co-payments and co-insurance amounts, and fee or benefit limits."[13] This nondiscriminatory policy extends to any "practice parameters, cost-effectiveness and clinical efficacy standards, and utilization review"[14] to which NDs may be subject. Health insurance plans are allowed to restrict normal coverage to those services provided by naturopathic physicians under contract with the insurance company, so long as unbiased out-of-network provider reimbursement policies are applied to non-contract naturopathic services.[15] Act No. 96 also clarifies the independence of ND practitioners by stating that although naturopathic physicians do not require supervision by other health care professionals in their practices, this does not supersede the regulatory capabilities of the Office of Professional Regulation. To achieve parity in information technology, the act urges increased financial support for electronic health record system upgrades in naturopathic practices.

Lastly, naturopathic physicians are given authorization to serve as the patient's "medical home" under the Blueprint for Health Program, meaning that they will receive per-person, per-month payments from insurers and Medicaid for their qualifying patients and community health contributions. In an effort to reform the Vermont healthcare system, one major element of the Blueprint for Health initiative is to provide better primary care. The program fosters collaboration between previously isolated primary care providers in forming practice teams, and the new "medical home" system gives patients a more significant role in managing their own health goals, education, and decisions.[16] As a result of this act, naturopathic physicians will become integrated into community health teams to better meet patient needs, reduce health spending costs, and strive towards universal healthcare coverage in Vermont.[17]

1.3 Naturopathic Physicians in Vermont

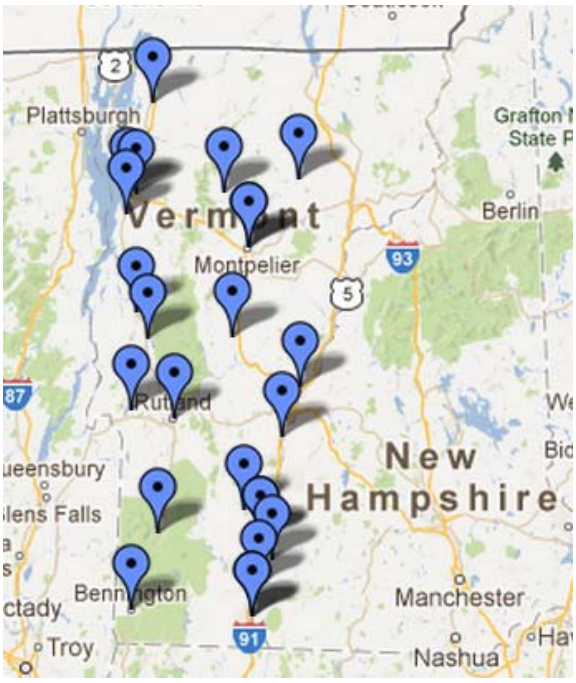
Appendix A contains information collected for all naturopathic practitioners in the state of Vermont that are registered with the Vermont Association of Naturopathic Physicians[18] (VANP) or with the American Association of Naturopathic Physicians[19] (AANP). Of the 52 practitioners who are members of at least one of these professional organizations, most practice in Brattleboro, Burlington, South Burlington, and Montpelier. However, there is a relatively wide geographical spread of practicing naturopaths across the state (refer to Table 1 and Figure 1).

Table 1: Practicing NDs in VT

locale	Freq.	Percent
Bennington, VT	3	5.77
Bomoseen, VT	1	1.92
Brattleboro, VT	10	19.23
Burlington, VT	6	11.54
Chester, VT	1	1.92
East Hardwick, VT	1	1.92
Hartland, VT	1	1.92
Manchester Center, VT	1	1.92
Middlebury, VT	3	5.77
Montpelier, VT	6	11.54
Norwich, VT	1	1.92
Putney, VT	1	1.92
Randolph, VT	2	3.85
Rutland, VT	1	1.92
Salisbury, VT	1	1.92
Saxtons River, VT	1	1.92
Shelburne, VT	1	1.92
South Burlington, VT	6	11.54
St. Albans, VT	1	1.92
Stowe, VT	1	1.92
Westminster, VT	3	5.77
Total	52	100.00

Source: Google Maps

Figure 1: Geographical spread of practicing naturopaths



In Vermont, the majority of NDs were trained at Bastyr University or the National College of Natural Medicine (NCNM) (refer to Table 2). NCNM has a limited selection of graduate programs and does not offer undergraduate programs while Bastyr only offers health-specific bachelor's degrees. Therefore, practitioners generally attended other schools for their B.A. and/or additional graduate degrees.

Table 2: Schools attended by VT NDs

accreditation	Freq.	Percent
Bastyr University	18	36.73
Canadian College of Naturopathic Medici	2	4.08
National College of Natural Medicine	19	38.78
Southwest College of Naturopathic Medic	6	12.24
University of Bridgeport	4	8.16
Total	49	100.00

Forty out of the 49 naturopathic physicians run private practices, and usually team up with other NDs and/or MDs. In a few cases, the practitioners work in a community health clinic. Under the current health infrastructure, no registered Vermont NDs work in a hospital.

Because some practitioners do not list their educational histories, data for this part of our analysis is incomplete. One possible avenue for future research is to examine educational background and training through interviews or surveys. Data is also unavailable for the size of the practice, involvement in teams of medical professionals, qualification for special licenses of prescription medications, contracts with insurance companies, and other characteristics that would be useful in evaluating the relationship between efficacy and education of Vermont's naturopathic physicians.

1.4 Shortage of Primary Care in Vermont

To set up a framework for how to proceed with naturopathy in Vermont, it is useful to first evaluate Vermont's current primary care situation. The data on primary care makes it clear that Vermont currently does not have enough primary care practitioners to meet the level of patient need. The Vermont Primary Care Workforce 2012 Snapshot generated by the Vermont Area Health Education Centers (AHEC) Program provides a comprehensive picture of primary care in the state. The report looks at primary care practitioner data for "MD/DOs, advanced practice registered nurses (APRNs), certified nurse midwives (CNMs), and certified physician assistants (PA-Cs) in primary care practices."[20] In 2012, Vermont had 814 non-naturopathic primary care practitioners, with 80 percent of practices having between one and five practitioners (mean of four, median of three). Also, 80 percent of practices had only one of four primary care specialties represented: family medicine, internal medicine, pediatrics, or obstetrics-gynecology.[21]

The main finding from the report was that although there were small increases in the aggregate number of non-naturopathic primary care practitioners, the need for primary care services is rising for the following reasons:[22]

1. Financial pressures have been causing healthcare trainees and medical students to choose more lucrative and stable sub-specializations rather than practicing in primary care.
2. In some primary care specialties, especially internal care, physicians are aging and retiring from practice, leading to gaps in specific services.
3. The elderly in Vermont are becoming an increasingly large share of the population, and these are generally the people who have the most need for primary care.
4. Primary care practitioners are drawn to other states, which are competing for the primary care workforce.

5. Due to lowered reimbursements and workload pressures, a staggering number of primary care practitioners are closing or limiting their practices to new patients. Statewide, 40 percent of MD/DOs and 28 percent of other non-naturopathic professions are closing or limiting their practice. In family medicine, these statistics increase to 47 percent for MD/DOs and 32 percent for APRNs, CNMs, and PA-Cs. For internal medicine, the change is more drastic, with increases to 66 percent of MD/DOs closing or limiting the inflow of new patients and 61 percent of the other professions.

The AHEC primary care snapshot also includes primary care shortages disaggregated by county and region, using changes in values of full-time equivalents (FTEs) of primary care practitioners because some practitioners decreased services without leaving their practice entirely. In 2012, only four of the 14 counties (Washington, Chittenden, Bennington, and Windham) experienced an increase in primary care services. Overall, Vermont had a net loss of 20 FTEs in MD/DOs and a net gain of 7 in APRNs, CNMs, and PA-Cs. While these numbers are an improvement from 2010 and 2011, there is a still concern for the many patients who are unable to access quality primary care services.

By overlaying the maps of Health Professional Shortage Areas (HPSAs), Rural Shortage Areas (GCRSAs), and the various distinctions of medically underserved areas from the Vermont Department of Health (i.e. dental care and mental health),[23] it is possible to see whether or not the AHEC's primary care shortage areas line up with other state-level data (See Appendix B). The map divides Vermont into service areas, generally corresponding to townships. Although shortages of care are spread throughout the state, there is more overlap in the north and northeast (color coding is retained from the original maps and are not significant in the overlay). Additionally, it is possible to determine whether current naturopathic physicians could fill the primary care gap given their distribution across the state (see Section 1.3). Unfortunately, NDs seem to be concentrated primarily in larger cities and are not more accessible to the rural or poor populations in designated shortage and underserved areas. Increased integration into the hospital system may allow the currently concentrated ND practices to diffuse into regions of medical need.

2. EDUCATION AND ACCREDITATION OF NDS

2.1 Education at ND-Granting Institutions

To evaluate the role and ability of naturopaths to prescribe medication, it is useful to first examine their education requirements, training, and continuing education procedures. Doing so also allows us to draw comparisons between ND-training and MD-training, and to highlight differences or synergies that may be present.

All licensed naturopathic physicians complete a minimum of three years university level pre-medical training (must be equivalent in coursework to a four-year degree) and then four years at an accredited naturopathic medical college. There are two such colleges in Canada (Boucher Institute of Naturopathic Medicine, Canadian College of Naturopathic Medicine) and five in the United States (Bastyr University, National College of Natural Medicine, National University of Health Science, Southwest College of Naturopathic Medicine and Health Sciences, University of Bridgeport College of Naturopathic Medicine). Students of naturopathy study subjects such as systems physiology, microbiology and botany, pharmacology, and pathology. They also study health counseling and basic management, both of which are needed to run an independent, patient-directed practice.

For the seven accredited ND-granting institutions, all candidates for admission must have completed a bachelor's degree from an accredited, degree-granting institution. Successful applicants are expected to have a GPA of 3.0-3.5 or greater. Undergraduate course requirements vary greatly in quantity between the schools, but in general, applicants must have completed two semesters of general chemistry and general biology, one semester each of organic chemistry, biochemistry, psychology, and math/physics, and up to five credits in the social sciences and humanities. Credit hours are comprised of: 1) classroom instruction (3,200 hours) and 2) clinical training (1,200 hours); (see Appendix C). Some more specific courses in a naturopathic education include acupuncture and Oriental medicine, Ayurvedic sciences, exercise science and wellness, health psychology, homeopathy, herbal medicine, integrated human biology, midwifery, naturopathic history, and nutrition.

The AANMC's Council of Chief Academic and Clinic Officers (CCACO), which is comprised of deans and assistant deans from all the schools, create knowledge and practice-based competency requirements for ND program graduates.[24] Additionally, the Council on Naturopathic Medical Education (CNME), the programmatic accrediting body of the ND schools, sets and enforces high academic standards. Currently, the CNME is encouraging schools to perform more outcome-based assessments, which are used to support curriculum development.[25]

2.2 Testing, Accreditation, and Reaccreditation

The Naturopathic Physicians Licensing Examinations (NPLEX) is a two-part professional licensing exam administered by the North American Board of Naturopathic Examiners (NABNE).[26] Graduates of the accredited four-year naturopathic medical schools are required to pass the NPLEX before receiving permission to practice naturopathic medicine in the United States or Canada. However, in addition to the core NPLEX exam, each state or Canadian province can require different Part II sections to be completed as well for licensure.[27] If a naturopathic physician graduated before the NPLEX was implemented, licensure is considered on a state-by-state basis.

Table 3: NPLEX requirements by state or province

NPLEX EXAMINATION	AB	AK	AZ	BC	CA	CT	HI	DC	KS	ME	MB	MN	MT	NH	ON	OR	PR	SK	UT	VT	WA
Part I – Biomedical Science	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Part II – Core Clinical Science	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•	•	•	•	•	•
Part II – Clinical Elective Minor Surgery	Opt[1]		•	•			•			•			•	•		•			•		•
Part II – Clinical Elective Acupuncture	Opt[1]		•						•						•			•			

Source: North American Board of Naturopathic Examiners[28]

The NPLEX Part I is a basic science examination that tests anatomy, biochemistry, microbiology, pathology, and physiology, with 50 questions per section. A score of 75 percent or higher is needed to pass. Part II of the NPLEX has a core portion consisting of a three-day clinical science examination that tests botanical medicine, clinical nutrition, diagnostic imaging, emergency medicine, homeopathy, pharmacology, physical and clinical diagnosis, physical medicine, psychology, lab diagnosis, and medical procedures. There are three clinical elective sections for certificate or license: acupuncture, minor surgery, and homeopathy.

The American Naturopathic Medical Certification Board (ANMCB) requires Board Certified professionals to renew each year by completing 20 hours of natural health care continuing education units every year and submit documentation along with a renewal fee in order to keep the certification current.[29] Licensed naturopathic physicians who pass the NPLEX must also fulfill state-mandated continuing education requirements annually, and will have a specific scope of practice defined by their state's law.

In Maine, applicants for renewal must complete 37 hours of continuing education annually, with 15 of those hours specific to their specialties. At least seven hours must be in pharmacology, and no more than 10 hours may be in any single topic.[30] Oregon requires 50 hours of continuing education each year, 10 of which must be in pharmacology, and two in ethics.[31] New Hampshire requires documentation of completion of 150 hours of continuing education every three years. At least 60 of those hours must be taken in a professionally supervised setting with 24 hours in pharmacology.[32] Vermont currently requires the license to practice naturopathic medicine to be renewed every two years, with no more than 30 hours of continuing education biennially.[33] This is lower than the number of hours recommended by the ANMCB (40 per two years) and is the lowest of all the states except Wisconsin, which also requires 30 hours per two years.

Table 4: Comparison of continuing education hours by state

	ANMCB	VT	ME	OR	NH
	(recommended)				
Continuing Education Hours per year	20	15	37	50	50

2.3 Differences in Education Compared to MDs

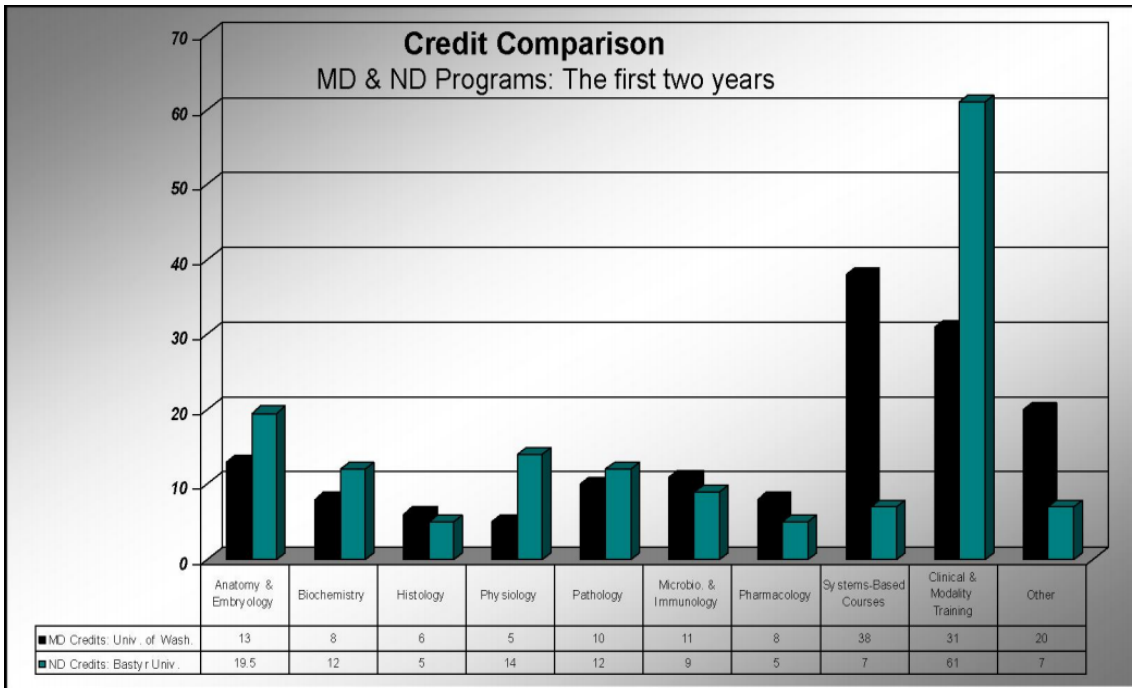
Physician education in the United States includes undergraduate premedical requirements, medical school, and clinical medical education (i.e., residencies and fellowship training).[34] Licensed physicians must complete four years at a college or university to earn a BS or BA degree, usually with a strong emphasis on basic sciences, such as biology, chemistry, and physics. They then must complete four years of education at one of the U.S. medical schools accredited by the Liaison Committee on Medical Education (LCME), consisting of preclinical and clinical parts. After completing medical school, students earn their doctor of medicine degrees (MDs), although they must complete additional training before practicing on their own as a physician. Some physicians receive a doctor of osteopathic medicine (DO) degree from a college of osteopathic medicine; (see Section 3.2 for additional information). Newly graduated MDs enter into a residency program that is three to seven years of professional training under the supervision of senior physician educators.

After completing a series of exams and four years of graduate medical education, physicians obtain a license to practice medicine from a state or jurisdiction of the United States in which they plan to practice.[35] The majority of physicians also choose to become board certified, which is an optional, voluntary process. Most certifications must be renewed after six to ten years, depending on the specialty. Once physicians begin practicing, they must continue to receive credits for continuing medical education (CME).[36] CME requirements vary by state, professional organizations, and hospital medical staff organizations.

Beginning with the 2014 license renewal, Vermont will require medical physicians to complete a minimum of at least 30 hours of qualifying CME during each two-year licensing period.[37] At least one of these hours must be on prescribing controlled substances. Currently, medical physicians in Vermont are required only to complete 10 hours of CME biannually. In Maine, medical doctors are required to complete 100 credits of CME biannually, while Oregon medical doctors are required to complete 60 hours of CME biannually.[38] Although programs vary in quality (low relevance, online, quick-to complete) for both NDs and MDs, there is a marked difference in CME topics between the two professions. A substantial number of naturopathic continuing education programs focus on applications of alternative medicine rather than modern advancements in medical understanding and technology. For example, the continuing education courses offered by NCNM include herbal formulations and Chinese medical astrology.[39] Both

types of providers do have options to learn about health policy and holistic patient care as a part of continuing education.

Table 5: Credit comparison of MD & ND programs—the first two years



Source: American Association of Accredited Naturopathic Medical Colleges[40]

Both NDs and MDs attend a four-year medical school after completing pre-medical classes and a bachelor's degree. However, unlike medical schools, the first two years of the ND curriculum also includes an early introduction to naturopathic modalities, such as homeopathy, nutrition and botanical medicine. While medical school courses divide material by systems (circulatory, nervous, digestive, etc.), classes in a typical ND program are not divided by system, but rather focus on how a symptom in one part of the body may affect the patient's entire anatomy and wellbeing. Third and fourth-year MD students complete clerkships and rotations, while third and fourth-year ND students have increasing opportunities for hands-on clinical training and practice, often at their schools' teaching clinics and off-site clinics, which offer diverse patient populations. Training in clinical practice is absolutely essential to a naturopathic education, so this is becoming introduced much earlier at several AANMC-member schools. Thus, during the first two years, NDs receive more clinical training than MDs while MDs continue to take more systems-based courses.[41] MD students also are required to complete a clinical residency after graduation in order to practice. NDs are not required to complete residencies, though such programs are available and approved by the CNME. Only five to ten percent of new NDs participate in formally approved residency positions.

MDs obtain board certification through the United States Medical Licensing Examination (USMLE) while NDs take the NPLEX. The USMLE is longer and includes more content than the ND examination.[42] Like the NPLEX, the USMLE is divided into different sections. Unlike the NPLEX, which is taken only after receiving the ND degree, Step 1 of the USMLE is taken after the second year of medical school, Step 2 is taken during the fourth year, and Step 3 is taken during the residency.[43]

Another area of difference in education is the training focus and treatment approaches. ND training is focused on treating and preventing illness by strengthening the body's natural defense and repair system. NDs draw from a variety of health disciplines when creating personalized treatment plans for patients. Therapies may include changes in diet, nutritional supplementation, plant medicine (herbal and homeopathic), and physical therapy (especially hot/cold spa therapies). In comparison, an MD's training is focused on treating illness by controlling the disease process with more aggressive pharmaceutical and surgical strategies. Should a patient's condition require more specialized care, NDs often will refer the patient to other practitioners, including MDs, chiropractors, acupuncturists, and counselors.

3. NATIONAL NATUROPATHIC PRIMARY CARE EFFORTS

3.1 Other States' Legislative Histories on NDs

As noted previously, naturopathic doctors are licensed as primary care doctors in 16 states. As primary care providers, NDs have the right to prescribe medication, order X-rays and blood work, and perform physical examinations. If the Affordable Care Act (ACA) is implemented as intended, NDs in all 16 states will be covered immediately by insurance. Currently, the states that mandate naturopathic services to be covered by health insurance include: Vermont, Washington, New Hampshire, Connecticut, Hawaii, and Alaska.[44] The American Association of Naturopathic Physicians (ANNP) recently announced its goal of licensure in 11 more states for 2013. To date, licensing legislation has been introduced in six states: Arkansas, Colorado, Illinois, Maryland, Massachusetts, and Michigan.

In the United States, 11 of 16 jurisdictions that license naturopathic medicine have given naturopathic doctors prescribing authority.[45] Although the pharmaceutical formulary varies in different states, it is extremely broad in Hawaii, California and Washington. In Arizona and Oregon, naturopaths are allowed to prescribe most pharmaceuticals except some therapeutics and narcotics. In Utah, they may prescribe and dispense all non-controlled drugs, while in Maine, they must first complete a one-year collaborative relationship with a medical doctor.[46]

In June 2009, a bill passed in Oregon that allows naturopaths to prescribe drugs. The original bill would have allowed naturopaths to prescribe almost any drug, but with the

medical lobby in opposition, the bill lacked votes. The bill was amended to apply to only a list of drugs approved by the state regulatory board, eventually passing the Senate 22-7 and the House unanimously.[47] Oregon has a shortage of primary care doctors, especially in rural areas. Medical doctors in Oregon occasionally work with NDs.

3.2 Comparisons between DOs and NDs

NDs face a similar challenge within the health care system as osteopathic physicians, who receive their training from osteopathic colleges for a DO degree. Like naturopathy, osteopathy is characterized by some traditional practices that have little scientific backing, the most controversial of these being osteopathic manipulative treatment (OMT). Like NDs, DOs are primary care physicians that focus on preventative care using a "whole person" approach. Unlike NDs and MDs, they receive special training in musculoskeletal system health, OMT being a part of this training. Currently, the DO education process is nearly equivalent to that of MDs, with four years of osteopathic medical education and the completion of either DO or MD residencies afterward that prepare the physician in a specialty like "pediatrics, family medicine, psychiatry, surgery, or ophthalmology."[48]

Criticisms of osteopathy in the past have included its continued use of outdated treatments, the lower competitiveness of osteopathic programs compared to MD programs, the lower prestige of osteopathic schools in research and teaching, and the lower GPAs of DO applicants.[49] However, what used to be major gaps in quality have been quickly closing following the large increase in the number of health professionals who choose osteopathy. Moreover, osteopathic physicians recently have been crucial in filling primary care gaps, especially in rural areas.

3.3 Insurance Policies for Naturopathic Care

Due to Vermont Act No. 96 (S.209), all insurance companies regulated by the state of Vermont must cover naturopathic physicians under the same policies it uses for other primary care providers. This policy applies to Blue Cross/Blue Shield of Vermont, MVP, Medicaid, VHAP, Dr. Dynasaur, and others.[50] CIGNA currently does not allow naturopathic physicians to serve as primary care providers, and the policy does not apply to Medicare, out-of-state plans, and certain self-insured employers. Most insurance plans also do not cover unique naturopathic services like acupuncture and allergy neutralization treatments, natural medicines like nutritional supplements and herbal formulas, and homeopathic remedies.

4. IMPLICATIONS FOR VERMONT PRIMARY CARE

4.1 Addressing the Education Gap

Based on the information available about education, licensing, and continued education, our research suggests that there are several educational differences between NDs and MDs:

- **Prerequisites:** The college course prerequisites for enrollment in an ND-granting program are currently inconsistent across the seven institutions, much more so than the premed requirements for applying to MD programs.

- **Medical Coursework:** ND-granting institutions teach homeopathy with classes in acupuncture, herbal medicine, and other alternative medical practices. It is useful to keep in mind that NDs treat patients holistically, and can refer patients to MDs for specialized care.

- **Residencies:** NDs are not required to complete residencies, while MDs must complete between three to seven years of residency.[51] The purpose of a residency is to engage in a particular field of practice under the supervision of an experienced physician, and the rigorous work often helps teach new MDs and DOs best practices for when they begin to practice independently.

- **Continuing Education:** NDs in Vermont are undertaking fewer continuing education hours than NDs in all other states except for Wisconsin. This is true for MDs in Vermont as well, who also need only 30 hours biennially for reaccreditation. Moreover, the continuing education programs available for naturopaths are often less relevant to modern health applications than the standard programs for MDs.

Given these educational differences, the State of Vermont can consider several options as part of an effort to address the quality of education and service provided by naturopathic practitioners:

- **Prerequisites and Medical Coursework:** Because NDs in Vermont will have received their degree in another state and moved here to practice, they likely took the NPLEX examination in another state. This means that while some practitioners will have taken additional clinical elective exams, others will have only passed the core sections. Similar to New Hampshire, one option for Vermont is to mandate at least one of the clinical elective exams. With time, an additional state-specific examination can be constructed and administered to newly practicing NDs as a means of quality control.

- **Residencies:** While NDs are not required to complete residencies, Vermont can create policies that encourage NDs to complete residencies. The Council on Naturopathic Medical Education (CNME) has approved several residency programs around the nation, with one program located in Westminster, VT (Sojourns Community Health Clinic).[52] Also, the Office of Professional Regulation can partner with the Vermont Association of Naturopathic Physicians to create more ND internships and residencies at naturopathic clinics in the state. Not only will this bring in more primary care naturopathic practitioners to Vermont, but also the mentorship of successful NDs can ensure that naturopathic practices are better standardized across the state.

- **Continuing Education:** To better match the standards set in other states, Vermont can consider increasing the mandated number of continuing education hours. NDs need to be kept up to date on the most recent peer-reviewed research on homeopathy and other alternative medical techniques. As a comparison, New Hampshire currently requires NDs to complete 100 hours biennially. This could be supplemented by an increased scope of courses offered in naturopathic continuing education programs to include topics that will aid further MD/ND collaboration.

  Furthermore, the Office of Professional Regulation in conjunction with VANP can promote continuing education programs that share information about cutting-edge medical innovation and procedures among MDs and NDs. Academic partners could take the lead in designing joint MD and ND continuing education programs and conferences, and the increased interaction between the two professions may help to bridge the differences in education.

- **Integration of Alternative Medicine:** In order to attract more primary care NDs to the state, hospitals can develop strategies for integrating alternative medicine divisions. Increased integration may help regulate the efficacy of naturopathic treatments used on patients and improve bilateral understanding between MD and ND practices. This process has been observed previously among DOs and MDs who have increased collaboration in recent years.

4.2 Addressing NDs as Insured Primary Care Providers

Given the current shortage of primary care in Vermont, there are many benefits to improving the integration of NDs in the existing healthcare infrastructure. Despite potential gaps in education, naturopathic physicians have the potential to be among the most effective players in Vermont's primary care system. The naturopathic philosophy of patient-driven health gives NDs a critical role in the success of the Blueprint for Health community health teams. By creating holistic treatment plans for patients that includes naturopathic and allopathic medicine, the program aims to lower healthcare costs by

reducing the number of expensive operations and medications. In synergizing naturopathic and specialist care, the team-care approach allows the patient to receive the best overall treatment appropriate to his or her specific medical condition. Many NDs currently operate joint clinics with MDs, and have experience in bridging specialized care with holistic primary care, providing a valuable perspective to the Blueprint for Health. Increased integration of NDs into hospitals and increased ND internships and residencies can help attract more primary care providers to Vermont while providing a quality control measure because of supervision by MDs or experienced NDs.

A challenge that naturopathic practitioners continue to face is setting up contracts with insurance companies to become in-network providers, and establishing referral networks with hospitals to guarantee that seriously ill patients get the treatments they need. With the continued implementation of Act 96, The State of Vermont may choose to work with insurance companies to promote the inclusion of NDs, as equal insurance coverage is a necessary part of the Blueprint for Health teams.

APPENDICES

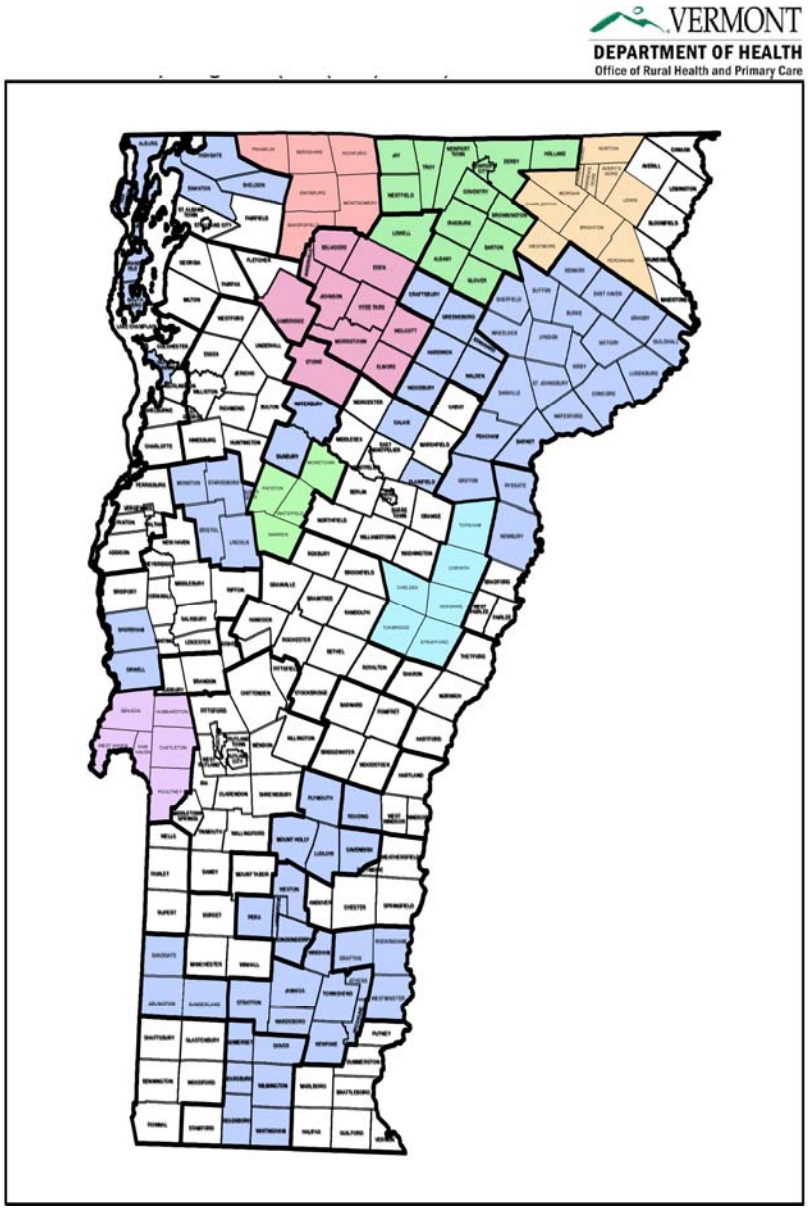
Appendix A. VT ND Database

Name	Locale	Accreditation	Previous Degree	College	Clinic/Company
from the AANP directory	http://www.naturopathic.org/AF_MemberDirectory.asp				
Bernie Noe	Montpelier, VT	Bastyr University	Bachelor of Science in electrical engineering	Virginia Tech	Green Mountain Natural Health
Lydia Faesy	Montpelier, VT	Bastyr University			
Melanie Meyer	Montpelier, VT	University of Bridgeport			Well-Natured PLLC
Lorilee Schoenbeck	South Burlington, VT	National College of Natural Medicine	BA in Nutrition	Goddard College	Mountain View Natural Medicine
Jessica Stadtmauer	South Burlington, VT	National College of Natural Medicine	Bachelor of Arts	The University of Minnesota - Twin Cities	Mountain View Natural Medicine
Catharine Guaraldi	South Burlington, VT	National College of Natural Medicine	BA in Italian and Biochemistry	Middlebury College	Mountain View Natural Medicine
Bill Warnock	Shelburne, VT	Bastyr University	BS in Botany	University of Washington	Champlain Center for Natural Medicine
Michelle Haff	Burlington, VT	Southwest College of Naturopathic Medicine	Bachelor of Arts	Smith College	Avalon Natural Medicine
Jen Williamson	Burlington, VT	Southwest College of Naturopathic Medicine	Bachelor of Science	Gannon University	
Teri March	Burlington, VT	Southwest College of Naturopathic Medicine			Maplewood Natural Medicine
Susan B. Kowalsky	Norwich, VT	National College of Natural Medicine			
Greg Burkland	Rutland, VT	Bastyr University			Sanctuary Integrative Medicine
Rebecca Chollet	Hartland, VT	Bastyr University		Middlebury College	Upper Valley Natural Health Center
Samantha Kane Eagle	Brattleboro, VT	University of Bridgeport	Masters Degree in Human Nutrition	University of Bridgeport	Biologic Integrative Healthcare
Liz Kaltman	Brattleboro, VT	National College of Natural Medicine	MPH	University of California at Berkeley	Biologic Integrative Healthcare
Jody E. Noé	Brattleboro, VT	Bastyr University	MS	Old Dominion University	Biologic Integrative Healthcare
Cheryl D. Proctor	Brattleboro, VT	Canadian College of Naturopathic Medicine in Toronto	Masters Degree in Ecopsychology	Naropa University	Biologic Integrative Healthcare
Mary Louise Bove	Brattleboro, VT	Bastyr University	Diploma of Phytotherapy/Herbal Medicine	School of Phytotherapy in Great Britain	Brattleboro Naturopathic Clinic
Thomas DeClemente	Brattleboro, VT	Bastyr University			Brattleboro Naturopathic Clinic
Emily Maiella	Brattleboro, VT	Bastyr University	BS	University of Massachusetts, Amherst	Brattleboro Naturopathic Clinic
Michele Sayball	Brattleboro, VT	Bastyr University	BS in Herbal Medicine	Bastyr University	Brattleboro Naturopathic Clinic
Glenn R. Finley	Manchester Center, VT	National College of Natural Medicine			New Leaf Holistic Health (satellite clinic)
Ileana Tecchio	Bennington, VT	National College of Natural Medicine			New Leaf Holistic Health (satellite clinic)
from the VANP directory	http://www.vanp.org/member_directory.php				
Anna R. Abele	Brattleboro, VT	Bastyr University	BA in Psychology	Marlboro College	A Natural Path
Thauna Abrin	East Hardwick, VT	National College of Natural Medicine	BA in Anthropology	University of California at Santa Cruz	Whole Family Wellness
Gabriel T. Archdeacon	Montpelier, VT	National College of Natural Medicine	BA in Biotechnology	Rochester Institute of Technology	Tree of Life Medicine
Susanne Booth	Westminster, VT				Sojourns Community Health Clinic
Alexis Chesney	Westminster, VT	University of Bridgeport	MS in Acupuncture	University of Bridgeport Acupuncture Institute	Sojourns Community Health Clinic
Clif Steinberg	Westminster, VT				Sojourns Community Health Clinic
Korey DiRoma	Bennington, VT	Southwest College of Naturopathic Medicine	BS in Molecular and Cellular Biology	University of Arizona	The Center for Integrative Health and Healing
Kirsten Carle	Bennington, VT	National College of Natural Medicine	BS in Biology	Marist College	The Center for Integrative Health and Healing
Jennifer Edlund	St. Albans, VT	Bastyr University			
Casey Lynn Ellison	Montpelier, VT	Bastyr University	BA in Fine Arts	University of Colorado at Boulder	Vermont Natural Health
Maxine Fidler	Middlebury, VT	Bastyr University	Masters Degree in Acupuncture and Oriental Medicine	Bastyr University	Acorn Natural Medicine
Jillian Finker	Bomoseen, VT	Southwest College of Naturopathic Medicine			Finker Wellness, Inc.
Molly Fleming	Burlington, VT	National College of Natural Medicine	BS in Biology and Psychology	Southern Oregon State College	Health Resolutions
Donna Powell	Burlington, VT				Health Resolutions
Michael Friedman	Montpelier, VT	Canadian College of Naturopathic Medicine			Association for the Advancement of Restorative Medicine
Joshua Green	Burlington, VT	National College of Natural Medicine	BS in Whole Foods Nutrition		Vermont Natural Family Medicine
Ani Hawkinson	Putney, VT	University of Bridgeport	PhD in Linguistics	University of California, Berkeley	HeartSong Health In Community, Inc.

Appendix A Continued. VT ND Database

Christopher Hollis	Randolph, VT	National College of Natural Medicine	MS in Oriental Medicine	National College of Natural Medicine	Integrative Health
Erica Koch	Randolph, VT	National College of Natural Medicine	Master of Education	Rutgers University	Integrative Health
Aimee Knauff	Chester, VT	Southwest College of Naturopathic Medicine			Chester Community Acupuncture
Amy Voishan Littlefield	South Burlington, VT	National College of Natural Medicine			Vermont Naturopathic Clinic
Sam Russo	South Burlington, VT	Bastyr University	Masters Degree in Acupuncture	Bastyr University	Vermont Naturopathic Clinic
Michael Stadtmauer	South Burlington, VT	National College of Natural Medicine		University of Vermont College of Agriculture and Life Science	Vermont Naturopathic Clinic
Emily Mahar Cannon	Middlebury, VT	National College of Natural Medicine	BA in Biology and Environmental Science	Dartmouth College	Integrated Medicine
Katina Martin	Salisbury, VT	National College of Natural Medicine		Bowdoin College	Salisbury Natural Family Health
Karen Miller-Lane	Middlebury, VT	Bastyr University	Masters Degree in Acupuncture	Bastyr University	Natural Medicine of Vermont, P.C.
Angela J. Robens	Stowe, VT	Bastyr University	Bachelors of Nursing	West Virginia University	Stowe Natural Family Wellness
Laura Senes	Saxtons River, VT	National College of Natural Medicine	BA in Religious Studies	Hamilton College	Rockingham Natural Health Clinic
Rebecca S. Shwartz	Brattleboro, VT	Bastyr University	BA in Biology and Environmental Science	Oberlin College	

Appendix B. VT Overlay of Areas of Primary Care Need



Appendix C. Database of ND-Granting Institutions

Curriculum Comparison Between Accredited Naturopathic Medical Schools

All licensed naturopathic physicians complete the equivalent of four years of undergraduate work and then four years at an accredited naturopathic medical college. There are two such colleges in Canada*, and four in the United States. Topics of study genereally include systems physiology, pathology, nutrition, pharmacology, health counseling, business management, and naturopathic history practices.

	Bastyr University	Boucher Institute of Naturopathic Medicine*	Canadian College of Naturopathic Medicine*	National College of Natural Medicine	National University of Health Sciences	Southwest College of Naturopathic Medicine & Health Sciences	University of Bridgeport College of Naturopathic Medicine
4-Year Course Design	Fall, Winter, and Spring for Years 1 and 2 with about 345 credit hours per quarter; Summer, Fall, Winter, and Spring for Years 3 and 4 with much fewer core credits but with preceptorshisp and more clinical hours	Five categories of instruction (Biomedical Sciences, Professional Development, Naturopathic Therapeutic Modalities, Clinical Science, and Clinical Practice and Integration) interwoven into four years	Biomedical Sciences, Clinical Sciences, and Art and Practice of Naturopathic Medicine are interwoven into four years with a 3rd year summer	Fall, Winter, and Spring for Years 1,2, and 3 with 300-400 credit hours per quarter, but many more clinical rotations in the third year Summer, Fall, Winter, and Spring for Year 4 with nearly just clinical rotations	Three phases (Basic Sciences, Clinical Sciences, and Clinical Practice) with 4 trimesters each that can be completed in 3 years and four months if continuous	Three quarters in Years 1 and 4 and four quarters in Years 2 and 3 with clinical clerkships in Years 3 and 4	8 semesters of courses with fieldwork and clinical work during several summer terms
Core Credit Hours	3,130	3,500	3,000	2,304	109, 107, and 35 credits in each phase, repsectively	3,720	3,519
					Applied Southwest College credits-to-credit hours calculation		
Clinical Training Credit Hours	1,208	1,400	1,200	1,548	10 hours per course credit, 20 hours per clinical credit	1,340	1,396
Elective/Other Credit Hours	88			756			
Total Credit Hours	4,426	4,900	4,200	4,608	2,860	5,060	4,915
Prior Coursework Required (# of semesters)	Algebra: 1	Biology: 2	Biology: 2	Mathematics: 1	English: 2	Biology: 4	Communication/Language: 2
	Chemistry: 2	Chemistry: 2	Physiology: 2	Chemistry: 2	Psychology: 1	Organic Chemistry: 1	Psychology: 1
	Organic Chemistry: 2	Biochem: 1	Biochemistry: 1	Organic Chemistry/Biochemistry: 2	Social Sciences/Humanities: 5	Biochemistry: 1	Social Science/Humanities: 5
	Biology: 2	Psychology/Counseling: 2	Organic Chemistry: 1	Biology: 2	Biology: 2	Psychology: 2	Biology: 2
	Physics: 1	English/Humanities: 2	Psychology: 2	Physics: 1	Chemistry: 2	English: 2	Chemistry: 2
	Psychology: 1		Humanities: 2	Social Science: 2	Organic Chemistry/Biochemistry: 2	Humanities: 2	Organic Chemistry: 2
				English/Humanities: 2	Physics/Statistics/Biomechanics: 2		Physics: 1

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[3] "American Association of Naturopathic Physicians." *American Association of Naturopathic Physicians*. <http://www.naturopathic.org/>.
[4] The states that currently have licensing laws for naturopathic physicians are Alaska, Arizona, California, Connecticut, District of Columbia, Hawaii, Idaho, Kansas, Maine, Minnesota, Montana, New Hampshire, North Dakota, Oregon, Utah, Vermont, and Washington.
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