

Information Summary and Recommendations

COLON HYDROTHERAPIST

Sunrise Review

January 2009



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THE SUNRISE REVIEW PROCESS

A sunrise review is an evaluation of a proposal to change the laws regulating health professions in Washington. The legislature's intent, as stated in the Sunrise Act, chapter 18.120 RCW, is to permit all qualified individuals to provide health services unless there is an overwhelming need for the state to protect the interests of the public by restricting entry into the profession.

The Sunrise Act, RCW 18.120.010, says a health care profession should be regulated only when:

- Unregulated practice can clearly harm or endanger the health, safety, or welfare of the public, and the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;
- The public needs, and can reasonably be expected to benefit from, an assurance of initial continuing professional ability; and
- The public cannot be effectively protected by other means in a more cost-beneficial manner.

If the legislature identifies a need and finds it necessary to regulate a health profession not previously regulated by law, it should select the least restrictive alternative method of regulation, consistent with the public interest. Five types of regulation may be considered as set forth in RCW 18.120.010(3):

1. Stricter civil actions and criminal prosecutions. To be used when existing common law, statutory civil actions, and criminal prohibitions are not sufficient to eradicate existing harm.
2. Inspection requirements. A process enabling an appropriate state agency to enforce violations by injunctive relief in court, including but not limited to, regulation of the business activity providing the service rather than the employees of the business, when a service being performed for individuals involves a hazard to the public health, safety, or welfare.
3. Registration. A process by which the state maintains an official roster of names and addresses of the practitioners in a given profession. The roster contains the location, nature, and operation of the health care activity practices and, if required, a description of the service provided. A registrant is subject to the Uniform Disciplinary Act, chapter 18.120 RCW.
4. Certification. A voluntary process by which the state grants recognition to an individual who has met certain qualifications. Non-certified persons may perform the same tasks, but may not use "certified" in the title. A certified person is subject to the Uniform Disciplinary Act, chapter 18.130 RCW.
5. Licensure. A method of regulation by which the state grants permission to engage in a health care profession only to persons who meet predetermined qualifications. Licensure protects the scope of practice and the title. A licensee is subject to the Uniform Disciplinary Act, chapter 18.130 RCW.

OVERVIEW OF PROCEEDINGS

The Department of Health (department) notified the applicant group, all professional associations, interested parties, and staff of the sunrise review. The applicant group, the International Association for Colon Hydrotherapy (association), completed the sunrise application. The application was shared with people who were interested in the review. The applicant group provided written answers to additional questions. A review panel of Department of Health staff and one public member was created.

The department requested information from other states, including regulatory standards, sunrise reviews, and other information that would be useful in evaluating the proposal. Staff conducted literature and internet research. Staff reviewed all information received.

The department conducted a public hearing on August 29, 2007. The applicant group provided a PowerPoint presentation covering the history, theory, concerns, contraindications, and medical benefits of colon hydrotherapy. The applicant group included information about the association. The group showed a video demonstrating what happens during a colon hydrotherapy session. They provided an outline of the association's Colon Hydrotherapy Manual, the lesson plans, and a syllabus for association-approved schools and instructors. Public testimony was taken. The testimony generally focused on the procedure of colon hydrotherapy. Some comments supported the sunrise proposal to regulate colon hydrotherapists in Washington. Several people testified in support of the procedure but opposed to regulation that would establish colon hydrotherapists as a new health profession under the department's jurisdiction.

A 10-day written comment period followed the public hearing. On December 21, 2007, the department distributed a draft report to participants and interested parties for review. A rebuttal period was allowed for comment on the draft report. A recommendation was made based upon all information received. The proposed final draft was reviewed and approved by the Health Systems Quality Assurance assistant secretary and the secretary of the Department of Health. The final report was transmitted to the Legislature via the Office of Financial Management.

The final report is the department's recommendation to the legislature regarding the applicant's proposal to certify colon hydrotherapists as a new health profession in Washington. The report reflects the department's understanding of current law. It is not, however, a decision that is legally binding or precedent setting.

EXECUTIVE SUMMARY

The House Health Care Committee requested the Department of Health review a draft bill proposing to establish certification of colon hydrotherapists. The proposal would allow colon hydrotherapists to practice independently, without referral or supervision by another health care provider. Colon hydrotherapy would be the only procedure in this new provider's scope of practice. Sunrise review typically includes a range of activities under a profession's scope of practice. This review is unusual because the analysis is focused on a single procedure.

Findings

- Colon hydrotherapists are not currently recognized or regulated under the Uniform Disciplinary Act in Washington.
- In Florida, the definition of "massage" includes colonic irrigation, and a licensed massage therapist may obtain a certification to perform the procedure. No other state was identified as licensing colon hydrotherapists.
- Colon hydrotherapy is performed using "colonic irrigation systems," which are prescriptive devices regulated by the federal Food and Drug Administration (FDA).
- No clinical studies were found that validate colon hydrotherapy as a practice that promotes health.
- The applicant group, health providers, and treatment recipients provided written and oral statements attributing a wide variety of health benefits to the procedure.
- There are numerous medical contraindications for colon hydrotherapy.
- Colon hydrotherapy is associated with a small but real risk of serious injury or death.
- Colon hydrotherapy is the practice of medicine in Washington.
- Colon hydrotherapy is a medical procedure within the scope of practice of allopathic, osteopathic, and naturopathic physicians. The procedure may be delegated to other licensed staff under limited circumstances.

The proposal meets the first sunrise criterion. However, this criterion does not support regulation of the profession because the practice of colon hydrotherapy is already regulated in other professions in Washington. The proposal does not meet the second and third criteria. In addition, the Washington State Court of Appeals recently ruled that colon hydrotherapy is the practice of medicine in Washington. Given this court decision, there is no legal basis for the sunrise review to consider arguments that colon hydrotherapy is not a medical procedure.

Recommendation

Based on the analysis of the sunrise criteria, the department recommends that the legislature not adopt the proposed bill establishing certification for colon hydrotherapists. The proposal does not satisfy all three sunrise criteria. In addition, adoption of the proposal would set precedent for regulating a single medical procedure. The department does not believe this approach would be an efficient means of regulation.

SUMMARY OF INFORMATION

Sunrise review request

The House Health Care and Wellness Committee referred draft bill (H-3505.1/07) for a sunrise review. The draft bill would establish certification of colon hydrotherapists as a new profession. The proposal would establish education and training standards for individuals who choose to be certified as colon hydrotherapists.

Applicant information

The applicant group for this sunrise review is the International Association for Colon Hydrotherapy (association). This association offers training and certification for colon hydrotherapists. The association has adopted standard operating procedures, regulations, and guidelines for colon hydrotherapy.¹

Current regulation

Colon hydrotherapists are not currently regulated in Washington. The association proposal would change current law; colon hydrotherapists would be regulated as a new profession with authority to practice completely independently. The proposal does not require referral or supervision by another health care provider. Colon hydrotherapy would be the only procedure in this new provider's scope of practice.

The draft bill describes the practice of colon hydrotherapy as, "the removal of waste from the large intestine without the use of drugs by a client-administered application of filtered and temperature-regulated water into the large intestine." Colon hydrotherapy is sometimes referred to as colonic irrigation.

The department identified only one state that issues a credential specifically including colon hydrotherapy practice. In Florida, the definition of "massage" includes colonic irrigation. In that state, a licensed massage therapist may perform colonic irrigation after proving completion of education and testing requirements.

Sunrise criteria

The department is required to evaluate the proposal to regulate colon hydrotherapists according to the three sunrise criteria listed in RCW 18.120.010. Under these criteria, the proposal must demonstrate:

- Unregulated practice can clearly harm or endanger the health, safety, or welfare of the public, and the potential for harm is easily recognizable and not remote or dependent upon tenuous argument;
- The public needs and can be reasonably expected to benefit from an assurance of initial and continuing professional ability;
- The public cannot be effectively protected by other means in a more cost beneficial manner.

¹ See Appendix B.

Sunrise reviews for health professionals typically include consideration of a range of activities to be included as a scope of practice. This proposal is unusual because it requires analysis of one specific procedure rather than on a scope of practice with a range of activities.

As a result, this sunrise review focuses on patient safety issues for the practice of colon hydrotherapy. It also includes an analysis of the practitioners already authorized by law in Washington to perform the procedure. This review provides background about the colon hydrotherapy procedure and the current legal status of colon hydrotherapy as a medical practice.

Background: Colon hydrotherapy practice

The “practice of colon hydrotherapy” is defined in the applicant’s proposal as “the removal of waste from the large intestine without the use of drugs by a client-administered application of filtered and temperature-regulated water into the large intestine.” The actual procedure was described in significant detail at the public hearing and in written materials submitted by the applicant group. The procedure is performed in a clinic-like setting, using a “colonic irrigation system.” While the person receiving the treatment may self-insert the nozzle, the practitioner provides the equipment and operates the device.

A colonic irrigation system is a device regulated by the Food and Drug Administration (FDA).² Under FDA regulations, these systems are considered to be a class II medical device, which means the equipment must be obtained with a prescription.³ The device is described in federal regulations as:

...intended to instill water into the colon through a nozzle inserted into the rectum to cleanse (evacuate) the contents of the lower colon... The device consists of a container for fluid connected to the nozzle via tubing and includes a system which enables the pressure, temperature, or flow of water to be controlled.⁴

The FDA recognizes the use of a colonic irrigation system for colon cleansing when medically indicated, such as before radiologic or endoscopic examinations.⁵

Benefits, risks, and effectiveness

The applicant group asserts colon hydrotherapy is safe and effective if performed by properly trained personnel using FDA-approved equipment. In the public hearing, the applicant group identified the following benefits:

- health maintenance (detoxification to correct imbalances)
- symptomatic relief of constipation, indigestion, and functional bowel problems
- assessment of bowel function
- removal of impacted feces and foreign material
- rehydration, toning, and retraining of the bowel
- improved bowel elimination
- removal of toxins (that) may cause chronic inflammatory disease

² See 21 C.F.R. Section 876.5220

³ Ibid.

⁴ Ibid.

⁵ Ibid.

- improved sense of well-being, immune response, and quality of life
- assistance in bowel cleansing and elimination of stored toxins
- assistance in restoring the integrity of mucosal lining

In addition, many people testified at the public hearing on the health benefits of the procedure.⁶

However, the applicant group acknowledges that there are many medical conditions recognized by the FDA as contraindications for the procedure, including:

- uncontrolled hypertension or congestive heart failure
- aneurysm
- severe anemia
- gastrointestinal hemorrhage or perforation
- severe hemorrhoids
- renal insufficiency
- cirrhosis
- carcinoma of the colon
- fissures or fistulas
- Crohn's disease
- abdominal hernia
- recent colon surgery
- first and third trimester of pregnancy

Colon hydrotherapy can cause adverse effects and injury if not properly administered. Someone receiving frequent treatments can absorb too much water into the bloodstream.⁷ This can lead to electrolyte imbalances in the blood, nausea, vomiting, heart failure, fluid in the lungs, abnormal heart rhythms, or coma.⁸ The risk of bowel perforation is rare, but complications are serious when this occurs.⁹ Infection can result when the equipment used is not properly cleaned or is not FDA-approved.¹⁰ Death and serious injury have followed colon hydrotherapy treatment performed without physician involvement.¹¹

The department was not able to find any clinical or evidence-based studies showing the effectiveness of colon hydrotherapy outside of the medically indicated procedures. The applicant group did not provide data regarding effectiveness of this procedure. The department contacted several gastroenterologists for information. While recognizing the risk of harm is small, one practitioner indicated colon hydrotherapy has no scientifically proven merit. In rebuttal to the department's initial draft report, a number of physicians (including several gastroenterologists), chiropractors, and naturopathic physicians provided statements in support of

⁶ See Appendix D.

⁷ Colonic Irrigation, <http://www.intelihealth.com/IH/ihtIH/WSIHW000/8513/34968/358752.html?d=dmt>

⁸ Ibid.

⁹ Ibid.

¹⁰ Istre GR, Kriess K, Hopkins RS, et al. An outbreak of amebiasis spread by colonic irrigation at a chiropractic clinic. N Eng J Med 1982; 307(6):339-342; Anon. Amebiasis associated with colonic irrigation: Colorady. MMWR Morb Mortal Wkly Rep 1981; 30(9):101-102.

¹¹ "Attorney General Abbott Sues 'Colonic Hydrotherapy' Providers for Abuse of Medical Devices; One Death Reported", <http://www.oag.state.tx.us/oagnews/release.php?id=295>.

colon hydrotherapy as a treatment modality. In many cases, the practitioners did not comment regarding certification of colon hydrotherapists as a new category of health provider in Washington. Several practitioners expressed reservations about colon hydrotherapists practicing as independent practitioners given the risks identified above.

The “Practice of Medicine” under Washington Law as applied to colon hydrotherapy

In Washington, the practice of medicine is defined under RCW 18.71.011 as:

A person is practicing medicine if he does one or more of the following:

- (1) Offers or undertakes to diagnose, cure, advise, or prescribe for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, physical or mental, real or imaginary, by any means or instrumentality;
- (2) Administers or prescribes drugs or medicinal preparations to be used by any other person;
- (3) Severs or penetrates the tissues of human beings...

This definition is the basis for deciding when an activity or procedure is, in fact, a medical procedure. To protect the public, procedures that fall within this definition can only be lawfully performed by a licensed health care provider. The procedure has to be within that practitioner’s scope of practice. All invasive procedures, from surgery to a finger-stick blood-draw, are in this definition under current law.

The State of Washington Court of Appeals recently ruled that colon hydrotherapy is the practice of medicine in Washington.¹² The court determined the procedure is within the broad definition of medical practice as defined in RCW 18.71.011. In reaching this decision, the court looked to the procedure used to perform colonic irrigation, considered the invasive nature of the procedure (insertion of the nozzle into the rectum), and potential patient safety issues. Given the court’s decision, there is no legal basis for this sunrise review to consider arguments by the applicant group and others that the procedure is not the practice of medicine and not a medical procedure.

Existing authority to perform colon hydrotherapy

Prior to addressing the three sunrise review criteria, it is appropriate to first assess which of the health professions already licensed are lawfully authorized to practice colon hydrotherapy as a medical procedure.

Colon hydrotherapy is within the scope of practice of allopathic and osteopathic physicians. The scope of practice for physicians broadly includes any procedure that fits in the definition of medical practice, as discussed above. Since colon hydrotherapy is the practice of medicine in Washington, it follows that physicians regulated in our state include the procedure in their scope of practice. This means they are authorized to perform the procedure.

¹² Dept. of Health v. Yow, 146 Wn. App. 1075 (Wash. Ct. App. 2008). See Appendix G. On December 29, 2008, the Court of Appeals granted the Department’s motion to publish the opinion. See also Appendix F, Final Order from Administrative Hearing.

Colon hydrotherapy is also within the scope of practice for naturopathic physicians. The procedure's reported benefits reasonably fit within description of the naturopathy scope as the practice of "diagnosis, prevention, and treatment by stimulation or support, or both, of the natural processes of the human body."¹³ The procedure is also taught as part of the curriculum in naturopathy schools.¹⁴

All types of physicians may delegate medical procedures, including colon hydrotherapy, to other licensed persons in limited circumstances. The delegating physician is responsible to ensure the training, competence, and appropriate supervision of the person performing the procedure. The procedure must be within the scope of practice of the person performing the task. In Washington, the professions with the training and practice scopes that allow penetration of the tissue include allopathic physician assistants, osteopathic physician assistants, nurse practitioners, registered nurses, and licensed practical nurses. Colon hydrotherapy, therefore, could be delegated to a practitioner holding one of these licenses. Under current law, a person not licensed in one of the professions listed above may not perform or delegate colon hydrotherapy in Washington.

FINDINGS

Based on the information presented in the applicant report, responses to follow-up questions, public input through written submissions, and public hearing testimony:

- Colon hydrotherapists are not currently recognized or regulated under the Uniform Disciplinary Act in Washington.
- In Florida, the definition of "massage" includes colonic irrigation, and a licensed massage therapist may obtain a certification to practice the procedure. No other state was found to license colon hydrotherapists.
- Colon hydrotherapy is performed using "colonic irrigation systems," which are prescriptive devices regulated by the FDA.
- No clinical studies were found that validate colon hydrotherapy as a practice that promotes health.
- The applicant group, health providers, and treatment recipients provided written and oral statements attributing a wide variety of health benefits to the procedure.
- There are numerous medical contraindications for colon hydrotherapy.
- Colon hydrotherapy is associated with a small but real risk of serious injury or death.
- Colon hydrotherapy is the practice of medicine in Washington.
- Colon hydrotherapy is a medical procedure within the scope of practice of allopathic, osteopathic, and naturopathic physicians. The procedure may be delegated to other licensed staff under limited circumstances.

¹³ See RCW 18.36A.040

¹⁴ Dean Neary with the Bastyr Center for Natural Health indicated the procedure is part of their curriculum and practiced in their teaching clinic. E-mail communication, October 3, 2007.

REVIEW OF SUNRISE CRITERIA

First criterion: Unregulated practice can harm or endanger health and safety.

The applicant group acknowledges there is a small, but real risk of harm from colon hydrotherapy treatment. Harm may occur if treatment is provided when a contraindicating condition exists. Overuse carries the risk of electrolyte imbalance. Bowel perforation is a rare, but serious complication. Improperly cleaned equipment can cause serious infection. Injuries and death following colon hydrotherapy have been documented.

While the risk of harm may be small, it underscores the need to have colon hydrotherapy done by appropriately trained health professionals. Regulation of the health professionals who administer the treatment is appropriate and necessary to protect patient health and safety.

Colon hydrotherapy is already regulated in Washington because it is the practice of medicine. It is within the scope of practice of allopathic, osteopathic, and naturopathic physicians. These professionals may delegate the task to other personnel if the delegate is properly trained and has colon hydrotherapy within his or her scope of practice.

The department concludes that unregulated practice of the single procedure proposed for this profession can harm or endanger health and safety. However, this conclusion alone does not support the need to regulate colon hydrotherapists as an independent profession. Professionals already regulated in Washington can provide this treatment. The procedure can also be delegated to other licensed professionals when there is appropriate training and supervision.

Second criterion: Public needs and will benefit from an assurance of professional ability

The analysis of this criterion is similar to the first, because it focuses only on the treatment of colon hydrotherapy. The public already benefits from an assurance of professional ability for the scope of practice proposed for this profession. The procedure is already regulated through the scope of practice of other health professionals. Allowing independent practice for a medical procedure carrying a small, but real, risk of harm would not benefit the public need for patient safety. The department concludes that the proposal does not satisfy the second sunrise criterion.

Third criterion: Public protection cannot be met by other means in a cost-effective manner

The proposal would create a new credential that the department would regulate by establishing a colon hydrotherapy program. Program costs would be those typically associated with setting up a new health profession program. These include staff salary and benefits, rule-making activities, and the investigative and legal expenses for enforcement actions.

The scope of practice for the proposed profession would include only one procedure. As discussed, the court has ruled that colon hydrotherapy is the practice of medicine in Washington. The procedure is within the scope of practice of other professions with established programs within the department. There are other more cost effective means of providing public protection, such as recognition of the procedure as within the scope of an established profession.

Establishing a new profession includes incurring the administrative costs associated with it. These costs can be avoided by assessing the scopes of practice already recognized by law. As a result, the department concludes the proposal does not satisfy the third sunrise criteria.

Conclusion

The proposal meets the first sunrise criterion. However, this criterion does not support regulation of the profession because the practice of colon hydrotherapy is already regulated within other licensed professions in Washington. The proposal does not meet the second and third criteria.

RECOMMENDATION

Based on the analysis of the sunrise criteria, the department recommends that the legislature not adopt the proposed bill establishing certification for colon hydrotherapists. The proposal does not satisfy all three sunrise criteria. In addition, adopting the proposal would set precedent for regulation based on a single medical procedure. The department does not believe this is an efficient approach to regulating the health care delivery system.

REBUTTALS TO DRAFT REPORT

Applicant Group's Comments in Response to Draft

Following is a summary of the comments made by the applicant group in their written response to the initial draft report issued on December 21, 2007. The department's response to each comment is provided.

1. *Comment:* The review of the “Sunrise Review Process” should note that an added benefit of the process is giving the legislative body the opportunity to identify bias in the Department of Health that is inconsistent with the direction of the legislature.

Response: In the request for this sunrise review, the legislature did not indicate a specific direction. The department made a good faith effort to objectively apply the sunrise criteria to the applicant’s proposal. The analysis required consideration of current law, and the recent Court of Appeals decision that colon hydrotherapy is the practice of medicine.

2. *Comment:* The “Overview of Proceedings” should reflect the date of the initial draft report and rebuttal period.

Response: The final report includes these changes.

3. *Comment:* The “Summary of Information” included an error in citing the case *State v Pacific Health Center, Inc.* as the rationale for colon hydrotherapy as the practice of medicine.

Response: The department realized this citation was in error and the final report does not cite *State v. Pacific Health Center, Inc.* as the rationale for colon hydrotherapy as the practice of medicine.

4. *Comment:* Colon hydrotherapy should not be recognized in Washington as a medical practice. The sunrise review hearing documented that colon hydrotherapists do not prescribe and treat medical conditions. They also do not insert any device into any orifice of the body.

Response: The department appreciates that the applicant group provided documentation in their rebuttal comments that colon hydrotherapists do not practice medicine. However, their

documentation is not sufficient to override legal precedent. The State of Washington Court of Appeals recently decided that colon hydrotherapy is considered a medical practice.¹⁵ The court upheld the department's finding from the administrative case that administering colon hydrotherapy is an invasive procedure. As such, it is the practice of medicine.¹⁶ Diagnosis and treatment are only part of the definition of medical practice. Activities that sever or penetrate the tissue are also part of the definition. The fact that the colon hydrotherapy patient self-inserts the nozzle does not change the character of the procedure, or eliminate the risks acknowledged by the applicant group. The practitioner provides the "colonic irrigation system," the instrumentality, and the clinic-like setting for the procedure.

The applicant group asserts colon hydrotherapists are performing an activity that is not the practice of medicine; however, they asked for certification of colon hydrotherapists as health care providers.

5. *Comment:* The department's position that medical procedures "can only be performed by appropriately licensed health professionals acting within the scope of his or her license" shows bias, is inaccurate, and is not factual.

Response: The department stands by this statement, and does not agree the statement shows bias. The department believes the statement accurately reflects activities within the scope of practice for the professions discussed in the report. This does not reflect bias, but rather an objective review of lawful scope of practice for the professions discussed. The final report provides additional information about why the department views colon hydrotherapy as being within the scope of practice of allopathic, osteopathic, and naturopathic physicians. It also has additional information about the department's interpretation of delegation to other professions.

6. *Comment:* The department is both inaccurate and showing bias by stating that allopathic, osteopathic, and naturopathic physicians "may delegate colon hydrotherapy to other practitioners under limited circumstances. When delegated, colon hydrotherapy must be in the scope of practice and training of the licensee performing the task."

Response: This statement reflects the long-standing view of the department. In order to protect the public, delegation of medical procedures can be made only to appropriately licensed individuals with a scope of practice that includes the procedure. The department's position is consistent with the approach of the Medical Quality Assurance Commission regarding delegation.

7. *Comment:* When discussing FDA regulations, the report should change its reference to reflect that the FDA regulates "colon hydrotherapy systems." The FDA regulations do not discuss "colon hydrotherapy."

Response: The final report has been changed to more accurately reflect the language in FDA regulations.

¹⁵ Dept. of Health v. Yow, 146 Wn. App. 1075 (Wash. Ct. App. 2008). See Appendix G. On December 29, 2008, the Court of Appeals granted the Department's motion to publish the opinion.

¹⁶ See Appendix F, Final Order from Administrative Hearing.

8. *Comment:* Under “Safety and Efficacy” in the draft report, the applicant group objects to the statement that “Frequent treatments can result in the absorption of too much water. This can lead to electrolyte imbalances in the blood, nausea, vomiting, heart failure, fluid in the lungs, abnormal heart rhythms, or coma.” The applicant group contends this statement is inaccurate, as reflected on an evidence-based article they provided.

Response: The department appreciates the applicant group providing the published article: Effects of Colon Irrigation on Serum Electrolytes.¹⁷ The article discusses seventeen health patients receiving three colonic irrigation treatments over a one-week period. While none of the test subjects experienced clinically significant symptoms, the article noted “altered serum electrolytes” during the research trial. There is no suggestion of the long term consequences if the treatments had continued beyond the one-week period. The article (Table 4) includes a list of references to articles where complications were associated with colonic therapies. The article the applicant group provided to support the safety of the procedure does not support the applicant group’s position.

9. *Comment:* Under “Safety and Efficacy,” the statement “Death and serious injury have been associated with colon hydrotherapy treatment without physician involvement” is misleading.

Response: The final report includes citations to each statement about injury and risk from the colon hydrotherapy procedure. Wording in the final report has been changed to distinguish between the treatment, and injury, and risk of harm.

10. *Comment:* Regarding the finding that colon hydrotherapy is the practice of medicine, following the direction of a licensed practitioner does not make an activity or procedure the practice of medicine.

Response: The Washington Court of Appeals has made its decision about whether or not colon hydrotherapy is the practice of medicine. Following the direction of a licensed practitioner in making the procedure available does not change the character of the procedure: it is still the practice of medicine. As a result, under Washington law, it must be performed by a licensed provider or delegated to a provider with the procedure within his or her scope of practice.

11. *Comment:* Regarding the Department’s analysis of the first sunrise criterion (that unregulated practice can clearly harm or endanger public health): The analysis includes statements that are inaccurate, misleading, and support regulation of colon hydrotherapists as independent practitioners. The department’s analysis reflects bias. No medical school or naturopathic school in Washington trains or teaches about colon hydrotherapy.

Response: The applicant group’s points are redundant with those made above. The department’s research confirmed that colon hydrotherapy is taught at Bastyr University as part of the curriculum and practice in its teaching clinic (Bastyr Center for Natural Health).

¹⁷ Collins, J. G, and Mittman,P, Journal of Naturopathic Medicne, 1,1, accepted for publication February 1, 1009. The department was not able to confirm that this article was from a peer-reviewed journal that could be seen as a reliable comment on standard of care. The applicants provided a copy of the article noting an internet address. However, that address is currently inactive.

The applicant group does not agree with the department's analysis and conclusions, but this does not indicate bias in analysis of the sunrise criteria.

12. *Comment:* Regarding the department's analysis of the second sunrise criterion (that the public needs and will benefit from an assurance of professional ability): The opposite is true from the department's conclusion that the second sunrise criterion is not met in the applicant group's proposal.

Response: The department stands by its analysis of this criterion. The procedure is already regulated through the scope of practice of professionals. Through proper delegation, the assurance of professional ability would be in place without the need to create a new profession with a single procedure as the scope of practice.

13. *Comment:* Regarding the department's analysis of the third sunrise criterion (that public protection cannot be met by other means in a cost-effective manner): Other professions do not have any required training for colon hydrotherapy in any schools and the only way the legislature can ensure individuals performing this valuable service are trained is by certification or regulation by law.

Response: The department stands by its analysis of the third sunrise criterion. The department's analysis clearly indicates that colon hydrotherapy is already within the scope of practice of a number of health care providers in Washington. These professions already have established regulatory programs. Creating a new program with associated administrative costs (for staff, rule-making, testing, and enforcement actions) is not the most cost effective method of regulation. Regulation could be met by other means (such as recognition of the procedure as within the scope of practice for established professions).

14. *Comment:* The testimony at the public hearing established that colon hydrotherapy is not the practice of medicine. There is no training in any Washington medical school or naturopathic school on colon hydrotherapy.

Response: Bastyr Center for Naturopathic Medicine told the department that colon hydrotherapy is in the curriculum and practice and is included in its teaching clinic. We acknowledge that use of a "colonic irrigation system" may not be taught in the curriculum at allopathic or osteopathic medical schools. The analysis, as discussed above, indicates that the determining factor is the character of the procedure. The Court of Appeals decided that colon hydrotherapy is the practice of medicine in Washington. It is in the scope of practice for allopathic, osteopathic, and naturopathic physicians given the broad scope of practice for these professions.

Public comments in response to draft

1. *Comment:* There are many benefits of the colon hydrotherapy procedure and it should be licensed.

Response: The Sunrise Review Process focuses on whether or not a particular profession should be recognized as health care providers and not on specific procedures. The department appreciates comments that the "procedure" should be "licensed," but licensing specific procedures is outside the focus of this sunrise review.

2. *Comment (from many physicians, including naturopathic physicians):* Colon hydrotherapy is not the practice of medicine. The procedure should be available because it is a “wellness” procedure outside of the scope of medicine. Allopathic, osteopathic, and naturopathic physicians do not have time to do the procedure. They have to delegate it.

Response: The department appreciates this comment. However, the department can not ignore court precedent that has determined colon hydrotherapy is the practice of medicine.

3. *Comment:* Colon hydrotherapy is a wellness procedure. It is a “service” (cleansing service) and not a medical procedure. It should not be the practice of medicine. The department should not take this service away from people who need it.

Response: The Court of Appeals has set precedent, in publishing the Yow decision, that colon hydrotherapy is the practice of medicine. The department cannot ignore this decision.

4. *Comment:* Colon hydrotherapists should not be licensed as practitioners who can practice independently.

Response: This is consistent with the department’s recommendation. The department does not recommend creating a new health care provider for colon hydrotherapists.

5. *Comment:* Colon hydrotherapy should continue to be totally unregulated in Washington. The department should not move forward with the sunrise recommendations.

Response: Under Washington law, we are required to perform a review and report back to the legislature when requested to perform a sunrise review.

APPENDIX: A

Proposed Legislation

BILL REQUEST - CODE REVISER'S OFFICE

BILL REQ. #: H-3505.1/07

ATTY/TYPIST: ML:mos

BRIEF DESCRIPTION:Regulating the practice of colon hydrotherapy.

AN ACT Relating to the regulation of the practice of colon hydrotherapy; amending RCW 18.130.040; adding a new chapter to Title 18 RCW; creating a new section; and providing an effective date.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. Sec. 1. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Colon hydrotherapist" means an individual who is certified to engage in the practice of providing and assisting with colon hydrotherapy services under this chapter.

(2) "Client" means an individual who is receiving colon hydrotherapy services.

(3) "Department" means the department of health.

(4) "Practice of colon hydrotherapy" means the removal of waste from the large intestine without the use of drugs by a client-administered application of filtered and temperature regulated water into the large intestine.

(5) "Secretary" means the secretary of health.

NEW SECTION. Sec. 2. In addition to any other authority, the

secretary has the authority to:

- (1) Adopt rules under chapter 34.05 RCW necessary to implement this chapter;
- (2) Establish all certification, examination, and renewal fees in accordance with RCW 43.70.110 and 43.70.250;
- (3) Establish forms and procedures necessary to administer this chapter;
- (4) Issue certifications to applicants who have met the education, training, and examination requirements for obtaining a certification and to deny a certification to applicants who do not meet the requirements;
- (5) Hire clerical, administrative, investigative, and other staff as needed to implement this chapter to serve as examiners for any examinations;
- (6) Determine minimum education and training requirements and evaluate and designate those educational and training programs from which graduation will be accepted as proof of eligibility to take a qualifying examination for applicants for obtaining a certificate;
- (7) Establish practice parameters consistent with the practice of colon hydrotherapy, and considering developments in the field, with the advice and recommendations of any work groups that the secretary may establish;
- (8) Prepare, grade, and administer, or determine the nature of, and supervise the grading and administration of examinations for obtaining a certificate;
- (9) Determine which states have credentialing requirements equivalent to those of this state, and issue certificates to applicants credentialed in those states without examination;
- (10) Establish work groups as necessary to provide advice and recommendations to the secretary on issues relating to the practice of colon hydrotherapy and the certification of colon hydrotherapists;
- (11) Maintain the official department record of all applicants and certificate holders; and
- (12) Establish by rule the procedures for an appeal of an examination failure.

NEW SECTION. Sec. 3. Nothing in this chapter shall be construed to prohibit or restrict:

- (1) An individual who holds a credential issued by this state,

other than as a colon hydrotherapist, to engage in the practice of that occupation or profession without obtaining an additional credential from the state. The individual may not use the title "colon hydrotherapist" unless certified as such in this state;

(2) The practice of colon hydrotherapy by a person who is employed by the government of the United States while engaged in the performance of duties prescribed by the laws of the United States; or

(3) The practice of colon hydrotherapy by a person who is a regular student in an educational program approved by the secretary, and whose performance of services is pursuant to a regular course of instruction or assignments from an instructor and under the general supervision of the instructor.

NEW SECTION. Sec. 4. The secretary shall issue a certificate to any applicant who demonstrates to the satisfaction of the secretary that the applicant meets the following requirements:

(1) Completion of an education or training program approved by the secretary; and

(2) Successful completion of an examination administered or approved by the secretary.

NEW SECTION. Sec. 5. (1) The date and location of examinations must be established by the secretary. Applicants who have been found by the secretary to meet the other requirements for obtaining a certificate must be scheduled for the next examination following the filing of the application. The secretary shall establish by rule the examination application deadline.

(2) The secretary or the secretary's designees shall examine each applicant, by means determined most effective, on subjects appropriate to the scope of practice, as applicable. The examinations must be limited to the purpose of determining whether the applicant possesses the minimum skill and knowledge necessary to practice competently.

(3) The examination papers, all grading of the papers, and the grading of any practical work shall be preserved for a period of not less than one year after the secretary has made and published the decisions. All examinations must be conducted under fair and wholly impartial methods.

(4) Any applicant failing to make the required grade in the first examination may take up to two subsequent examinations as the

applicant desires upon prepaying a fee determined by the secretary under RCW 43.70.250 for each subsequent examination. Upon failing three examinations, the secretary may invalidate the original application and require remedial education before the person may take future examinations.

(5) The secretary may approve an examination prepared or administered by a private testing agency or association of credentialing agencies for use by an applicant in meeting the credentialing requirements.

NEW SECTION. Sec. 6. Applications for certification must be submitted on forms provided by the secretary. The secretary may require any information and documentation that reasonably relates to the need to determine whether the applicant meets the criteria for certification provided for in this chapter and chapter 18.130 RCW. Each applicant shall pay a fee determined by the secretary under RCW 43.70.250. The fee must accompany the application.

NEW SECTION. Sec. 7. The secretary shall establish by rule the requirements and fees for renewal of a certification. Failure to renew the certification invalidates the certificate and all privileges granted by the certificate. If a certificate has lapsed for a period longer than three years, the person shall demonstrate competence to the satisfaction of the secretary by completing continuing competency requirements or meeting other standards determined by the secretary.

NEW SECTION. Sec. 8. An applicant holding a certificate in another state may be certified to practice in this state without examination if the secretary determines that the certification standards of the other state are substantially equivalent to the certification standards of this state.

NEW SECTION. Sec. 9. (1) A person not certified with the secretary to practice colon hydrotherapy may not represent himself or herself as a "colon hydrotherapist," "certified colon hydrotherapist," or other letters, words, signs, numbers, or insignia indicating or implying that he or she is a colon hydrotherapist.

(2) The secretary may, by rule, proscribe or regulate advertising and other forms of patient solicitation that are likely to mislead or

deceive the public as to whether an individual is certified under this chapter.

NEW SECTION. Sec. 10. The uniform disciplinary act, chapter 18.130 RCW, governs uncertified practice, the issuance and denial of a certificate, and the discipline of persons certified under this chapter. The secretary shall be the disciplining authority under this chapter.

NEW SECTION. Sec. 11. Sections 1 through 10 of this act constitute a new chapter in Title 18 RCW.

Sec. 12. RCW 18.130.040 and 2004 c 38 s 2 are each amended to read as follows:

(1) This chapter applies only to the secretary and the boards and commissions having jurisdiction in relation to the professions licensed under the chapters specified in this section. This chapter does not apply to any business or profession not licensed under the chapters specified in this section.

(2) (a) The secretary has authority under this chapter in relation to the following professions:

(i) Dispensing opticians licensed and designated apprentices under chapter 18.34 RCW;

(ii) Naturopaths licensed under chapter 18.36A RCW;

(iii) Midwives licensed under chapter 18.50 RCW;

(iv) Ocularists licensed under chapter 18.55 RCW;

(v) Massage operators and businesses licensed under chapter 18.108 RCW;

(vi) Dental hygienists licensed under chapter 18.29 RCW;

(vii) Acupuncturists licensed under chapter 18.06 RCW;

(viii) Radiologic technologists certified and X-ray technicians registered under chapter 18.84 RCW;

(ix) Respiratory care practitioners licensed under chapter 18.89 RCW;

(x) Persons registered under chapter 18.19 RCW;

(xi) Persons licensed as mental health counselors, marriage and family therapists, and social workers under chapter 18.225 RCW;

(xii) Persons registered as nursing pool operators under chapter 18.52C RCW;

(xiii) Nursing assistants registered or certified under chapter 18.88A RCW;

(xiv) Health care assistants certified under chapter 18.135 RCW;

(xv) Dietitians and nutritionists certified under chapter 18.138 RCW;

(xvi) Chemical dependency professionals certified under chapter 18.205 RCW;

(xvii) Sex offender treatment providers and certified affiliate sex offender treatment providers certified under chapter 18.155 RCW;

(xviii) Persons licensed and certified under chapter 18.73 RCW or RCW 18.71.205;

(xix) Denturists licensed under chapter 18.30 RCW;

(xx) Orthotists and prosthodontists licensed under chapter 18.200 RCW;

(xxi) Surgical technologists registered under chapter 18.215 RCW;

((and))

(xxii) Recreational therapists; and

(xxiii) Colon hydrotherapists certified under chapter 18.-- RCW (sections 1 through 10 of this act).

(b) The boards and commissions having authority under this chapter are as follows:

(i) The podiatric medical board as established in chapter 18.22 RCW;

(ii) The chiropractic quality assurance commission as established in chapter 18.25 RCW;

(iii) The dental quality assurance commission as established in chapter 18.32 RCW;

(iv) The board of hearing and speech as established in chapter 18.35 RCW;

(v) The board of examiners for nursing home administrators as established in chapter 18.52 RCW;

(vi) The optometry board as established in chapter 18.54 RCW governing licenses issued under chapter 18.53 RCW;

(vii) The board of osteopathic medicine and surgery as established in chapter 18.57 RCW governing licenses issued under chapters 18.57 and 18.57A RCW;

(viii) The board of pharmacy as established in chapter 18.64 RCW governing licenses issued under chapters 18.64 and 18.64A RCW;

(ix) The medical quality assurance commission as established in

chapter 18.71 RCW governing licenses and registrations issued under chapters 18.71 and 18.71A RCW;

(x) The board of physical therapy as established in chapter 18.74 RCW;

(xi) The board of occupational therapy practice as established in chapter 18.59 RCW;

(xii) The nursing care quality assurance commission as established in chapter 18.79 RCW governing licenses and registrations issued under that chapter;

(xiii) The examining board of psychology and its disciplinary committee as established in chapter 18.83 RCW; and

(xiv) The veterinary board of governors as established in chapter 18.92 RCW.

(3) In addition to the authority to discipline license holders, the disciplining authority has the authority to grant or deny licenses based on the conditions and criteria established in this chapter and the chapters specified in subsection (2) of this section. This chapter also governs any investigation, hearing, or proceeding relating to denial of licensure or issuance of a license conditioned on the applicant's compliance with an order entered pursuant to RCW 18.130.160 by the disciplining authority.

(4) All disciplining authorities shall adopt procedures to ensure substantially consistent application of this chapter, the Uniform Disciplinary Act, among the disciplining authorities listed in subsection (2) of this section.

NEW SECTION. Sec. 13. This act takes effect August 1, 2009.

NEW SECTION. Sec. 14. The secretary of health may adopt such rules as authorized under section 2 of this act to ensure that this act is implemented on its effective date.

APPENDIX B:

Applicant Report

Applicant Report Cover Sheet and Outline
Washington State Department of Health Sunrise Review

COVER SHEET

- Legislative proposal being reviewed under the sunrise process (include bill number if available): H-3505-1/07 - Regulating the practice of colon hydrotherapy.

AN ACT Relating to the regulation of the practice of colon hydrotherapy; amending RCW 18.130.040; adding a new chapter to Title 18 RCW; creating a new section; and providing an effective date.

- Name and title of profession the applicant seeks to credential/institute change in scope of practice: Colon Hydrotherapy

- Applicant's organization: International Association for Colon Hydrotherapy (I-ACT)
Contact person: Russell Kolbo, DC, ND, I-ACT President
Address: 11103 San Pedro, Suite 117, San Antonio, TX 78216

Telephone number: 210-366-2888 Email address: homeoffice@i-act.org

- Number of members in the organization: 2124
Approximate number of individuals practicing in Washington: 67 (in the association)
Name(s) and address(es) of national organization(s) with which the state organization is affiliated: International Association for Colon Hydrotherapy (I-ACT)
11103 San Pedro, Suite 117, San Antonio, TX 78216

Name(s) of other state organizations representing the profession: None

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OUTLINE OF FACTORS TO BE ADDRESSED

Please refer to RCW 18.120.030 (attached) for more detail. Concise, narrative answers are encouraged. Please explain the following:

(1) Define the problem and why regulation is necessary:

Currently there are no federal statutes or regulations that govern colon hydrotherapists. Regulation does exist that govern the manufacturers of colon hydrotherapy equipment, but not the end users. This guidance is provided in the Code of Federal Regulations volume 21, Food and Drug Administration (FDA).

In Washington, there are no state statutory standards for colon hydrotherapists. In fact, there is only one state that provides licensure for colon hydrotherapists, and that state is Florida. The remaining states do not have any specific regulatory statutes that define the standards of practice for this profession. Without specific regulations, it is incumbent upon the states to promulgate statutes to regulate the practice of colon hydrotherapy.

House Bill H-3505.1/07 will provide the necessary statutes and regulation for colon hydrotherapist.

(2) The efforts made to address the problem:

Without regulation, colon hydrotherapists may be confused as there are no specific regulations and laws.

In the most recent legislative session there was an initial attempt to generate regulation covering alternative health modalities, but the effort was not concluded prior to the session ending

(3) The alternatives considered:

The author of the bill considered requiring licensure, but after evaluating the anticipated cost to manage a licensing program, the decision was made to request simple certification vice licensure.

(4) The benefit to the public if regulation is granted:

Once regulation is granted, the public can be assured that the certified colon hydrotherapists will have a minimum set of standards, procedures, and practices will be in effect that can help to ensure the safety of the public and the efficacy of the process.

In addition, all colon hydrotherapists in Washington will understand the standards, procedures, and practices that must be complied with to achieve certification. A copy of I-ACT

Standard Operating Procedures, Regulations & Guidelines are at appendix A.

In these guidelines, there is special emphasis placed on using colon hydrotherapy equipment that is currently registered with the FDA. We recommend the use of disposable speculums and rectal tubes to ensure the safety of the consuming public. State regulations would ensure that only FDA registered equipment may be used on the public.

There have been allegations of injury to individuals (outside of Washington), but in the state of Florida where colon Hydrotherapists have been licensed for over 30 years there are no reports of any alleged or actual injuries in that state.

The result of this regulation will be to help ensure public safety.

(5) The extent to which regulation might harm the public:

If regulation is granted, there are no foreseeable situations or conditions that might result in any harm to the public; on the contrary, this regulation can only decrease any potential for harm to the public.

(6) The maintenance of standards:

Currently, the International Association for Colon Hydrotherapy (I-ACT) has developed policies, procedures and standards (see appendix A) that help to ensure the safety of the public. These policies, procedures and standards may be adopted by the State of Washington and the Association has agreed to help ensure the standards are promulgated and enforced with all colon hydrotherapists in Washington.

(7) A description of the group proposed for regulation, including a list of associations, organizations, and other groups representing the practitioners in this state, an estimate of the number of practitioners in each group, and whether the groups represent different levels of practice.

This bill will regulate the practice of colon hydrotherapists that are certified by the State of Washington and all associations should ensure their membership is aware of these new regulations.

Currently the International Association for Colon Hydrotherapy (I-ACT) has 67 members that are located in Washington. These members utilize colon hydrotherapy equipment that is registered with the FDA and are in compliance with the current policies and procedures (appendix A).

I-ACT has established a Board of Certification called the National Board for Colon Hydrotherapy. Both I-ACT and the NBCHT are members of the National Organization for Certifying Agencies (NOCA) and the NBCHT has applied to the National Certification Commission Agency (NCCA) the certification body of NOCA.

I-ACT has had established training standards for over 15 years, and has been providing testing to assure their members have achieved certain levels of training.

The NBCHT has been working on establishing a National Exam for Colon Hydrotherapists and has a contract with Schroeder Measurement Technologies, Inc. for psychometric services for their National Board exam question verification.

(8) The expected costs of regulation:

Implementation of this Bill should not have any increased expense to the public.

The colon hydrotherapist will have certification fees and an annual renewal fee that will be collected by Washington state.

The state may need to establish a position or two to monitor and maintain the records of the certification process. Both I-ACT and the NBCHT have volunteered (without any cost to the state) their services and expertise as subject matter experts to assist the State to establish and promulgate the new standards, policies and procedures.

By adopting the policies, procedures and standards promulgated by I-ACT the state may be able to save initial start up costs (See appendix A).

Additional savings to the state might be received by utilizing the current question databases that have been established by both I-ACT and the National Board for Colon Hydrotherapy.

This application is NOT requesting that colon hydrotherapy services be reimbursed by insurance.

(9) List and describe major functions and procedures performed by members of the profession (refer to titles listed above). Indicate percentage of time typical individual spends performing each function or procedure:

5% - Office procedures – Includes taking client history, maintain files, office procedures, scheduling appointments, etc.

15% - Office cleanliness – Ensure office cleanliness, colon hydrotherapy equipment maintenance (change filters, etc) according to manufacturer specifications, disinfect equipment after each client, prepare equipment prior to each client session.

80% - Client consultation (pre and post procedure), performing colon hydrotherapy procedure, consultation with referring MD, DC, ND.

Appendix A

**Standard
Operating Procedures,
Regulations &
Guidelines
For
I-ACT Recognized Schools
&
I-ACT Recognized Colon Hydrotherapy Establishments
OF THE
**INTERNATIONAL
ASSOCIATION
COLON HYDROTHERAPY****

(I-ACT)

These guidelines are a compilation of material gathered from experience and several colon hydrotherapy manuals to establish a mutual understanding. Thanks to all contributors.

Sept 1 , 2004
Appendix A

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Appendix A

Purpose

(1) These Business and Professional Regulations are promulgated in an effort to protect the health, safety and welfare of the public by ensuring that only those who are qualified by certification to administer colon hydrotherapy may do so.

(2) Prior to the administration of colon hydrotherapy, any person shall be required to present certification to the Board of successful completion of a course of study approved by I-ACT through an I-ACT approved colon hydrotherapy school or instructor and certified at the Foundation Level.

Scope of Practice

Colon Hydrotherapy is the introduction of warm, filtered and temperature regulated water into the colon, the waste is softened and loosened, resulting in evacuation through natural peristalsis. This is repeated several times during the session.

Definitions

(1) "Board" means the Board of Directors of the International Association for Colon Hydrotherapy (I-ACT).

(2) "Education Committee" is a group of dedicated members of I-ACT who volunteer their service to recommend educational guidelines to the Board.

(3) "Establishment" means an appropriate site or premises, or portion thereof, where a colon hydrotherapy session occurs

(4) "Colon Hydrotherapy" is the introduction of warm, filtered and temperature regulated

water into the colon, the waste is softened and loosened, resulting in evacuation through natural peristalsis. This is repeated several times during the session.

(5) "Student" means a person studying colon hydrotherapy at any of the four Levels of training (i.e., Foundation Level, Intermediate Level, Advanced Level, or Instructor Level).

(6) "Instructor" means a certified colon hydrotherapist who plans to carry out the training and instruction of a student for a limited period of time.

(7) "Certification" means the procedure by which a colon hydrotherapist applies to the Board for approval the student has successfully passed the I-ACT certification examination and fulfilled all requirements for each level of certification.

(8) "I-ACT recognized colon hydrotherapy school" means a facility which agrees to comply with the training and curriculum as recommended by I-ACT. Each school must be in compliance with the laws of their state.

Appendix A

(9) Equipment Classification

Enema Kit

From the code of federal regulations (CFR) 876.5210 Enema Kit.

a) Identification. An enema kit is a device intended to instill water or other fluids into the colon through a nozzle inserted into the rectum to promote evacuation of the contents of the lower colon. The device consists of a container for fluid connected to the nozzle either directly or via tubing. This device does not include the colonic irrigation system (Sec. 876.5220).

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to Sec. 876.9. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of Sec. 820.180 of this chapter, with respect to general requirements concerning records, and Sec. 820.198 of this chapter, with respect to complaint files. [48 FR 53023, Nov. 23, 1983, as amended at 65 FR 2317, Jan. 14, 2000]

Colonic Irrigation System

From the code of federal regulations (CFR) Sec. 876.5220 Colonic irrigation system.

(a) Identification. A colonic irrigation system is a device intended to instill water into the colon through a nozzle inserted into the rectum to cleanse (evacuate) the contents of the lower colon. The system is designed to allow evacuation of the contents of the colon during the administration of the colonic irrigation. The device consists of a container for fluid connected to the nozzle via tubing and includes a system which enables the pressure, temperature, or flow of water through the nozzle to be controlled. The device may include a console-type toilet and

necessary fittings to allow the device to be connected to water and sewer pipes. The device may use electrical power to heat the water. The device does not include the enema kit (Sec. 876.5210).

(b) Classification. (1) Class II (performance standards) when the device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations. (2) Class III (premarket approval) when the device is intended for other uses, including colon cleansing routinely for general well being.

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any colonic irrigation system described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a colonic irrigation system described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976. Any other colonic irrigation system shall have an approved PMA in effect before being placed in commercial distribution. [48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 61 FR 50707, Sept. 27, 1996]

Qualifications for Individual Certification

(1) Any person is qualified for certification as a colon hydrotherapist who:

(a) Has presented certification to the Board of successful completion of a course of study approved by I-ACT through an I-ACT recognized colon hydrotherapy school or instructor and certified at the

Appendix A

Foundation Level, or who has presented documentation they have been practicing in the field of colon hydrotherapy for more than one year and have performed more than 100 colonics in the past year.

(b) Has taken the I-ACT written test and received a passing grade.

(c) Has completed the remaining requirements as directed by the I-ACT Board.

Examinations

(1) A written examination for each level of certification shall be offered by I-ACT at least once yearly (at the annual convention), at regional meetings, at I-ACT recognized schools or with an I-ACT Instructor.

(a) The testing for Level 4 (Instructor Level) requires a total of four instructor

hours. Three {3} hours may be accomplished at an I-ACT recognized school, with an I-ACT Instructor, or at a Regional meeting (it is desired that minimum of 8 individuals attend the instructor presentations). One hour must be completed at an I-ACT Convention. In addition, the prospective instructor must attend a mandatory two hour instructor workshop provided during the convention.

(2) Upon an applicant's passing the test and paying the initial certification fee and fulfilling all requirements for I-ACT Level 1, I-ACT shall then certify the individual at the Foundation Level. Completion of the requirements for Level 2, 3 or 4 will cause I-ACT to certify the individual at that level.

(3) All certification examinations must be proctored and an accurate record of each examination shall be made; and that record, together with all examination papers, shall be filed by I-ACT or the school certifying the examination and be kept indefinitely.

(4) For reexamination of applicants who have failed the examination, the applicants may retake the examination one time without a second charge.

Posting of Certificates

(1) All members shall post their I-ACT Certificate in their colonic establishment for easy viewing by the public.

Inactive Status

(1) A member becomes inactive when an I-ACT member fails to renew their I-ACT membership, within 90 days of expiration of membership and pays an Inactive status fee of \$25.00 per year. Once a member goes inactive, they may reinstate their status by paying current years dues. However, any individual that allows their membership to I-ACT to be terminated automatically loses all levels of certification they had received. This individual must retest on each level before that level of certification may be reinstated.

Appendix A

I-ACT Recognized Colon Hydrotherapy School Criteria

(1) The Board shall adopt reasonable standards, for I-ACT recognized schools.

(a) An I-ACT school must have at least one certified I-ACT Instructor on staff, and all training shall be conducted or supervised by an I-ACT Instructor.

(b) The school shall teach colon hydrotherapy utilizing the I-ACT Syllabus for the Foundation, Intermediate, Advanced, or Instructor Level as appropriate to the class.

(c) The school must provide I-ACT testing at the completion of each course of training.

(d) The school must comply with all guidelines of the I-ACT's Standard Operating Procedures, Regulations & Guidelines.

(2) Any person, firm, or corporation desiring to operate a colon hydrotherapy school shall submit to I-ACT, accompanied by any information requested by I-ACT, an application for recognition fee as directed by the I-ACT Board. Additionally the school must submit proof that they are in compliance with all state laws.

(3) I-ACT retains the right to visit any recognized school as it deems necessary.

Disciplinary Guidelines

Grounds for Disciplinary Action

(1) Attempting to procure a certificate to administer colon hydrotherapy by bribery or fraudulent misrepresentation.

(2) Practice or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities which the certified colon hydrotherapist knows or has reason to know that he/she is not competent nor authorized to perform.

(3) Refusing to permit I-ACT to visit the business premises of the certified colon hydrotherapist on reasonable notice.

(4) Failing to keep the equipment and premises of the colon hydrotherapy establishment in a clean and sanitary condition on the inside and outside of the building.

(5) Conviction of felony after membership and certification.

(6) Behavior detrimental to the profession or goals of the association.

(7) Inappropriate advertising inconsistent with I-ACT guidelines.

Appendix A

(8) Three verifiable grievances that have gone through the grievance process and have

been determined by the Board to have merit.

Disciplinary Action

When the Board finds any person is acting in violation of any rules, it may enter an order imposing one or more of the following penalties:

(a) Refusal to certify any person, but that person can reapply within 90 days with a new application fee of \$75.00.

(b) Issuance of a reprimand or censure by promulgated, unanimous decision of the Board.

(c) Revocation of a certificate and suspension of the right to hold themselves out as an I-ACT certified colon hydrotherapist.

It is understood that any investigation, decertification, or censuring of a member, may cause I-ACT to expend funds for that investigation and may result in an expense or a cost. The person or member involved will be expected to pay this cost within 30 days. If the fee is not paid it will cause expulsion for the applicant.

Grievance Policy

1) Grievances brought forth by the public will be considered for review by the grievance committee for issues involving the following criteria:

Those within the Standard Operating Procedures and By-Laws of I-ACT. (for example: complaints concerning scope of practice, ethics, advertising, facilities, cleanliness, and reuse of disposables. This is not an all inclusive list.)

A grievance must be in written form and signed.

2) Grievances brought forth by members of I-ACT against an Officer of the Board or Board Member, or fellow member:

Grievances considered will be those within the Standard Operating Procedures and By-Laws of I-ACT.

A grievance must be in written form and signed.

3) Grievances regarding I-ACT recognized schools will only be accepted if they pertain to, education, testing and the Standard Operating Procedures or I-ACT By-Laws.

A grievance must be in written form and signed.

- 4) Grievances regarding manufacturers or products are not within I-ACT authority or responsibility.

Appendix A

Disclaimer: I-ACT assumes no responsibility, legal or otherwise, for the outcome and/or resolution of any grievance.

APPENDIX: C

Follow-Up Questions to Applicant Report

Colon Hydrotherapy Sunrise
Follow-up Questions to Applicant Report
August 8, 2007

I-ACT's response provided on August 17, 2007

Cover sheet: Name of other organizations representing the profession

Please clarify the relationship between I-ACT and the NBCHT.

I-ACT stands for the International Association for Colon Hydrotherapy. It was founded as a non-profit association in 1989. In the By-Laws of the Corporation, there is established the Board of I-ACT, which is responsible for setting training standards, establishing training syllabi, and certifying (by exam) that the members have achieved one of four levels (Foundation Level – level 1, Intermediate Level – level 2, Advanced Level – level 3, and Instructor Level – level 4) of training competence. Also in the I-ACAT By-Laws, a separate and independent Board is established called the National Board for Colon Hydrotherapy (NBCHT). The responsibility of this Board is to establish certification standards by working with the National Organization of Competency Assurance (NOCA) and establish a National Examination that might be used by municipalities and states in the US, and also by other foreign countries.

Question 1 of the applicant report

Please provide additional information about the problem and why regulation is necessary.

- (a) What is the nature of the potential harm to the public if colon hydrotherapists are not regulated, and the extent to which there is a threat to public health and safety?

Colon Hydrotherapy is relatively safe when practiced within the guidelines as promulgated by I-ACT. However, when left unregulated, there could be severe and devastating harm to the public.

As reported in The New England Journal of Medicine, Vol 307, #6, August 5, 1982, "at least 36 cases of amebiasis occurred in persons who had a colonic irrigation therapy at a chiropractic clinic in Western Colorado. Of 10 persons who required colectomy, six died." It was reported that the cause was improperly cleaned and maintained colon hydrotherapy equipment that did not have proper safety features and requirements for disinfecting.

In order to preclude the possibility of this even happening, I-ACT has established a policy that all colon hydrotherapist MUST use equipment that is currently registered with the Food and Drug Administration (FDA). This equipment must have appropriate backflow prevention, must use disposable tubing and disposable speculums or rectal tubes. The equipment must be disinfected after each use following the FDA approved cleaning guidelines for the manufacturer of that equipment.

A recent check with the Center for Disease Control and Prevention found that there has been no reports of any such spread of disease in the past 25 years.

Although there have been a few allegations of injury as a result of bowel perforation during a colon hydrotherapy session, there have been no verified cases that that has ever happened. In one case of an allegation of injury, from Las Vegas, NV, the therapist was found to have done absolutely no harm to the client and the client was ordered to pay restitution.

The only way to actively help to protect the safety of the public is to establish standards for colon hydrotherapists that must be adhered with. The best example is the State of Florida. In Florida, they have licensed colon hydrotherapists for 30 years, in that time there have been no reports of any injuries or deaths as a result of colon hydrotherapy in that time frame.

The FDA regulates colon hydrotherapy manufacturers, however, it is the responsibility of each state to regulate the profession in that state.

(b) What is the extent to which consumers need and will benefit from a method of regulation identifying competent practitioners?

Colon Hydrotherapy is relatively safe when practiced within the guidelines as promulgated by I-ACT. Be establishing similar, or identical guidelines, the state:

- will ensure that only trained and qualified practitioners are performing colon hydrotherapy
- will guarantee that the equipment is registered with the FDA
- will guarantee that only disposable tubing will be used
- will guarantee the cleanliness of the facility
- will guarantee that the public has the safest facility possible

(c) What is the extent of autonomy a practitioner has, as indicated by:

(i) the extent to which colon hydrotherapy calls for independent judgment and the extent of skill or experience required in making the independent judgment; and

(ii) the extent to which practitioners are supervised? Are there any supervision requirements?

Are colon hydrotherapists being supervised and if so, by whom? Are there any internship or clinical supervised experience requirements?

Prior to each session, the colon hydrotherapist reviews the current intake form with the client. This intake form has a list of contraindications. If there are any contraindications, then the colon hydrotherapist will refer the client back to their attending physician for approval to perform the colonic.

The colon hydrotherapist is trained in how to take the intake form, and what to look for during the pre-session interview.

There is no requirement for the colon hydrotherapist to be supervised.

The I-ACT training syllabus requires that each colon hydrotherapist perform a minimum of 25 colonics under the supervision of an I-ACT Certified Instructor.

Question 3 of the applicant report

You indicate you are seeking certification rather than licensure due to the anticipated costs to manage a licensing program. What did you base this differential on? (We are unaware of decreased costs due to a profession being certified as compared to licensed.)

Perhaps we are mistaken, since we now understand that certification is just as costly to manage as licensure, we would accept either certification or licensure which ever is deemed more appropriate.

Question 4 of the applicant report

Your answer mentions that there have been allegations of injury. Please provide additional information on injuries.

- What types of injuries can occur?
- How often do they occur?
- Are there particular patient populations at greater risk for injury?
- What are the contraindications for this therapy?
- What are the warning signs of injury?

Although this procedure is relatively harmless and extremely safe when practiced according to I-ACT Guidelines, there always is the potential for the spread of disease if the equipment is not registered

with the FDA, and if the equipment is not cleaned and disinfected according to the guidelines of the manufacturer.

In addition, there is an extremely rare possibility that an external or internal hemorrhoid can bleed, or that the rectum may be punctured during the insertion of the speculum or rectal nozzle. Although the possibility exists, there have been no verified reports of actual injury as a result of colon hydrotherapy.

There are certain drugs that thin the wall of the colon, and clients that are taking them should only do so at the direction of their attending physician or health care provider. Our therapist are made aware of such drugs during their training.

The population that is at the greatest risk are paraplegics and quadriplegics.

Following is a generic list of the contraindications for colon hydrotherapy (the list is generic as each manufacturer of colon hydrotherapy equipment has a list of FDA recognized contraindications specific to that equipment):

- Uncontrolled Hypertension or Congestive Heart Failure
- Aneurysm
- Severe Anemia
- GI Hemorrhage/Perforation
- Severe Hemorrhoids
- Renal Insufficiency
- Cirrhosis,
- Carcinoma of the Colon
- Fissures/Fistulas
- Crohn's Disease
- Abdominal Hernia
- Recent Colon Surgery (less than three months)
- First and third trimester of pregnancies

Please provide a copy of the Florida law establishing licensure for colon hydrotherapists in Florida. Our research indicates Florida issues an endorsement on a massage therapist license for colon hydrotherapy. We have not located a law granting colon hydrotherapists independent licensure.

Our reference to Florida licensing colon hydrotherapists is a general statement that means a person may not perform colon hydrotherapy in Florida without being licensed by the state of Florida. The state of Florida requires the individuals to be licensed in massage therapy and can then gain a certification to perform colonics. Without that license they cannot perform colonics in Florida. There is not a separate and independent license for colon hydrotherapy that is separate from the massage license.

The purpose of the Florida massage law identifies the potential risk.

“480.032 Purpose.”--The Legislature recognizes that the practice of massage is potentially dangerous to the public in that massage therapists must have a knowledge of anatomy and physiology and an understanding of the relationship between the structure and the function of the tissues being treated and the total function of the body. Massage is therapeutic, and regulations are necessary to protect the public from unqualified practitioners. It is therefore deemed necessary in the interest of public health, safety, and welfare to regulate the practice of massage in this state; however, restrictions shall be imposed to the extent necessary to protect the public from significant and discernible danger to health and yet not in such a manner which will unreasonably affect the competitive market. Further, consumer protection for both health and economic matters shall be afforded the public through legal remedies provided for in this act.”

With colonics under the Florida Massage Board, the specific requirements are set forth in the Florida Administrative code Chapter 64B7-31

64B7-31.001 Colonic Irrigation.

(1) Intent

- (a) The Board of Massage finds that the colonic irrigation procedures, while falling directly within the scope of Chapter 480, Florida Statutes, presents a substantial danger to the public if performed by incompetent practitioners.
- (b) The Board of Massage further finds that a significant proportion of licensees do not perform the colonic procedure and further that a significant proportion of those desiring to enter the profession do not intend to engage in the practice of colonics.
- (c) This rule is promulgated to ensure that only those who have been determined duly qualified to practice colonic irrigation may do so in an effort to protect the health, safety and welfare of the public.

(2) Prior to the practice of colonic irrigation, any licensed massage therapist, or apprentice shall be required to present certification to the Board of successful completion of examination by a Board approved massage school after completion of a supervised classroom course of study in colonic irrigation or in the case of a duly authorized apprenticeship training program, evidence of having completed 100 hours of colonic irrigation training, including a minimum of 45 hours of clinical practicum with a minimum of 20 treatments given.

(3) Prior to the practice of colonic irrigation, any licensed massage therapist, or apprentice shall be required to successfully complete and pass the colonic irrigation examination administered by the Department of Health.

(4) Any licensed massage therapist whose license has been in an inactive status for more than two consecutive biennial licensure cycles shall be required to successfully complete and pass the colonic irrigation examination administered by the Department prior to resuming the practice of colonic irrigation.

(5) Any applicant for massage therapist licensure or licensed massage therapist, who in conjunction with previous massage therapist licensure was certified to practice colonics, shall be required to successfully complete and pass the colonics examination administered by the Department prior to practicing colonic irrigation.

*Specific Authority 480.035(7), 480.041(4) FS. Law Implemented 480.032, 480.033, 480.041(4) FS.
History—New 12-18-84, Formerly 21L-31.01, Amended 1-30-90, 2-13-91, Formerly 21L-31.001, 61G11-31.001, Amended 1-26-00, 5-5-04.*

The Florida certification application follows:



Jeb Bush
Governor

M. Rony François, M.D., M.S.P.H., Ph.D.
Secretary, Department of Health

Department of Health Board of Massage Therapy

Application for Colonic Certification

GENERAL INFORMATION

In order to qualify for certification in colonics, you must hold a valid Florida Massage Therapy License or currently be in the process of obtaining licensure as a Massage Therapist in Florida (your application must be on file with our office).

The colonics exam is given six days a week, excluding Sundays, at several testing facilities across the State of Florida. You will receive additional site information upon completion of this application.

Where to send the application: The original application accompanied by the applicable fee should be addressed to the following:

Department of Health
Payment Management
P.O. Box 6330
Tallahassee, FL 32399-6330

Use of the above address will ensure receipt of the application and fee(s).

Where to send any additional documentation: Any additional documentation, sent either by the applicant or by any other source on your behalf, should be mailed to the following address:

Department of Health
Board of Massage Therapy
4052 Bald Cypress Way, BIN C06
Tallahassee, FL 32399-3256

DOCUMENTATION REQUIRED

No application will be considered complete until the following supporting documentation has been received in the Board office:

- A completed application, with all questions answered. Failure to provide an answer to every question will result in the application being deemed incomplete.
- Examination or Re-exam Fee - **\$435.00** (\$385 testing service fee and \$50 application fee which is non-refundable). Please make your check or money order payable to Department of Health. Please note, you will also be required to pay a fee directly to the testing company at the time of scheduling the exam.
- One current photograph of the applicant
- An official transcript from a school approved by the Florida Board of Massage Therapy to offer a program in Colonics or completion of a Board Approved Colonics Apprenticeship program.

In addition, please address the benefit to the public if regulation is granted. To help us understand your position better, please explain:

- (a) The extent to which the incidence of specific problems present from lack of regulation for colon hydrotherapists can reasonably be expected to be reduced by regulation.

Although colon hydrotherapy is relatively safe procedure, without regulation, there exists a potential risk. The state of Florida has recognized this potential risk and identifies it in the Florida Administrative Code, 64B7-31.001 Colonic Irrigation "... presents a substantial danger to the public if performed by incompetent practitioners."

- (b) Whether the public can identify qualified practitioners;

Once Washington accepts the need for certification, the public can then expect to find a state of Washington "certificate" designating the individual as being state certified. Currently I-ACT provides its members a certificate of membership and then also provides certificates designation that the therapist has achieved certain levels of training competence (Foundation, Intermediate, Advanced, and Instructor). With this information, the public can then make an informed decision about the therapist and the procedure.

With state certification the public will be secure in knowing the therapist is using equipment that is safe since it is registered with the FDA.

- (c) The extent to which the public can be confident that qualified practitioners are competent;

Once Washington accepts the need for certification, then the public will know that the therapist has demonstrated a certain level of knowledge and expertise and this will give the public confidence that the therapist is qualified and competent.

- (d) The assurance to the public that practitioners have maintained their competence.

Once Washington accepts the need for certification, then the public will know that the therapist has demonstrated a certain level of knowledge and expertise and this will give the public confidence that the therapist is qualified and competent, and with a requirement for continuing education credits, the public will understand that the original level of qualification and competence will be maintained.

Question 6 of the applicant report

Maintenance of standards – legal requirements that define or enforce standards.

What are the core curriculum requirements in colon hydrotherapy school?

I-ACT has established a syllabi for each level of training. The Foundation level is similar with the requirements of the state of Florida training for colon hydrotherapy. The outline for the Foundation Level syllabus is shown here:

I-ACT Lesson Plan Outline

Section..... Unit / Lesson (100 hours)..... Page

Business Ethics/Office Procedures	Unit 1 (5 hours)	
.....	Introduction	2
.....	Section 1 - Regulations	3-5
.....	Section 2 - Career Paths.....	6-8
.....	Section 3 - Marketing	9-11
.....	Section 4 - Management/Ops	12-15
Health & Sanitation.....	Unit 2 (5 hours)	
.....	Section 1 - Stress Mgt.....	16
.....	Section 2 - Human Relations	17
.....	Section 3 - Disease & Infection.....	18
.....	Section 4 - Sanitizing	19
.....	Section 5 - Personal Hygiene.....	20
.....	Section 6 - Therapeutic Exercise	21
.....	Section 7 - Physical Development	22
Anatomy & Physiology.....	Unit 3 (45 hours)	
.....	Section 1 - Terms/Organization Levels....	23
.....	Section 2 - Skeletal System.....	24
.....	Section 3 - Muscular System.....	24
.....	Section 4 - Nervous System	25
.....	Section 5 - Cardiovascular System.....	26
.....	Section 6 - Lymphatic System	26
.....	Section 7 - Endocrine System	27
.....	Section 8 - Respiratory System	27
.....	Section 9 - Digestive System.....	28
.....	Section 10 - Urinary System	29
.....	Section 11 - Reproductive System	29
.....	Section 12- Special Senses.....	29
Colon Hydrotherapy		
Theory/History/Practice	Unit 4 (10 hours)	
.....	Section 1 - History	30
.....	Section 2 - Theory	30
.....	Section 3 - Indications/contraindications .	30
Complementary Modalities	Unit 5 (5 hours)	
.....	Section 1 - Alternative Therapies.....	31
Internship/Apprenticeship.....	Unit 6 (30 hours)	
.....	Section 1 - Internship/apprenticeship	32

What subjects are covered in the certification examination?

The certification exam for the Foundation Level (Level 1) has 100 questions and covers; Business Ethics, Office Procedures, Health & Sanitation, Anatomy & Physiology, Colon Hydrotherapy Theory, History and Practice.

Is first aid part of the curriculum?

Yes, it is covered under health & sanitation, and again in the internship/apprenticeship. In 2008, I-ACT will require all new students be trained in CPR prior to enrolling in a course of training.

Does the curriculum prepare students for emergencies they may face and how to properly address them or make emergency referrals?

This is determined by the licenses of the colon hydrotherapy student. MDs, DOs, NDs, RNs, PAs, etc. will be able to offer greater levels of support during a potential emergency situation, but a colon hydrotherapist should leave emergency reactions to the experts, the same as any other service provider, and should simply dial 911 for assistance.

How do the curriculum requirement and examination assure public safety?

Yes, it is covered under health & sanitation, and again in the internship/apprenticeship. Safety of the public is a primary concern of I-ACT.

Do any of the FDA-approved devices used in colon hydrotherapy require a prescription? If yes, how are colon hydrotherapists acquiring them?

Yes, the FDA has registered equipment used for colon irrigation under two categories, Class 1 devices (generally called enema kits) do not require prescriptions. The Class 2 devices do require prescriptions to purchase the equipment and order the supplies. I-ACT recommends that the therapist get prescriptions for the procedure. The therapists in the state of Florida do not require prescriptions licensed and certified.

The prescription may come from any individual that has script authority in their state.

Question 7 of the applicant report

Do you have any information on how many colon hydrotherapists in Washington are not I-ACT certified.

Unfortunately, there is no way for us to gather this information; however, during a Washington meeting in April 2007, there were over 20 non-I-ACT members in attendance.

Question 9 of applicant report

You state that functions include consultation with referring MD, DC, ND, DO
Are referrals before or after medical procedures the only reason people are referred to you by these doctors? Is this the only time you consult with doctors?

Since I-ACT is recommending that the therapists get prescriptions for the procedure, each client should have a prescription on file. We request the colon hydrotherapist report the results of the colonic irrigation to the referring physician.

Additionally, if there are any contraindications noted on the intake form, the colon hydrotherapist would report to the referring health care practitioner the contraindication and their concern, and seek the physician's consent prior to continuing with the procedure.

APPENDIX: D

Summary of Public Hearing

Colon Hydrotherapist Sunrise Hearing Summary
August 29, 2007

MEETING OPENED AND APPLICANT REPORT PRESENTED

Karen Jensen, Policy Director at the Department of Health, opened the meeting with a brief overview of the Sunrise review process. She explained how the hearing would run and how the remainder of the review will work.

INTRODUCTION OF SUNRISE PANEL

Margaret Gilbert, Department of Health, Senior Staff Attorney
Joshua Shipe, Department of Health, Customer Service Manager
Mike Nath, public member

Dick Hoenninger, Executive Director of I-ACT, was the first presenter on behalf of the applicant group. Mr. Hoenninger presented a PowerPoint presentation of the Sunrise proposal, which is attached at the end of this appendix.

Our delegation members are:

Dr. Russel Kolbo, I-ACT President, Naturopath, and Chiropractor
Dr. Kornberg, Medical Doctor
Dr. Derrick Kim, Naturopath
Dr. Brent Warner, Chiropractor
Rebecca Harder, I-ACT certified member from Washington
Carol Sivertz, I-ACT certified member from Washington
Cherie Kolbo, Dr. Kolbo's wife, I-ACT certified member and instructor

I-ACT is the International Association for Colon Hydrotherapy and we strongly believe legislation would be a very beneficial asset to Washington. I would like to give you my background on how I got involved in colon hydrotherapy. I was a pilot in the United States Air Force for 22 years. For six years, I flew an aircraft called a U-2, high altitude reconnaissance. Back in the 1960's, Gary Powers got shot down in one over Russia. This is a single seat, high altitude aircraft and you have to wear a pressure suit because the altitude you fly is well above 70,000 feet and the mission duration is well in excess of 12 hours. In that aircraft at that altitude, if we had a decompression, the blood would boil, so we flew in a pressure suit just like an astronaut. There was a system to urinate in the suit, but none to defecate. For those of you not used to this type of language, we will talk about the colon and defecation because that's part of our profession.

In that aircraft, because we had no way to defecate, after hours of flying if you felt the urge you had two choices: either soil your suit or hold it. All of us did the best we could so we wouldn't be embarrassed when we got down and were helped out of our pressure suit. It was extremely embarrassing and unimaginable to have to go through. In six years, over 1,000 hours of flying that aircraft I had trained my colon not to go on demand. It had actually become so bad that I might have a bowel movement once a week. And the flight surgeon would just tell me that was normal for my body, and that's what I heard for years, about 20 years. After I retired from the Air Force I became involved in naturopathic healing and found out about colon hydrotherapy, and I can tell you personally because of colon hydrotherapy, I am now extremely regular and have about two to three bowel movements a day because I was able to retrain my colon. If you've ever been constipated for a long time, you know it's very uncomfortable. Because I'm now regular, I've experienced a great sense of relief and it's actually changed my whole sense of well being. That's why I'm so committed to what we're doing.

See PowerPoint attached at the end of this hearing summary for Mr. Hoenninger's presentation.

Mr. Hoenninger read the introduction of the article, *An Outbreak of Amebiasis Spread by Colonic Irrigation at a Chiropractic Clinic*, from the New England Journal of Medicine, August 5, 1982. See article attached at the end of this hearing summary.

In the state of Colorado there was a chiropractor using equipment not registered with the FDA. They found this equipment had been contaminated and over continued use of this equipment, it resulted in the deaths of over six individuals. So in 1982, the New England Journal of Medicine identified colon hydrotherapy as hazardous and needing to be reviewed. In 1985, the U.S. Congress empowered the FDA to have greater involvement in these devices and so the FDA now registers and regulates colon hydrotherapy equipment. One of their concerns was the spread of amebic dysentery. One of the things we know now is that the equipment used has guarantees of safety. If it is clean, maintained, and disinfected according to manufacturer guidelines, the equipment is absolutely safe. Since the FDA began registering the equipment, there has not been a single incidence of the spread of disease from an FDA registered device. We use single-use, disposable rectal tubes and tubing. All of that is thrown away after each consumer. Then the table is cleaned extensively. And the room should be immaculate. Now the problem is that not everyone uses FDA registered equipment. There's equipment out there that may be a five-gallon drum on the wall. And we know there is equipment that is not registered with the FDA but is in use. We recommend and require our therapists to use that, but I can't tell you that every colon hydrotherapist in the state of Washington is using FDA registered equipment. If I could we'd know it was safe, but I can't tell you that.

Concerns: Puncturing of the Colon - See PowerPoint

Concerns: Electrolyte Imbalances – See PowerPoint

Dr. Russell Kolbo next presented the remainder of the PowerPoint. I've been licensed as a chiropractor in Washington since February of 1970 and as a naturopathic physician since 1971. I've presented on colon hydrotherapy at many conferences as well as one of our naturopathic institutions. I have over 40 years experience in using enemas and colon hydrotherapy. I'm presenting contraindications, precautions, risk management, and indications for this procedure.

First I'd like to emphasize and talk briefly about sanitation. Our therapists not only follow the manufacturers' guidelines for sanitizing their devices, but they make sure their facility is clean and maintained in the appropriate manner. Part of the certification process is to send in pictures of their facility which includes a picture of the device they're using, the room where the session is held, the waiting room, and the restrooms.

Personal hygiene is also one of the important parts of our training, including the frequency of hand washing, and the rest of the personal hygiene.

Contraindications are taught by our I-ACT certified instructors or certified schools. The difference is that an instructor can train one to three people at a time and the school can train as many students as they have the facilities to accommodate. Students are taught according to I-ACT standards by the syllabi, copies of which were given to Sherry Thomas this morning.

The following is a list of contraindications as submitted by the manufacturers of FDA registered equipment. When they submit for approval of their devices, they submit lists of contraindications. The individuals who have any of the contraindications we will be talking about must be referred to their primary health provider for evaluation before they continue to have a colon hydrotherapy session. It is I-ACT policy and is taught by I-ACT instructors that the list of contraindications as listed with the FDA must appear on their intake form. Rebecca will later show you an example of a generic intake form and show you where the contraindications are listed.

Contraindications:

- Abdominal distensions
- Adrenal exhaustion
- Anemia
- Aneuryxm
- Carcinomas

- Cardiac conditions such as uncontrolled blood pressure and congestive heart failure
- Crohn's disease
- Colitis
- Diverticulosis (and diverticulitis)
- Fistulas
- Fissures
- Hemorrhage
- Hemorrhoids
- Hernias
- Liver conditions such as Jaundice, acute failure, and Cirrhosis
- Lupus
- Perforations of the intestines or colon
- Pregnancy (first and third trimester)
- Renal conditions such as one kidney, insufficiency, and dialysis
- Surgery, including abdominal, colon, and rectal
- Benign prostatic hypertrophy
- Acute urinary tract infections
- Dialysis
- Abdominal pain
- Surgery without 12+ weeks for recovery

Precuations: These are areas we want to be concerned about but are not necessarily contraindications – these may merit a referral to the primary health care provider for evaluation prior to a colonic irrigation or hydrotherapy session.

Benign Prostatic Hypertrophy – tendency for restricted urinary flow and experience has shown us that we have rehydration of the colon and the water has to exit out, so if there's difficulty, we don't want to cause anyone stress. The same with urinary tract infections, during a hydrotherapy session you will have urine to pass which will cause discomfort.

One of the things we've tried to institute in I-ACT, particularly since I've been on the Board, as Vice President, President Elect, and now President, is that we're trying to raise our standards and awareness as we work with the medical community on how it affects our colon hydrotherapy sessions. In the last two years, at our convention level and instructor level, we are giving information out about medications and how they may affect the body during a colon hydrotherapy session. We are listing these medications so our therapists are aware of them and how they will affect the body. If someone checks a particular medication box on the intake form, they can refer that person back to their primary care provider for assurance that the session will be safe for them.

All the medications listed here either affect the body as far as causing anemia or increasing the severity of anemia, decreasing the immune responses, causing fatigue, weakness, abdominal pain, or in regard to diuretic affect.

Medications:

- Coumadin
- Digoxin
- Lasix (furosemide)
- Prednisone
- Lipitor
- ASA/NSAIDS
- Methotrexate
- Blood thinning herbs (garlic, gingko, ginseng, chlorophyll, hawthorne berry)

I-ACT also has three medical doctors that are members. One is from Singapore, a member at large. They are working on compiling a list of medications which have a tendency to weaken the bowel wall. It's very important that our certified therapists are aware of medications like these the public is taking, including street drugs as well as

prescribed drugs. Our therapists will be given these lists in their training as well. Hopefully it will be completed by next year's convention. As new drugs come out, we need to always be alert in updating the information.

Sanitation is not on the slide, but I want to talk about it again. We want to make sure our therapists are aware of all aspects of sanitation, from personal hygiene to sanitizing of the equipment they are using that is FDA registered and the facility walls.

Also not on the list is water temperature. FDA registered equipment is designed to shut off the hot water once the temperature reaches a certain degree. That temperature is 104 degrees.

Other items for risk management:

- Recent colonoscopy
- Recent colon polyp removal
- With 50-60% of adult population age 45, assume diverticula
- Working with the elderly 65+, assume dehydration and diverticulosis
- Working with children
- Working with clients with known contraindications
- When is a session too long (manufacturers recommend approximately 45 minutes)

When is a session too long? Dick referred to a study regarding electrolyte imbalances. The study shows they occurred in quadra and paraplegics. This is because of the retention of the water for longer. I want to refer to an incidence most of us have heard about that happened in the early part of the spring. It was a radio contest in San Francisco to see how much water you could drink, how long you could hold it, and you could win a video game. The lady entered the contest so she could win the video game for her son. She wasn't feeling well when she got home so she called the radio station who suggested she get medical help. Unfortunately, the lady died. She was 27 years old, I believe, and the mother of three young children. The cause of death was water auto-intoxication. It was set up from the electrolyte imbalance. So there is a concern and I recently surveyed all the manufacturers of FDA registered equipment and their average time for a session is approximately 45 minutes.

Indications:

- FDA states when medically indicated, such as before radiological or endoscopic examinations

As a physician who has practiced in Washington since 1969, and worked with a doctor while waiting to take my test, and having my naturopath license since 1971, the benefits I'm going to talk about have been experienced through enemas and colon hydrotherapy. The first thing I would do for infants to save me from making a house call was to have them receive an enema. Then if they weren't better I would go to the house. Nobody wanted to go to grandma's house when they were sick as a kid because they got enemas.

- Know benefits not listed by FDA:
 - Health maintenance including detoxification (correct imbalance)
 - Symptomatic relief of constipation, indigestion and functional bowel problems
 - After barium enema
 - Assessment of bowel function
 - Removal of impacted feces
 - Removal of foreign material
 - Rehydration of bowel
 - Toning of bowel
 - Aid in bowel re-training
 - Improved bowel elimination
 - Removal of bowel toxins which may be a cause of chronic inflammatory disease processes
 - Improved sense of well-being
 - Improved immune response
 - Aid in bowel cleansing
 - Aid in elimination of stored toxins
 - Aid in restoring integrity of the mucosal lining

- Improvement of quality of life

We at I-ACT are hopeful that the state of Washington realizes that we want to have colon hydrotherapy available for the public, that they are properly trained, and that they look at the guidelines.

Rebecca Harder, I-ACT certified colon hydrotherapist in Washington, presented the DVD of a colon hydrotherapy session, including the intake form.

Every day at my clinic I hear a common statement that I think every colon hydrotherapist in this room hears as well. "This is not what I thought it was going to be like." And they usually say it with a big smile on their face. I knew coming here today that I was addressing a panel that had probably never seen a colon hydrotherapy session, probably never been in a clinic or probably never seen FDA registered equipment. The best way to introduce you to that is to show it to you on a video. I've prepared a five-minute video of an overall colon hydrotherapy session. It shows one of the rooms at my place and it is using FDA registered equipment. As Dick and Russell both said, there are different types of FDA registered equipment. As I-ACT is not petitioning only one, we are recognizing all the different types of FDA registered equipment; this is just the one I use at my place. In this video, there are two things I want to point out before I show it. First is you are going to see a tube. I've brought you one. The tubes must be used with a prescription. You must be an I-ACT certified therapist with a prescription in order to receive this tube.

(Passed tube to panel). As you can see, this is a one use only, disposable rectal tube. In the video, I will be showing how far the client will insert this tube into themselves in privacy. The second point you will see is the intake form. Every therapist in this room that is I-ACT certified uses a form that has contraindications, and they go over it with clients before each session. In addition, I go over a consult so they understand what is going to happen and how their digestive system is going to be affected.

Showed Video

Now I would like to introduce Dr. Derrick Kim, naturopath in Portland, Board Certified in Washington and Oregon, who is here to answer any questions the panel may have. Also, Dr. Brent Warner is a chiropractor in Portland. He also taught at the naturopathic college and he's also here to answer questions.

Now I would like to introduce Dr. Jacob Kornberg, who is a medical doctor and surgeon and he would like to make a few statements.

Dr. Jacob Kornberg. I'm a licensed medical doctor in Washington. I am also a board certified surgeon and a fellow of the American College of Surgery. I've practiced medicine for over 30 years in Washington, 25 of them as a general surgeon in Puyallup and the last five years as a more holistic, functional medicine practitioner. You may ask how an allopathic, board surgeon would take his day off to come down here to testify for colon hydrotherapy. I was introduced to this marvelous modality about 10 years ago when a patient was sent to me by a gastroenterologist for something called Megacolon. This is a lady who was not on a U-2 plane but had been constipated for so long that her colon was so large that the gastroenterologist thought the only thing we could do was to remove that part of her colon. She was able to get back to fairly normal bowel function after having colon hydrotherapy.

As a surgeon, I was also sent all sorts of difficult cases. I was the elder surgeon in Puyallup, and I would be sent cases of abdominal pain. After listening to them and having this experience with the colon hydrotherapist, I got to realize that these patients who were sent to me with like sets of adhesions, really didn't have a surgeon problem. They had a functional problem of their bowel. I started my search for an answer, got hooked up with the Institute of Functional Medicine, got certified and the last few years of my surgical career, did very little surgery. I was able to help most of my patients through a more functional approach to their bowels. One of the things that was so amazing to me was how little you learned in medical school about the normal functions of the bowel. We learned about pathology and all the parasites but we didn't learn about the normal flora, the normal function of these cells that are actually over 100 trillion foreigners living within our bodies that are more than our own normal cells. I was very disappointed with all my gastroenterology friends and their approach in helping me. I would send these functional patients to them and they would get a colonoscopy, an endoscopy and they would get sent back to me saying they're ready for surgery. And these people needed no more surgery than you and I do.

Another great case was an older boy who was so constipated that he was on cups of Miralax. He would have a bowel movement once a week. It so destroyed his social life that he spent his whole morning and afternoon on the toilet. Finally with the help of a colon hydrotherapist, we retrained him and he sent me a letter saying he went out for football his senior year. All his life, all the pediatricians did was give him more laxatives, never addressing retraining his colon.

From a functional medicine point of view, we live in a country with very poor diet, very poor exercise, very poor fiber, and we are chronically constipated. About 95% of my patients I see who have chronic disease have constipation. I define that as anyone who doesn't go once or twice a day, have soft stools, and the amount of the stool equals from your elbow to your fingertips. If you're one of these people, you are constipated, and you need diet, exercise, stress reduction, and maybe the help of a colon hydrotherapist to retrain your bowel. I can still remember as a child having that urge, wanting to have a bowel movement and my mother telling me to finish my food before I could have a bowel movement. We are trained as children, just like the pilot, to hold our stool in.

I myself after this young man, went to the hydrotherapist and said that I needed to know more about this. My wife and I had several therapies and I actually stood there and watch about a dozen procedures. I was amazed at, when there is certification and FDA approved equipment (this was almost as clean as my operating room) that this is a great modality. I now use it frequently with my patients. I believe deeply that just like a medical doctor that I need to be certified, have continuing education. As a surgeon, every piece of my equipment has to be FDA approved, I believe the public needs the protection of certification of colon hydrotherapists. They need to have a level of education, level of internship, and continuing education. I have found it to be an excellent modality with my patients. I'm here to strongly recommend certification. Any questions?

Rebecca Harder: Do you believe an MD needs to be present during a colon hydrotherapy session?

Answer (Dr. Kornberg): Absolutely not. As a surgeon, I do not believe colon hydrotherapy is surgery. It is no more surgery than inserting a rectal thermometer. This boy, for example, will probably need recurrent training with a therapist. He doesn't need to pay \$290 to see me just to be referred to that colon hydrotherapist. I do believe the colon hydrotherapists need to be certified to protect the public.

Rebecca Harder: Have you seen the guidelines at I-ACT and do you think they are sufficient?

Answer (Dr. Kornberg): Yes, they are excellent.

QUESTIONS FOR APPLICANTS FROM SUNRISE PANELISTS

Mike Nath: Working with children, is there an age limit where maybe a medical doctor isn't necessary? Are there precautions that are common with children of a certain age?

Answer (Dr. Kornberg): I think you saw the precautions that an I-ACT certified colon hydrotherapist would use. I don't think you're going to have a real problem. What is amazing to me is that I consider a colon hydrotherapist as sort of a personal trainer for your bowel function muscles. One of the amazing things is they actually look at the stool. Nobody does that, even your gastroenterologist. And they can tell me about digestive and pancreatic function by the material. There's a lot of information, so when a child comes in, you can look and see poor eating habits, whether they have enough dietary fiber, enough hydration like water. I feel a physician does not need to be present for this type of treatment.

Mike Nath: Is there an age limit?

Answer (Rebecca Harder): I believe with I-ACT it is eight. A lot of it has to do with the size and emotions of a child. The mother is always present in the room. She helps the child insert the tube. You could have a very small eight year old. If you just look at the contraindications, what else is going on.

Answer (Dr. Kornberg): I think the emotional age of the child is important. They can look at this as an invasive thing and you don't want to traumatize a child. It's when you get into the teenage years and they've had 15 and 20 years of poor bowel habit that I really see the benefit of colon hydrotherapy.

Answer (Rebecca Harder): And the children have wanted it. They are not doing this against their will. They are in pain and are having problems. Their doctors have referred them.

Answer (Dr. Kornberg): Have you ever taken Miralax? It's the same exact purgative they give for colon therapy, which completely wipes you out. These little kids are taking cups of it because they have no other way. Colon hydrotherapy is an excellent alternative.

(Unknown responder): I think the doctor was referring to taking it for a colonoscopy.

Yes, it's the same strong stuff a G.I. guy would give you for cleaning out your colon before a colonoscopy. This is what these kids are on chronically today.

Josh Shipe: You had mentioned that colon hydrotherapists can view the waste material that comes out and give you some indications of diet and what-not. In that situation, would they be making particular diagnoses, as far as what types of food you shouldn't eat, or improper diet? Or would they refer you to someone like a dietitian?

Answer (Dr. Kornberg): What they normally do is put on the report what they see. They will write something like "undigested fiber" or "undigested fruit" or whatever. They don't make the diagnosis. It's up to the referring physician to do a follow up examination and use his or her clinical judgment to actually make a treatment. Work together in a team and it's an amazing amount of information that I don't get from any of my other colleagues in the medical profession.

Answer (Rebecca Harder): The size of the waste coming out, if there is a lot of gas or bloating, what color, we write down what we see and fax it into the doctor. We're there to assist and encourage the client. They don't need much encouragement because it's not an unpleasant session. They relax, listen to music, and feel so much better afterwards.

Margaret Gilbert: In at least some of the insurance programs in Washington, individuals can self-refer for a variety of therapies. How do you feel this fitting in to your proposed legislation?

Answer (Dick Hoenninger): It depends on how Washington establishes it. In Florida, the clients can self-refer because it's part of the state law and certification for the colon hydrotherapists. They do not require a prescription or anything. We recommend that our therapists are getting physician referrals of their primary health care practitioners. The FDA regulates the manufacturers of the devices. The state regulates the profession, so every state has the right to determine how this happens. For example in Georgia, the city of Stockbridge, they require the colon therapists to follow the national board CEU requirement, but the medical board of Georgia has said that it is not the practice of medicine so they don't want their doctors involved in it. In California, they have determined if the client does the insertion of the speculum or rectal tube, it's not the practice of medicine and the client can get it as they deem appropriate. So, every state will be slightly different, depending on the requirements of the state and what you determine. In all cases, we're going to recommend the client still do the intake form, check for the contraindications reported by the client and that they must go back to their health care provider if they check any.

Mike Nath: I'm confused about the water. Is this high temperature water?

Answer (Dr. Kolbo): No, the temperature of the water is between 98 and 104 degrees. We recommend they start out at about 99 or 100, but not to exceed 104. The devices are programmed to shut off at 104 and that's the FDA regulation. You may want to fluctuate it more to the warm side or cool side to get the bowel to respond better. All the water is filtered, most of them by carbon filter and ultraviolet, so the water is very clean. This is filtered tap water.

Answer (Dick Hoenninger): That's why we recommend the ultraviolet filtration because some city tap water still has problems.

Answer (Dr. Kolbo): In the FDA registered devices, most have at least two filtration systems.

Mike Nath: Nothing is added to the water, such as saline?

Answer (Dr. Kolbo): There can be substances added to the water as long as they're prescribed by a provider with state prescriptive authority. For example, if our medical doctor here wanted to have a substance or medication added to the water, he could do that. But without a prescription, it is pure water in, water waste out.

Mike Nath: What kind of medications?

Answer (Dr. Kornberg): Most of what I prescribe are called implants. I've prescribed probiotics. I've asked the colon hydrotherapist to instill into the colon a mixture of good, health bacteria. That's the main additive I've used. It's usually done at the end of the session to try to improve the health of the colon flora.

Answer (Dr. Kolbo): As a physician I've also prescribed the implants. For irritable bowel syndrome, I've used aloe vera. Some physicians may want to add in cortisone drugs for something like severe colitis.

Mike Nath: Are there I-ACT guidelines or lists for the types of things to be used?

Answer (Dick Hoenninger): That's up to the referring physician. All I-ACT recommends is water in, water out unless direction from a physician.

Mike Nath: I also wanted to ask in regard to precautions. Is there monitoring of blood pressure, heart rate, or anything? What if someone suddenly feels weak and their blood pressure drops?

Answer (Dr. Kolbo): They immediately stop the session, anything that's not within their training as far as a normal session, as far as cardiac conditions, uncontrolled blood pressure, high or low. I personally am conscious about if a client was going in for a session with low blood sugar, for example, I make sure they have something to eat before going in for a session. I think therapists are trained and listen to I-ACT and are made aware of these factors, will stop the session if anything is not normal.

Karen Jensen: I think he was asking if there is actual monitoring during the session?

Answer (Rebecca Harder): Yes. Not blood pressure.

Answer (Dr. Kolbo): They will be aware of the changing of the individual but not actual blood pressure monitoring.

Mike Nath: The first thing they do when I go into a doctor's office is check my blood pressure, heart rate, and maybe my temperature just to make sure I'm ok.

Answer (Dr. Kornberg): I've actually been impressed with over-cautiousness, having patients kicked back to me because they found something on the intake form that I overlooked and they wanted to patient rechecked and confirmed. I've actually found them over rather than under-cautious.

Mike Nath: You talked about contraindications that have to do with thinning blood, medications that would thin blood. Is there any attention given to aspirin? What if I just took five ibuprofen before I came in?

Answer (Dr. Kornberg): Five ibuprofen probably wouldn't matter. But any medications that thin the blood has the potential to increase the bleeding from a polyp. I used to do a lot of colonoscopies. People could start bleeding from just the prep. They would probably kick the patient back to me if there were any of the medications listed on the I-ACT list.

Mike Nath: What prevents the waste from going back into the tube?

Answer (Rebecca Harder): Excellent question.

Answer (Dr. Kolbo): Anatomically, we have a solid gate that only opens one way called the ileocecal valve, so the material doesn't pass back into the small intestine. There is also a backflow prevention valve on the FDA regulated devices. That's another safety factor built into the FDA regulated devices, where there are not these factors built into the home devices.

Answer (Dick Hoenninger): If there's equipment that doesn't have the backflow prevention, some of the evacuation may go back in. That's what happened to the chiropractor in Colorado. The tubing actually got contaminated.

Answer (Rebecca Harder): The FDA has done a very thorough job investigating the main factors. It's incredibly thorough what they've had to go through to get these devices registered with the FDA.

Answer (Dick Hoenninger): They will have engineering documents that show that there cannot be that possibility and to show what happens after the session is over. Everything is disinfected.

Answer (Rebecca Harder): It takes me at least 30 minutes to disinfect the room and system, every square inch of that system, the lines, the tube, everything. There is no way a germ could be passed from one client to the next.

Margaret Gilbert: How is the equipment inspected or monitored? Things leak, let's face it.

Answer (Dick Hoenninger): The unfortunate answer to that is that we direct our therapists to follow the manufacturer recommended guidelines for maintaining the equipment. Each manufacturer has to have a set of maintenance standards they want each user of that equipment to follow. If I happen to be going through an area, I'll swing in and see if they've got their logs of changing filters and all of that. If there's leaks or anything like that, the manufacturer will have to take it back and repair it or send a repairman out. But the bottom line is that it is I-ACT's recommendation to do this, but unless you're in a state that has regulations to do this, there's no entity that has the authority to go out and do that.

Margaret Gilbert: That kind of responsibility and maintenance is the responsibility of the therapist?

Answer (Dick Hoenninger): Yes.

Josh Shipe: You mentioned the treatment can be used for training the colon. Has there been any studies done on excessive treatment of colonic that could cause any issues of harm or overexpansion of the colon?

Answer (Dick Hoenninger): We haven't heard anything like that. We don't want people to become dependent on colonic any more than we want them to become dependent on laxatives. Each manufacturer has a certain set of guidelines on how their equipment should be used the way they registered it with the FDA. We truly don't want our therapists to exceed those guidelines because there may be problems. If you get a colonic every day for 30 days, that's not good. You would really be changing the electrolytes and structure of the body.

Answer (Rebecca Harder): There are different protocols doctors refer for. Some send in just for two sessions, some once a week for six weeks. Some are more than that. There is no cookie-cutter protocol for every client coming in. They're coming in with different health issues and trying to achieve different goals. Kind of like chiropractic.

Josh Shipe: You also mentioned the different levels of certification, I think it was one through four. Could you talk a little bit about the different training and what it means, how they affect the therapist when practicing colonic?

Answer (Dick Hoenninger): The initial training, they are taught business ethics, health and hygiene, how to sanitize equipment and maintain standards, how to protect themselves if working with clients with AIDS. They are taught about history of the profession, the procedure itself. During the foundation level training, each therapist must do a minimum of 20 colonic with an instructor under supervision so they can ensure this individual is going to be

practicing safely with the public. One of the biggest courses is anatomy and physiology, and they are given the entire structure with emphasis on the alimentary tract digestive system, functioning of the digestive function, etc., so they are able to communicate with referring physicians on a rudimentary level. That's the foundation or beginning level.

On the intermediate level, they are given greater levels of anatomy and physiology, the impact of the venus and nervous system on the colon, what is the structure of that. How do the parasympathetic and sympathetic nerves affect colon functioning, the stomach, etc? They get greater and greater levels at each level. The advanced level is the highest level and you must be at this level to become an instructor. That requires four hour of instruction in front of individuals. One must be done at a convention in front of the education committee to ensure the individual can speak appropriately and that requirement right now is they must teach on anatomy and physiology so we know they are able to communicate to another therapist on anatomy and physiology.

Josh Shipe: I'm still confused as far as, does level one qualify you to go out and practice and is there more or less things as you advance levels that you can do?

Answer (Dick Hoenninger): Level one does qualify them to practice. That's the level that was duplicated from what they used in Florida so we figured if that was ok for 30 years in Florida with no problems, it must be a good standard. We just wanted to establish greater levels. As I-ACT has been growing, we've wanted to continue to increment the bar of professionalism up. So, I mentioned that we're going to start requiring college anatomy and physiology before they even come into their training so we can focus on the digestive tract instead of teaching all the anatomy and physiology. It's patterned after Florida which has worked very well for 30 years with no problems. We think it's an acceptable level for certification to start practicing. The reality is that without legislation, people can open up their doors and have absolutely no training at all.

Answer (Dr. Kolbo): The differentiation between level one and level two, foundation level and intermediate level. In addition to the advancement of the degree of anatomy and physiology and neurology, they also have a greater number of colonics they have to do in that period of time and there's also a time period between how soon they can get to level two from foundation, so they're gaining more clinical experience during that time.

Answer (Rebecca Harder): They're not offering any different level of service. They just have greater knowledge and experience.

Answer (Dr. Kornberg): And as a physician, I look for that. My level of confidence goes up as I find that the colon hydrotherapist has the different levels of certification. In other words, if I find a new hydrotherapist that is just beginning, I'll do a lot of hands on myself to make sure. As I've found, the more advanced are actually telling me things I didn't learn in medical school. As a practitioner, it relieves me of a lot of worry with the increased certification and training. So when I send a patient, I know this person has had this many under her belt. Just like a surgeon, do you want to be the first patient? They're still certified, but would you rather have the surgeon with a fellowship and 1,000 cases? Both have certification and both are legal to do surgery but it's just a level of confidence a referring surgeon has between a first day surgeon and one that has been in practice 25 years.

Margaret Gilbert: You mentioned a number of medications that might create precautions. How are those medications identified on your list updated?

Answer (Dr. Kolbo): That's a good question. They are constantly being updated. This is something we've put into gear the last few years, as we get more knowledge and get more medical doctors working with this and in our association. Doctors coming to us to get training on how to do colon hydrotherapy and the ins and outs of it. We've asked them to start compiling a list of medications that our therapists should be aware of and maybe refer back to the primary care provider or make sure the primary provider is aware of the medications and how they may be affected by colon hydrotherapy. As you know, we have medical doctors and other doctors coming to us for training because they don't know what is really happening during these sessions. If our therapists see a medication and have been referred, they may want to check back to that referring doctor. More and more as we upgrade ourselves the list of contraindicated medications as well as ones we want to take precautions with, we'll update as we get different input from our medical practitioners.

Answer (Dick Hoenninger): That information is handed out at our conventions and regional meetings, as well as in our quarterly newsletter. An example is when we learned about the problem with water intoxication, we immediately put it in the newsletter and warned our therapists that if they exceed the manufacturers' guidelines on the duration of the session, they run the risk of water intoxication. We use that vehicle as well as the conventions.

Answer (Dr. Kornberg): It's also some of the modern medications that actually create the problem which a patient goes to a colon hydrotherapist for because it's a GI side effect of the medication. So having the colon hydrotherapist know this might be a problem, rather than just going on doing colon hydrotherapies forever, it could be a feedback to the physician. If you realize drug X has a slowing effect on the bowel, and this patient has reported increasing constipation, it is really helpful as the list of medications that affect the intestinal tract is created.

Josh Shipe: How many different are there available? Are they spread out across the country?

Answer (Dick Hoenninger): I believe we've got approximately 30 schools and over 200 instructors and an instructor can train just like a school can. The difference is that an instructor can train one or two individuals, whereas a school can train 10 or 15, depending on how many pieces of equipment they have to train on. There are six instructors in Washington, I believe. We are getting quite a large instructor core out there to be able to help train other people as we move forward.

Since we want to get to the public comment period, we're cutting off the panel questions now, but I will give them a chance to submit questions in writing for us to forward to the applicants. Any written follow questions and responses will be made available to the public.

PUBLIC COMMENT

Dirk Yow: See testimony attached at the end of the hearing summary.

Ann Clifton: I'm with Mercury Awareness Team of Washington and Health Freedom Washington. I'm also going to read testimony today from Mother's Against Mercury Amalgam. See testimony attached at the end of the hearing summary. Also, see additional information from Ms. Clifton attached at the end of the hearing summary.

Mike Nath: Is there some study that shows that colon hydrotherapy works with mercury detoxification?

Answer (Ann Clifton): I'm sure there are a lot of studies that show it does. It sure worked for me. I lost 56 pounds of toxic fat. I was using both oral detox with colon hydrotherapy and of course I had all the mercury fillings taken from my mouth a second time because the dentist had left the mercury in. My personal results were so astounding because it cleared my thyroid, my liver. The mercury was everywhere. I had the vaccine mercury in my hypothalamus. I'm sure there are a lot of studies that I can't quote at this point, but I will look them up for you.

Sandra Duffy: I'm board president of Consumers for Dental Choice, which is a national non-profit in Washington D.C. I'm a municipal lawyer in Oregon and have done litigation for 29 years and I've done administrative law for 23 years. I'm looking directly at the outline of factors to be looked at under 18.120.030. The keystone of the process is defining the problem and why regulation is necessary and this answer by I-ACT is that the problem is that there is no regulation. That is not what 18.120.030 is aimed at. That criteria requires proof of harm to the public if regulation is not imposed. There is no substantial evidence that has been presented either in this application or through I-ACT's presentation today of evidence from which one could conclude that harm exists because of colon hydrotherapy being practiced in this state and that the public could only be protected through regulation. One of the things that Dirk Yow didn't mention and is part of the materials he provided is that his malpractice insurance is \$300 per year. I guess Dr. Kornberg isn't here, but I would estimate that his is probably in the tens of thousands of dollars. The insurance companies are telling us that there is much risk with M.D.s, their surgeries, delivering babies, and the different things they do. But they've decided, and obviously they've got statistics to come up with that \$300 figure, that there is literally no risk of claims based on the practice of colon hydrotherapy. In fact, I would submit that the \$300 is probably the cost of them doing the paperwork each year to issue the policy. Going on to the second criteria, which is the efforts made to address the problem. First of all, there is no problem, so regulation can't be a

solution for something that isn't a problem. The intent of 18.120 is to allow these kinds of unlicensed practitioners to practice until there is proof of harm and then only with proof of harm to trigger a sunrise review like we're having here today. Then the evidence would come forward of what the harm is and if the proposed regulation is the way to protect citizens from harm. The real problem here is that there is a conflict between 18.120 which says we want unlicensed practitioners to be able to practice and 18.71, which defines the practice of medicine so broadly that it is interpreted by the Department of Health to include colon hydrotherapy. The real solution is the bill submitted by Health Freedom last year, which was Senate Bill 1714, which exempts colon hydrotherapists from the definition of the practice of medicine. That is the simple solution. As far as the third criteria under 18.120.030, as to what alternatives were considered. Here I-ACT states that the considerations were between certification and licensure and they decided certification was the better way to go. I submit that this is probably a Trojan horse and the reason I say this is that under the proposed legislation, DOH is delegated all the authority by the legislature to develop all the rules, even though I-ACT included a copy of its own rules and operating procedures, DOH is not bound by them at all under the legislation. DOH is authorized to go forward and make rules to certify colon hydrotherapists. In the case of Dirk Yow and the Department of Health that is in King County Superior Court, the Department of Health has submitted in a brief that is has been Department of Health's consistent position that colon hydrotherapy is the practice of medicine and that with that position, I submit very likely that if they get the ability to do regulations on this, they will require direct supervision of licensed physicians of colon hydrotherapists. The next criteria is number four, the benefit to the public if regulation is granted. The response by I-ACT is to ensure the safety of the public but there has been no proof of harm to the public. You don't need regulation to protect you from harm that doesn't exist. Also simple certification can become quite complicated depending on how much you want to encourage or discourage a practice. Criteria five, the extent to which regulation could harm the public and I-ACT has stated it sees no foreseeable situations or conditions that could result in harm. I submit that there are a number of ways the public could be harmed. One is lack of access to colon hydrotherapists of their choice. Dirk Yow is a good example of that. Increased costs is another. Any time you have regulation, you will have increased costs. Nowadays those costs are going to be put on those professionals. I belong to the Oregon State Bar. I pay \$500 per year so I can be regulated, and so does Dr. Kornberg, and the naturopaths and chiropractors as well. There is no question that those are going to be increased costs. As expenses, those are going to have to be calculated into what you need at the bottom line and they will be passed on to their clients. Another potential problem is that if this system ends up being under the direct supervision of physicians, they can veto patients own desires for colon hydrotherapy. It will no longer be the patient's choice. It will be the physician's choice. I have other materials to submit as well. As for number six, the maintenance of standards, again I-ACT has submitted its own standard operating procedures as the model. I've got two comments on that. One is that the Department of Health does have the carte blanche under the legislation. Two, I recently had the opportunity to review the standard operating procedures and found them to be internally inconsistent. In one place, it said that everyone that belongs to I-ACT SHALL only use FDA approved equipment, but in three other places, it indicated that they RECOMMENDED FDA equipment and if you weren't using it, you should try to come into compliance. It was very confusing whether it was a mandate or not. Also, there is no scope of practice at all. There is no specific prohibition against additives, yet they have interpreted it to say they are not allowed. The procedures for discipline or grievances allows the taking of potential property right of a profession without the required due process. Number seven is the description of the group proposed for regulation and their associations. I-ACT has 67 members in Washington State. There are approximately 200 colon hydrotherapists in Washington State, so I-ACT represents less than one-third of them. The other colon hydrotherapists could see this as an attempt to take away independent practices and they've had no input into this process other than what they're being given today. I consider myself a stakeholder and would like to be given the notice you are giving stakeholders.

Karen Jensen: Added a comment that anyone who wasn't previously on the interested parties list but signed in today will be added.

Rebecca Waggoner: I'm reading something from a client of Dirk Yow's and who was also a client of mine. Karen O'Connolly. According to the twenty plus doctors I've been examined by over twenty-five years, I was sent home to die. I told my family goodbye, made preparations and resigned myself to the fact that my mysterious illnesses that had kept me bedridden for a number of years had won. I had no more fight left in me. I had not experienced the quality of life for over a decade. Exhausted with no hope, I accepted the prognosis of medical doctors. Time was running out. A friend gently suggested that if I was willing to try just one more health option that she would take me to see this gentleman, Dirk Yow who worked with water therapy. At this point I felt that I had nothing to lose

and with a desire to someday see my grandchildren, I consented. My first session took place five years ago. I was so weak that I need help to get on the table. I was so sick that I didn't remember much about it. Dirk suggested I see a medical doctor and request that blood tests be done to determine if I had toxins in my system. What an understatement. The blood tests came back and resulted in a mercury reading so high it was off the charts. Also there were high levels of lead, arsenic, and other toxic substances. Now, I knew that the last 25 plus years, my death was being slowly poisoned to death literally. I was dying a very slow and painful death. As I embarked on my new journey to health, Dirk was my coach every step of the way. His kindness, encouragement, and expertise motivated me to keep going. What I had seen come out of my small body seemed like science fiction. If I hadn't seen it with my own eyes, I don't think I would have believed it. Today, I have passed over 1,500 adhesions, some six feet long. Other range from a few inches to three to four feet. I have seen the grey of the mercury, the gravel and destruction of toxins flushed out in colon hydrotherapy sessions. During this time, amazing transitions have taken place in my health. My hair now grows healthy and glowing. It had fallen out. My skin is clear. My legs can support my body and feel strong. I no longer need a wheelchair. The tumors and cysts that had spread throughout my system are gone. I can open doors with the strength in my arms and can digest and absorb my food which I hadn't done for years. My colon is no longer collapsed and is healing and in place. My mind is clear and I can enjoy reading once again. The list of rediscovering life is endless. I feel that I have come out of a time capsule from being suspended over a quarter of a century ago and now have been released into life again. I have no more pain and my energy level continues to improve. How can a person possibly do justice using only words when their life has been saved by colon hydrotherapy and Dirk Yow. I only hope with my renewed health and energy I can do things with my life to improve the world we live in and the people in it. Dirk, although always in the face of adversity, has been a shining example of caring for humanity and administering his extraordinary hydrotherapy techniques that give people another chance to have improved health. God bless you Dirk. Note: freedom of choice for citizens to choose their health care program must be protected. The state of Washington is taking aggressive measures to take alternative healing options away from us. The state is pursuing every means available to put successful doctors, dentists, massage therapists, colon therapists, etc. out of business just as quickly as they can. We need to support the people who have helped us to get well with alternative options, take a stand to let the state know we want our right to choose.

I'm Rebecca Waggoner and I'm a colon hydrotherapist and I'm kind of angry so I'll make this real quick. I'm more and more angry because I'm a person who received a letter from the health department. I'm being attacked by the health department. I've called and asked them questions and they have totally contradicted what they wrote me. I'm going to read a small paragraph. I was sent a letter that says the Washington State Department of Health is authorized under RCW 18.130.190 to investigate complaints concerning the alleged practice of healthcare by unlicensed persons. The department has received information that you are advertising performed colon hydrotherapy. It is the department's position that you are engaging in such conduct as alleged. You must have a license to practice under Chapter 18.71 or 18.36A RCW, or under a healthcare discipline that is within the scope of practice. According to our records, you are not licensed to practice as a medical doctor in the state of Washington. Based on the above, an investigation has been initiated into the complaint that was received against you. There has been no complaint against me. I called and they said they saw a flyer. The health department has been telling me that the following actions are to take place. To issue a cease and desist order to me, to impose a civil fine in the amount of \$1,000 per day for each day that I engage in unlicensed practice, and to seek an injunction in Superior Court with regard to unlicensed practice. They sent a list of things like I'm an unlicensed doctor practicing and I'm really angry about this. I'd like to change this and I need help.

Beth Christ: I can't speak of any RCW numbers or anything. I'm a wife, mother, grandmother, the President of BC Logo products and apparel, which means nothing to you. I am a patient of doctors, a client of Dirk Yow and many other alternative health care providers. I've spent 30 years of my life not being well and not knowing why. I was referred to this doctor, that doctor, this psychologist, that psychologist. I went to so much therapy, I could probably be one of those therapists. Finally, in February of '98, and I'm sorry to get a little uncomfortable here. I started having horrendous periods and throughout my normal life I had always had very slight periods. All of a sudden three weeks out of the month, I was bleeding extremely heavily and was in pain and in bed. My doctor who has been my doctor for 20 years, Dr. Joan Halley who I think the world of, referred me to a gynecologist who I had known very well. He said simple fix, we will do an endometrial oblation. It destroys the lining of the uterus and everything else is intact. He said that the bad news is when you wake up, you will be in the worst pain of your life. The good news is that I will medicate you for that. It is just for a day and you go home and rest for the weekend and

Monday you go back to running your business. We did the oblation and for six solid months I was in screaming pain in bed. It took me two years to recover. Finally, what Joan Halley had put on one of my pink slips years before, Fibromyalgia, was true. Finally I was diagnosed with Fibromyalgia, Chronic Fatigue Syndrome, Irritable Bowel Syndrome, etc. That was in February of '98. Luckily, none of my customers knew I was sitting in my pajamas talking to them. Luckily I didn't have to give up my business. I barely hung on to it. After 20 years of seeing Dr. Halley, still in so much pain and the gynecologist said he could not help me. I had told him right before the surgery I very well could have Fibromyalgia. But I'm doing everything I've learned to take care of this. He said go see the specialist. I had to wait six months to see him. He's one of the best specialists in this state, which I should know because I've seen most of the specialists in this state. I've joined Fibromyalgia support groups and have been through the University of Washington Pain Center, the very first twelve weeks of Fibromyalgia study. I've been to the Pain Clinic in Tacoma now known as Northwest Center for Integrated Medicine. I've been to Medegenics, a three-month, three times FM study, performed by Dr. Bob Leeman. Andrew Holman in Renton on Fibromyalgia. Everyone I know that was half as sick as I was filed for disability, got an attorney and got it. I've spoken to three attorneys. I've filled out for disability three years in a row and all three years, I've ripped up those papers. Once I file for disability, as far as I'm concerned, I'm disabled. I don't choose to be disabled. I choose to be as well as I can be. I choose to be a health mother, wife, grandmother, and President of BC Logo which means nothing to you, but a lot to me. I have large accounts like KIRO Television, like Washington State Bankers Association. I choose to work. I choose to be a vital part of this world. I pay taxes from my corporation. Finally, after seeing a renowned psychologist for many years, he knew he couldn't help me any further and he knew I wanted to be well. He had worked with someone who was quite unique and he had sent three patients to her. He said he didn't know if she would see me because the three patients he'd sent were terminal and he didn't know if I was terminal. I waited six months to see her and counted the days. When I got in to see her, I knew I was in the right place. We're not talking about a doctor. We're not talking any numbers here. We're just talking about someone I trusted who could help me. She saw me once and said that I needed to see Dirk Yow at least five times before she could see me again. Unknown to me, our energy flow in all human beings is all clear and is moving and flowing. Mine was dark, dark brown, almost black, barely, barely moving. I had had constipation most of my life. I had so many ulcers in my stomach that the scar tissue was unbelievable. I started seeing Dirk Yow. I'm a little girl born in Garden City, Kansas and believe, this is not the kind of thing I was raised with. I did not take to this easily but the people that recommended this were people I had known a long time and I trusted. When you're to the point you're in so much pain you want to die, and I'm a really up person, you will do just about anything to gain your life back. I started seeing Dirk Yow and when they mentioned adhesions, you wouldn't believe the rocks, grey. I too had all the mercury removed from my mouth. The adhesions, four feet long, and I lost 20 pounds. I walked out of there feeling like I'd been given back life, every single time. Currently because of my personal situation with my business, and I have three homes, I can't go to Portland. I don't have the time or money to go there. I've gained 20 pounds and don't feel well. I spend a lot of time back in the restroom and that is no way to live a life. I need my choice of my care providers. Dr. Joan E. Halley in Gig Harbor, Washington has been my doctor for 20 years. When I told her what I wanted to do, she told me she didn't learn about this in medical school, but that she had a friend who did it and had success. We've been working together. After coming home from one of these visits, my friend and my husband were waiting for me at the dinner table and they asked me when I was going to stop throwing away money seeing quacks. At that time, I told them that I would not mention these alternative health care providers to them for one year and neither will they. But I told them that in one year, if I'm not better, I will admit I made a mistake. In one year, if I'm better, you're going to get off my back. In that year, I progressed so much that my husband is eight years older than me and was a jock his entire life, and I could do circles around him. He was happy for me but he was never going to do anything like this. He now does it. My best friend can't believe how well she became. My daughter as well. I feel strongly that I worked so hard to find this that I have the right to do what is going to help my daughter be well.

Karen Jensen: I appreciate your comments, but could you please let us know your position on the advocates petition for regulation since that's the focus today.

I haven't had time to read all this, but my position is that I should have the right to choose and I know what kind of job Dirk Yow does, so why would we put people like him out of business. I hadn't even gotten to the part about that I had Stage Two Cancer. I was sent to the best oncologist at U.W. She gave me three months and wanted to start doing surgery immediately. I told her I was doing ozone colonics and I know you'll think I'm nuts but how long do I have. She gave me three months and within three months, I came back to the top oncologist in Washington with

six interns that put my private area on a screen as large as that for everyone to see and every single bit of what was called VIN 2, Moderate Squamous Dysplasia of the Vulva, not just a little spot here and there but everywhere. After three months with Dirk, she looked everywhere and there was not one spot. That was five years ago and there is still nothing. The proof is in the pudding. All I'm saying is that he's done no harm and saved my life.

Linda Kelley: I'm against licensing. I'm licensed with the city and state as far as all the licensed available to me. But I'm not for regulation that is going to change the scope and ability we've had as colon hydrotherapists. I'd like to let you off the hook at DOH because I'm sure you have enough to do and adding another area which would be a huge area to regulate when it's not actually needed. As I look at the criteria for regulation, it is only when unregulated practice can clearly harm or endanger the health, safety or welfare of the public and the potential for harm is easily recognizable and not remote or dependant on tenuous argument. There has not been harm done in Washington. There's been a lot of good done. I've completed a minimum, more than 2,000 hydrotherapy session and there has been no harm done. There have been no complaints. The people I've worked with, anywhere from telling me they feel better, have motivation, etc., to people who say I've saved their lives. There are people writing up their testimonies to submit as well. The company whose equipment I use has not had any problems for 20 plus years. As a lot of things have already been stated, people have always known inside that they need to cleanse their body and cleansing the colon is part of that. They've done it in all different ways. It's very non-invasive. It's an orifice of the body, not medical, not surgery. It's the same type of thing as cleaning your ears, brushing your teeth, cleansing your body. It's something we need to do to keep our health or sometimes regain it. It's very safe, very gentle, very non-invasive. We've seen testimony on that here as well. I have liability insurance and it's under \$200 per year. As was said before, the insurance companies look at harm, and they look at claims. I'm sure some of you have particularly lower car insurance because you haven't had accidents. That's they way they come up with the amount they charge you. Doctors who have higher liability and claims are tens of thousands per year. They are regulated. We are not medical. I have a license with the City of Lacey. I do a service and it's not a medical procedure. Therefore, I don't understand why there would need to be any other type of licensing. I have a master license. I pay all the taxes I need to pay and renew my licenses every year. If the only clients I had were clients referred by doctors, I would most likely be out of business because in the state of Washington, we have very few doctors like Dr. Kornberg. We have very few who I believe understand colon hydrotherapy and so they don't suggest it to their clients, in fact they suggest they not do it because there is a fear due to lack of knowledge. I would not want to need a prescription for every client that came to me because that would most likely not happen. All the things I've heard from I-ACT, I've had all the training they've suggested, been tested and certified. I've had all the things in place they talk about and to my knowledge, all the other therapists I know have done them too. If I-ACT or some group came in and said they need to regulate, it would be redundant because it's already being done. If the real problem is that there are people doing colon hydrotherapy in Washington with no training, that would be the issue to address. I can provide the four page form I provide asking them about medications they are taking, contraindications, etc. If there is anything out of place, I refer them to a doctor. I've actually had more than one client that I've referred back to their doctor to have something checked out more thoroughly before having colon hydrotherapy because I'm not a doctor or nurse. I always let everyone know I'm doing a cleansing service and that I'm not a medical professional. I let my clients tell me how it's helped them. How can hydrotherapists be made to desist what they're doing because they don't have a license with the state of Washington when there is no such license? Rather than working on that, I don't understand how they can be stopped from doing what they're doing. They're not doing anything illegal and haven't caused any harm. A few times I've worked with doctors, I always fill out a form to send back to them so we can work together. If the doctors wanted to work with us, that would be a different story. We need to have our freedom of choice in healthcare as well as other things. People are very upset about losing their freedoms.

Bill Kelley: I wanted to speak separately as a client because that's all I can speak to. At 61 years, I'm healthier than ever and I attribute it to colonics. It's a good thing. I go to doctors for what I think they're good at, which is surgery and drugs. I don't see much else. I make my decisions when I go to my regular doctor. I'm an adult able to make my own decisions about my own body. I believe you can sense when you're healthy and when you're not. Concerning the situation here, I'm against it because I see I-ACT as a union. You have to follow the money to see if that's true or not. I don't believe there's any need for this and for people to control what I do.

Tim Zimmer: I'm one of the owners of the Tummy Temple. I support a lot of what people are saying here but not in the way you might think. We've employed over 16 colon hydrotherapists in the last five years. According to the

training they go through, they aren't performing certified hydrotherapy on clients until they've had 125 sessions. We use FDA certified equipment. We haven't had one complaint, but 90 percent of our clients are referred. I'd say over 90 percent of those clients are constipated. We can't diagnose because we're not doctors. We don't take insurance. We only work with people paying cash. Based on rectal speculum use from one of the largest rectal speculum manufacturers in the country, we are one of the busiest colon hydrotherapy practices in the country. I'm fully in support of certification. You should work as a regulatory body to support this industry. When I look at the three points mentioned in the sunrise process. Unregulated practice can clearly harm or endanger the health, safety, or welfare of the public and the potential for harm is easily recognizable and not remote or dependent upon tenuous argument, I'd like to address that from a slightly different perspective than I think you've been looking at it so far. I believe it's important that the equipment used is FDA regulated. I know because we've used equipment that was not FDA regulated and it was out of our practice very quickly. It was in the learning process as a business. I believe that the regulation establishes the safety mechanisms that I as a business owner with trained, responsible, intelligent, capable therapists still will minimize and eliminate the potential for manual error. When we look at pressure, temperature, backflow, these are things we want to ensure the people coming to see us don't have to think about. They can rest assured that when they come in, there are mechanisms to protect their safety. No harm has been done. Let it continue in that direction. When I look at the "no harm has been done...", I think of Dirk Yow. No harm was done and yet as an unregulated practice, he is out of business. Not to be overly dramatic, but they are unsung heroes in this industry doing a job that nobody else wants to do. They're doing with a major organ of elimination that has a severe issue across the United States. If you take this industry out, people are taken out of business who support a major organ of elimination, in a way that an enema at home can't do, that surgical practice of taking out the actual organ cannot do, then you are actually harming the people of Washington State. It would be like saying we should take out inoculations because they're not safe anymore. Let's take out a major tool that has been going on for 1,000s of years. If it didn't work, it wouldn't be used. The same goes for massage. You have respect for the massage industry. Let's do the same for colon hydrotherapy. Let's ensure that it maintains a strong position for Washingtonians and for the rest of the United States. Florida has taken a fantastic position supporting the industry and we should follow suit. As far as right to choose, I'm 100 percent behind everyone. We're seeing people in my clinic because they're getting results. I can tell you that my wife and I don't sleep at night because we're thinking about how many people we've seen. We don't sleep because we're afraid we're going to be put out of business. We do this because we care about the people in our community. We've thought about relocating to another state because what we've seen in Washington State doesn't bode well. I get concerned when I hear about a business getting put out of business without doing any harm to anyone. To me, that is not justice. I believe in the Department of Health. I implore you to create a certification program because we don't have standards right now. We don't have standards in this industry to give the community a sense of comfort, to give the business owners and therapists a sense of comfort that within a defined scope, we know what we are doing is legal. We pay taxes and provide taxes for people so they can take care of themselves and stay in Washington, support their communities in being healthy. As far as the second part about the public needing and expecting to benefit from assurance of initial and continuing ability, I can't tell you how many people I've spoken with over the phone asking what is the certification or licensure. There is value to establishing a level of comfort for the people in Washington State that they know there are fundamentals being addressed in standardizing what is necessary to ensure the safety and quality of service being provided for them. I've seen people get colon hydrotherapy training in a weekend. I don't think that's reasonable. There are people using equipment that is not FDA regulated. I don't think it's safe. With the best of intentions, with the most experienced colon hydrotherapists, manual error can happen. The FDA in its job has established criteria with its equipment that minimizes or eliminates major issues with potential manual error, such as temperature, pressure, backflow. The public cannot be effectively protected by other means in a more cost-beneficial manner. They can't. I haven't seen other ways they can be better protected. Right now though no harm has been done, we recognize the potential for harm. I think about that for every client that comes through my door, what can I do to eliminate the potential harm. I can tell you that manual error occurs so you need to use the equipment that can eliminate that. I can tell you that when I look at protected by other means, it means two things. One is that they are protected by standards they know and trust. Two is protecting their health. I think all three of the criteria apply. I want to continue to live and practice in Washington State, but I don't feel comfortable with it right now. We have invested everything in our lives to take care of our community and if I got a knock on the door by Department of Health without doing any harm to anybody and it ruined our lives financially, I would be devastated. My family would be devastated. You all did a fabulous job in your presentation and I thank you and all the colon hydrotherapist who have put themselves at risk to help people in their communities.

Terry Kohl: I'm with the Washington Association of Naturopathic Physicians. See testimony attached at the end of the hearing summary.

Lori Lively: I'm not health dependent upon colon hydrotherapy but I do employ it and feel very strongly about it. What I'd like to leave you all with is, as a long-time writer and I work in the natural food industry, I've seen this practice develop through the years. I'm all in favor of certification. I'm all in favor of registration. I'd have to draw the line at regulation for all the reasons that have already been mentioned. I strongly believe in my right to self-refer. I'm an adult. I'm educated and I'm very uncomfortable with one agency or group, when clearly as statistics show, only one-third in our own state are members of I-ACT, that you should be regulating all practitioners, many of whom have excellent training that may or may not fall under your guidelines. But it still is excellent training.

Carol Sivertz: I've been a colon therapist for almost seven years in the state of Washington and have a clinic. I'm a member of I-ACT and have sort of been on both sides of the fence. It may have seemed like a nice idea to not be regulated at some point, but when I spent time in Olympia I was assured that we need to go there by more than one representative. That's why I feel like this is a good idea. It's good to see everyone here and I hope we can come to a conclusion everyone can be happy with. A few follow up points are: I-ACT and the bill are not asking for insurance. About 80 percent of the therapists are getting some medical referrals. I think I fall a little below that but I also get medical referrals. Another point, when you have one I-ACT member, you may have four in the clinic working under them, so I'm not sure the numbers represent everyone. I support the applicants. I feel like this is a long time in coming. I think everyone has done a great job here of saying everything I wanted to say. We need to save our testimony for when we go to the legislative hearings on the hill.

Susan LoForti: I am a healer and ashaman from Olympia. I've had a very dysfunctional life with potentially going crazy with double incest from both parents. At a certain point, I realized I couldn't be in any situation where I would be vulnerable with any medical professional or anybody who was going to dominate me or the same kind of thing I'd been through before. In 1978 I decided I didn't want anything to do with any pharmaceutical drugs because I didn't want the side-effects, so I divorced myself from that and started reading everything I could about herbs and American Indian and felt God's love going through the plant force and all that. I have been totally independent from everybody except chiropractors and colon hygienists since that time. In 1983, I was sallow and went to somebody and in the monitor where the water was coming through, what I saw was a green ball the size of a cherry tomato which supposedly was a collection of toxic substances which had collected ever since my childhood. Thank God that came out and then everything was vital and wonderful. What I do is prayer and fasting. I'm a religious nut, not a Christian scientist. I just go to the roots of it. Buddha, Christ, meditation, whatever I can do so I can be vital. And I care about everyone. I care so thoroughly about everyone having the highest level of vibrancy and the ability to find themselves in life and do what they have to do with the God-given intelligence to find out their uniqueness instead of just pushing papers and when it's time to die you never knew who you really were. That's who I am and I didn't know I was going to say all this but this is why I'm so fervent and I'm against regulation because I believe in healers. There have been people who have helped me so deeply in my life where nobody else could have. You can't regulate a healer. I want everyone here to be totally happy and find themselves and never have to commit suicide because they're suffering so much physically.

Dr. Kolbo: I just want to make a clarification. I-ACT is not here to regulate the state. We're here to assist the Department of Health if they want our help to establish regulations. Also, referring to naturopathic doctors and assisting, the clarification is that we assist our clients in hydrotherapy sessions and may communicate back to the doctor, but we are not assisting the doctors. As far as the education, there is no medical institution, chiropractic, naturopathic, or medical that teaches colon hydrotherapy.

MEETING CLOSED

Karen Jensen closed the public hearing and reminded the audience that there is now an additional 10-day comment period to follow up on anything additional anyone wants to add to the record. She reminded the group that the department will then begin drafting the report, which will be shared with the interested parties. There will then be a "rebuttal period" before the report is finalized.

Testimony from Dirk Yow

I am opposed to BILL REQ. #: H-3505.1/07 as it is written. Please consider this letter as our input to the Sunrise Hearing on Colon Hydrotherapy scheduled for August 29, 2007. As a practicing Colon Hygienist for over 26 years and having performed a minimum of over 40,000 sessions, I have worked and trained as a specialist who has put much time, energy and money into providing a service for the public. Because of this I believe myself to be a stakeholder in the outcome of this hearing both personally and professionally. For 25 years I offered this service in Washington State until it was abruptly shut down in December of last year by the DOH. Even though after years of harassment and investigation concluding with the final summary of the Health Department's own judge that I had "done no physical harm". I was still shut down because I was not licensed! When I first learned colon hydrotherapy it was from a semi-retired colon therapist who had done colonics for over 20 years. I initially trained on a Combes instrument. I fine tuned my knowledge in whatever way I could with other colon therapists such as Bob Rogers another "unlicensed" practitioner who did Edgar Cayce style colonics on a Durker system for over 25 years here in WA state. Over the years I trained with many others as well A Chiropractor in Idaho who had used colonic irrigation in his and his wife's practice for over thirty years in Idaho. I ended up eventually getting three Tox-Eliminator's (another type of colonic instrument with additive capacity for instillations) from them as they thought they were 'the best'. Over the years I have worked with 12 different types of colonic instruments and many different techniques both here in the states and abroad (Germany and Cuba to name a few). Interestingly enough NONE of the gifted and knowledgeable individuals that I trained with, according to the Dept of Health standards should be allowed to practice, as they are not licensed! Having lost my practice here in WA State I have since moved to restart what I have invested half of my life to be the best at. Many of my former clients have since started seeing other colon therapists and some of my more loyal following make the trek 'just south of the border' to see me when they can in the hopes that I will be back in Washington State. Therefore because of the above-mentioned reasons I list the following points along with some of my clients testimonials from whom I have had the privilege of serving for the last 25 years. In fact, it is because of them and the multitude like them that quite frankly are the most important reasons of all!

- 1) I am opposed to the New Section. Sec. 1 items (1) and (4) as written and copied below:

NEW SECTION. Sec. 1. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

- (1) "Colon hydrotherapist" means an individual who is certified to engage in the practice of providing and assisting with colon hydrotherapy services under this chapter.
- (2) "Client" means an individual who is receiving colon hydrotherapy services.
- (3) "Department" means the department of health.
- (4) "Practice of colon hydrotherapy" means the removal of waste from the large intestine without the use of drugs by a client-administered application of filtered and temperature regulated water into the large intestine.
- (5) "Secretary" means the secretary of health.

My opposition is:

- a) The client should have the **freedom of choice** of receiving colon hydrotherapy administered by the hydro therapist (closed system) **or** by client administered, item (4), (open system). The client administered system is frequently done un-assisted as a home enema. Does a person have to be **certified** to give himself or herself an enema?
- b) The client should have the **freedom of choice** of receiving **or not** receiving other non-drug items through the colon hydrotherapy specifically ozone, herbs and foods. Ozone is used in many water systems to purify the water and herbs and foods are frequently taken orally. Does the requirement for filtered water imply that tap water is not safe to drink?
- c) Why is it that the practice of Colon Hydrotherapy with an apparently long history here in WA State, which has been done for many years and a great, many types of techniques and equipment need to be state regulated now?
- d) Why is it that the apparent stance of the DOH is that "only a MD/Licensed Physician" should be allowed to do it when after many years of my own experience I have found them to be a group the most least informed of all. In fact of the many "holistic/alternative" Doctors I have meet at the multitude of conferences I have attended, only a very few who have displayed any interest whatsoever. Why should they? If they have been brainwashed and discouraged from the medical schools here in the US that colon hydrotherapy is quackery. Even when they have their own patients, who on their own desire for answers or out of desperation, finding a colon therapist and coming back to the MD reporting feeling better having had a colonic session. The likely hood of the average MD taking a genuine interest is very remote, because even if they were interested, the threat of losing their own license is always in the background. I can sight many examples of this. In one incident many years ago, an MD who had referred a number of his patients to me because of what he felt were improvements had to stop because two GI 'specialists' threatened to report him which could have resulted in the loss of his license. In other instances I have trained several MDs in colon hydrotherapy techniques and have spoken and published both here in the states and in international conferences to MDs on Colon Hydro therapy. Here in WA State I have taught Doctors and nurses as well as many others including some of the people present at this meeting!

I am opposed to the NEW SECTION. Sec. 2 items (6), (7) and (8) as written:

With out requiring a peer board (although allowing outside help), these sections give the Department (of Health) powers to eliminate Certification of Colon Hydro therapists

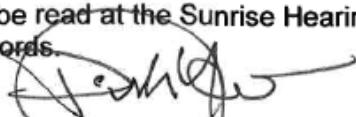
- a) by exams that no one can pass,
- b) extreme education and training requirements
- c) outrageous fees.

It seems elimination of alternative health care including colon hydrotherapy is the goal of the DOH based on the cease and desist orders issued recently. This is **not** the desire of the citizens of Washington or of the Legislature in our opinion.

- 2) I am in agreement that action is needed to stop the vendetta the DOH appears to be on without cause or justification or legality. This will be clearly shown when the appeal from a DOH administrative Law Judge decision is heard in Superior Court in King County this fall. **Registration only** seems a better answer than certification.
- 3) The **best answer** is to add unlicensed practitioners to SB 5509 (HB 2266) from the 2007 legislature and pass that bill which was without a nay vote in the Senate. The very Legislator requesting the Sunrise Hearing on H3505 stopped SB 5509, HB 2266 and a House Bill to include unlicensed practitioners. The chairperson(who also happens to be the representative in my district) refusing to even hold hearings on the bills stopped them all.
- 4) Washington residents should not have to go out of state to obtain therapies of their choice.
- 5) Other Washington residents, others and I should have the right to choose alternative health care. When practitioners cannot practice we have *lost our choice*. A prescription or referral from an MD or ND should not be required to receive colon hydrotherapy, a more thorough cleansing than can be practically accomplished at home. Likewise we should not have to go to a hospital to receive colon hydrotherapy or to a medical doctor to receive colon hydrotherapy. The costs of services administered at a hospital or by an M.D. would likely be far above current rates charged by any colon hydro therapists not already withdrawn from providing services.

I request this letter be read at the Sunrise Hearing and along with my client testimonials be entered into the records.

Thank you,



Mr. Dirk Yow, Colon Coach, IOT Diplomat
6523 California Ave. SW
Seattle, WA 98136 (206) 459-0102

Testimony from Ann Clifton:

I am Ann Clifton, Co-Chair of Mercury Awareness Team of Washington (a group which is dedicated to the abolition of mercury in health care); and, I am a Board Member of Health Freedom Washington (a group dedicated to having independent practitioners available to us as clients). We must have health choices and it is clear that this is the legislature's intent in RCW 18.120.010.

Both Mercury Awareness Team and Health Freedom Washington feel that the vicious attack by Department of Health on holistic practitioners of all types is contrary to legislative intent in RCW 18.120.010.

Independent practitioners are accused of practicing medicine without a license. In the case of colon hydrotherapists, DOH/MQAC accuses them of practicing medicine and surgery without a license. DOH issues cease and desist orders to the colon hydrotherapists in Washington in order to bankrupt them so they cannot fight back because they now have no money. The goal of DOH in this process is to force us, as clients, to go out of the state for our chosen health care. We in Mercury Awareness Team are very mercury toxic and we have to use detoxification methods to improve our health. Colon hydrotherapy is a chosen health care method for many of us.

On average, according to the World Health Organization, 80% of our body burden of mercury comes from mercury amalgam dental fillings.

Testimony from Terry Kohl on behalf of Owen Miller, ND

I was asked by Doug Lewis, ND, WANP President to draft the following document. I recommend that it be reviewed and revised by the WANP LL & I Committee after receiving input from doctors Dan Labriola, Jennifer Huntoon, Ken Harmon, and Eva Urbaniak. I request that the WANP office be responsible for sharing this document with the above listed individuals. I am leaving for Wyoming tomorrow morning and will be in and out of cell service until the 27th of August. I can be reached intermittently at (206) 369-2247 or (206) 604-2582. I will respond to e-mails on August 27th.

Respectfully,
Owen Miller, ND

APPENDIX: E

Written Comments

**Colon Hydrotherapy Sunrise
Public Written Comments Received
(Reproduced as submitted to the department)**

I literally had my health reversed from chemical poison. I had been exposed to herbicides on a golf course and the result was extreme swelling of organs and edema with joint pain. I tried traditional medicine but only got worse. I finally found Dirk Yow. He administered colon therapy over a two month period and I fully recovered. I want to continue to receive these treatments from him but because you have stopped him from practicing this modality that literally saved my life, I now am at risk of diseases that can not be treated effectively any other way. The professional treatment, care and expertise I experienced was given with the utmost of care and expertise. Please listen to those of us that have benefitted tremendously from this modality. The knowledge that this man has about the colon is remarkable. Open your eyes. Get a treatment and if you will look at the high rate of colon cancer in our society and get it that traditional medicine has not found a way to battle this awful disease you might discover that colon therapy saves lives.

Brackin, Roxie

I believe licensing of colon therapists is important, and could be done through the board of massage therapy. This is done in my old state of Florida, in addition to massage training, an additional 100 hours of training, minimum of 45 hours clinical practicum with minimum of 20 treatments given. Ref Fla administrative code chapter 64 B7, 64 B7-31 paragraph 1, 2. See also chapter 480.033(6)480.041 (4)(b)480.044 (1) (i)(j)
Thank you for your attention. GARY VIGEANT

I am writing this letter in support of having colon hydrotherapy be available through certified practitioners, and not require licensure.

As a consumer, I have the right to choose who and how I want colon hydrotherapy to be available. For many years now, I have both self-administered enemas, and have seen colon hydrotherapists. This has benefited my comfort and my health in multiple ways, including increasing my energy. I should not be required to have a prescription, nor to see a medical doctor in a clinic or hospital in order to receive this health care.

The professionalism and cleanliness of the colon hydrotherapists that I have seen rivals that of any doctor's office where I've had gynecological and other personal exams. There is no legitimate reason to restrict this practice to licensed individuals.

Please consider my request to certify colon hydrotherapy as a service allowable in the state of Washington. Thank you. Ruth M. Cooper

I have just been informed that the DOH in WA State is considering banning trained colon hydrotherapists from practicing in this state. I ask that you do not ban them from their profession, but instead research the practice and form a licensure program for them so that they would be licensed healthcare professionals. What do other states do about this? This is a very legitimate form of healthcare with many benefits.

I have personally benefitted from this form of therapy in the past. I plan on using it in the near future as well. The places have always been clean, sterile, with disposable pieces of equipment where pertinent. The practitioners were all trained and very professional and informative. This therapy helps many digestive and elimination problems. It is safe, effective, and has been used for centuries in many cultures. I want and should be able to decide for myself if I want this form of therapy. The western medical model is very different and does not commonly utilize this. It should be kept separate from doctors and hospitals and insurance companies in order to continue to make it affordable, and to also keep this work with the trained specialists who devote their entire time and effort in this.

I am a Licensed Acupuncturist in Washington. I have had many patients who have chosen hydrotherapy on their own and have told me only of positive results and experiences.

Please do what is right and look into this issue and adjust what needs fixing. Please do not act impulsively and limit access to the long-standing practice of colon hydrotherapy.

Sincerely, Nancy Kreider, L.Ac.

Please certify colon hydrotherapy and establish it as a recognized and legitimate health care profession in the state of Washington. I live in WA and would like to continue to be able to choose this therapy as an option for my health.

I have greatly benefited from colon hydrotherapy for over 30 years now and I consider it a very important part of my staying healthy. I would not be doing this if I had to go to a doctor or a hospital to get this done. I have used both the closed and the open systems, and never had a problem or indiscretion from any of my therapists.

Again, I hope you will certify colon hydrotherapy as a recognized and legitimate health care option, with our right to choose it. Thank you. Ann Labe

I heard about the recent action of the DOH in WA regarding colon hydrotherapy. Please consider licensing colon hydrotherapists as an additional practitioner in Washington. I have taken courses while in naturopathic medical school (National College of Natural Medicine in Portland, OR) on colon hydrotherapy and find its application quite beneficial. While there is no location in our office to offer the service we do refer patients out to others for the procedure.

Again, Please consider certifying colon hydrotherapists in the State of Washington.

In Health,

Johan Keller, LAc, MSOM, Oregon licensed Naturopathic Physician, Washington licensed Acupuncturist, Medical Director - Harmony Event Medicine (501 c 3) org

I am writing to request that Washington State establish Colon Hydrotherapy as a recognized and legitimate health care profession in the state of Washington.

Since 2003 I have undergone numerous colon hydrotherapy sessions in an effort to detox myself. The benefits have been enormous consisting of improved gastrointestinal functioning and an increased overall sense of well-being.

The sessions were performed in an immaculate setting at the hands of a consummate professional. The setting was infinitely cleaner and less chemically toxic than any hospital or doctor's office I've ever been to. The practitioner also provided more sound nutritional information than any traditional Western medicine practitioner I'd ever met. I think it would be great if Washington State wanted to license this practice and mandate insurance coverage for it but I would not want to have it performed in a medical setting by an untrained physician's employee.

Thank you for your consideration in this matter.

Regards, Marianne Pendleton

My name is Diane Miller and I am the Director of Law and Public Policy for National Health Freedom Action (NHFA). NHFA works to protect health seekers' options in health care and are supportive of maintaining the availability of all types of colon hydrotherapists in the public domain. We support consumer access bills that protect access to all unlicensed practitioners, and support disclosure requirements by practitioners of their education and background and modality. We also support the ability of state government to prohibit practice on an individual case basis if the government has shown that they have presented an imminent and significant risk of significant harm to a client. We have been instrumental in the passing of safe harbor exemption bills for unlicensed practitioners in a number of states (Minnesota, California, Rhode Island, Louisiana etc.) as well as introduction of many state bills in this area. If you are open to receiving our contact information I would like to let you know that we see ourselves as a stakeholder in your hearing agenda. We would not support mandatory government credentialing of Colon Hydro

therapists. We see colon hydrotherapy as an age-old art learned in many different ways that has powerful healing capabilities and a very good track record of safety across the country.

If you would be open to formal comments from our organization please let us know. Thank you so much for your consideration.

Very Best Regards, Diane Miller JD

I-ACT is a chartered association in Texas. I oppose regulating Colon Hydrotherapy with I-Act as the agent simply because they have no connection with any school of higher learning, college or university. The CEUs are worthless because they are not backed up by an accredited college or university. Also they are an association in Texas and by what authority do they have jurisdiction over the state of Washington?

Also, I want to know who validates their test? In addition I-ACT is not licensed by any health dept.

I pay approximately \$50. per year for my massage license and they want \$250. for just membership. This just does not feel quite appropriate. Robin Sharan

I strongly support that colon hydrotherapists do NOT need to be regulated by WA DOH.
Thank you,
Mary Ann Newell

I wonder who keeps statistics on the number of patient's these unlicensed colonic irrigationists have perforated. I doubt that any one does. When I saw a patient in my office who was in septic shock due to three colonic perforations after receiving irrigation therapy, I was amazed to find out that there are no standards of education for these people. He had gone to this person while having acute abdominal pain and underwent the placement of water under pressure in his colon, enough to perforate him in two places. He required emergent surgery and removal of most of his colon.

Carole Buckner D.O.
Gastroenterologist/Hepatologist

I am writing to provide written comments regarding the Washington State DOH Sunrise Hearing, held August 28, 2007, regarding evaluating mandatory certification of colon hydro therapists.

My name is Diane Miller and I am the Legal and Public Policy Director for National Health Freedom Action (NHFA). I am also an attorney licensed to practice in the state of Minnesota.

NHFA is a non-profit organization working to protect access to health care options for health seekers of all kinds. We provide resources and information to states grassroots organizations, information to state legislatures and governments, and information and presentations to individual lawmakers. Our work also provides leadership training, guidance regarding federal substance and device issues, and attendance at international gatherings including UN Codex gatherings.

Recently we learned that the state of Washington, Department of Health, has held a hearing on evaluating whether to mandate certification for colon hydro therapists. We considered coming to this hearing but because of short notice were unable to attend. We do apologize for needing to send written comments instead of providing public testimony.

As a national leader, NHFA has designed health care bills to protect access to holistic practitioners and natural products. One of the models we have drafted is a safe harbor exemption law for unlicensed practitioners of all kinds. The purpose of this type of bill is to statutorily exempt certain unlicensed health care practitioners from

criminal violations of practicing a licensed profession without a license as long as they disclose certain background information and that they are not licensed and as long as they avoid the prohibited conduct set out in the exemption language. This type of law is constitutionally least restrictive and founded on the presumption that there are many healing arts that do not rise to the level of requiring regulation under the police power of a state, including licensure, certification, or registration. This presumption acknowledges the inherent right of health seekers to access whom they wish when they are on a personal healing journey. It also acknowledges the state's interest in restricting professions that cause an imminent risk of significant harm to the public.

NHFA does not support mandatory state certification of colon hydro therapists. We understand that colon hydrotherapy is an age old healing art, existing in many cultures around the world, and we understand that it does not pose an imminent risk of significant harm to the public requiring mandatory regulation. We believe that a safe harbor exemption bill addresses any concerns a state government might have regarding the practice of this profession. For those reasons we ask you to consider this less restrictive form of regulation and adopt a safe harbor freedom of access exemption law. This would allow the practitioners to practice as they always have in your state, as long as they practice within the safe harbor parameters that the state of Washington sets up. It avoids the mandate that they need to obtain permission from the government before doing their healing acts, and would also provide the consumer with important background information about the practitioner providing those services.

Thus far, six states have safe harbor exemption laws for unlicensed practitioners, exempting them out of criminal violations for practicing medicine without a license as long as they remain in the parameters of the exemption language. They are Minnesota, Rhode Island, California, Louisiana, Idaho, and Oklahoma. And 20 more states including the state of Washington (Session 2007 SB6034 which we were in support of) have recently introduced such legislation. In addition, it is my understanding that the state of Washington is unique in that it has very clear law that supports unlicensed practitioners practicing their trade, i.e.:

“...The legislature believes that all individuals should be permitted to enter into a health profession unless there is an overwhelming need for the state to protect the interests of the public by restricting entry into the profession. Where such a need is identified, the regulation adopted by the state should be set at the least restrictive level consistent with the public interest to be protected...” WA Stat 18.120.010.

We hope that these comments have been helpful. We are aware of many consumers obtaining colon hydrotherapy services with great benefit and appreciation. We hope that you protect this long time healing art by regulating it in the least restrictive means possible including only disclosures and prohibitions that are necessary for public safety. Colon hydrotherapy is practiced freely around the world and NHFA would like to maintain it in the public domain.
My Very Best Regards,
Diane Miller JD
Director of Law and Public Policy

Since the NIH has not studies Colon hydrotherapy performed by inexperienced health professionals it behooves me to allow a person with the lowest education on the health care totem pole to be permitted to such forceful power of water being thrust up the colon without a physician's prescription.

In addition, is this not part of the genital area that keeps getting massage therapists in trouble?

After twenty years of experience in this field, I am opposed to allowing any person with such a limited education to perform such a risky procedure on the public without a physician's prescription. What if there is the beginning of colon cancer? Will the force of water progress the disease? Have you discussed this with a panel of physicians?

What is the research to prove the benefit to the public?

I would be curious to have the panel hear the answers to these questions before proceeding.

Thank you,

Karen Zaharatos, M.Ed., LMT, ACR, Director
Massage online Professor

I am writing to provide my comments on the proposal that is currently under Sunrise Review consideration that seeks to credential colon hydrotherapists in Washington.

While I do not believe that there is a need to credential colon hydrotherapists, I hope that the Sunrise Review process will consider whether or not colon hydrotherapy procedures should continue to be classified as the practice of medicine and make any necessary recommendations to the Legislature. The services provided by these practitioners support the work of several types of credentialed health care providers, including physicians, naturopaths, and chiropractors. Without the availability of these services the ability to comprehensively treat certain patients is diminished. Restrictions on the practice of colon hydrotherapy also limit patient choice. In many cases, individuals are forced to seek these services in other states where the practice is permitted. It is my hope that the Sunrise Review process will help to establish an exception from the practice of medicine that will protect patients while also allowing them choice in health care decision making.

Thank you for the opportunity to contribute these comments to this discussion.

Sincerely,
REP. RICHARD CURTIS
House Health Care and Wellness Committee
Assistant Ranking Minority Member

I am writing to you to express my personal concern that I may lose my right to choose an alternative health care professional such as a Certified Colon Hydrotherapist, or a Certified Chiropractor.

I strongly oppose WA DOH making a law that limits my personal choice of a health care professional to MD's.
Thank you
Steven Kellas

I am writing to say that I have used colon hydrotherapy and feel that this treatment is very beneficial. I want it to continue to be available.

Sincerely,
Steve Bennett

Please, please certify colon hydrotherapy as a legal procedure. It is crucial that this not be taken away from people who are benefitting from it. It is a cleansing. It has nothing to do with surgery or prescribing drugs or doing the things MDs do.

Thank you for your consideration,
Alice Cotton

My letter was read at the sunrise meeting held on Wednesday August 29th, 2007

I am Karen Connolly and a citizen who has discovered that the process of colonic irrigation has not only benefited my over-all health, but literally saved my life. I have received sessions several times a week for well over 6 years.

We do not need this modality to be registered or licensed. As mature adults, surely, citizens do not need the State nor any government, deciding for us what we can and cannot choose to help our body heal itself.

The Russian population here cannot understand and are dismayed that the very reasons they left Russia are happening here in Washington State. The Department of Health is becoming the "police" and are attempting to regulate areas that do not need licensing or regulating. Creativity and progress are slowed and usually prevented by too much regulation and control.

Who, of this panel to recommend what should be done, have ever had a colonic? Especially from the world reknown expert, Mr. Dirk Yow. Who, in the Department of Health, can oversee or even begin to regulate someone who has 26 years in the business, is recognized in Japan, Germany, Cuba, Malta, Great Britain and other countries as the most respected and knowledgeable authority on ozone colonics in the world, and our tiny state has decided he should be regulated with other colon hygienists?

This is absurd. Stay out, stay away. Eileen Codys bill is based on nothing but political jargon and just how much knowledge or experience does she have on the subject matter of colonics. Medical doctors don't want to do this and don't have any understanding or experience in this art. Neither do natureopaths.

Next we will require regulation to take a shower and do studies on that activity to find out if we really feel better or are cleaner for it?

I do suggest support for HB2266 and SB6034. Eileen Codys bill is just a decoy from the real grass root efforts. She is no friend of freedom of choice for the citizens or the alternative arts.

To continue my quest for wellness and even survival I have followed Mr. Yow to Sitka, Alaska for sessions and now to Portland Oregon.

I have the State DOH to thank for disrupting my life and adding additional stress to continue something as natural as cleaning my colon.

Colon Cleansing used to be taught in grade school in the early 1900's. We need to get back to basics, brush our teeth, clean our colons and be aware that pharmaceutical drugs are not the answer for a lot of us.

Please do the right thing, and allow the citizens to direct their own health path and leave our drugless healers, who cause no harm the freedom to use their art without regulation.

Karen M. Connolly
Tumwater, WA.

I am opposed to BILL REQ. #: H-3505.1/07 as it is written. Please consider this letter as my input to the Sunrise Hearing on Colon Hydrotherapy, which occurred August 29, 2007.

It seems to me that the proposed licensing/certification/registration of CHT's in the state of Washington is not a cost-effective thing to do. A major role of the DOH is to protect Washington citizens from harm. As far as I or anyone knows, there has never been a case of harm on the part of CHT's in the history of their activity in Washington. There has never been a client complaint. Liability insurance premiums for CHT's are among the lowest of any of the health care disciplines, licensed or unlicensed.

So why spend a significant amount of money to implement something that is unnecessary? You propose to "protect" the people from something that is completely safe. Why? The obvious answer is: "They asked us to do it." However, "they" (I-ACT) do not represent a majority of CHT's in Washington, and based on what I have "heard", a majority of CHT's in Washington do not want this (I have not taken a formal poll).

The most compelling reason I oppose this proposal is my compassion for the medically uninsured folks in Washington. There are a great many of them, and they must find a way to maintain their health outside of the medical mainstream. Licensing/certification/registration would cause the cost to the consumer to escalate. The fees the CHT's would be encumbered with would have to be passed on to the consumer. And there is the specter of the possibility of a further (dramatic) escalation of costs by requiring "prescriptions" from Naturopaths or MD's. This

would be the death knell for the uninsured. There is already a proposal to require a "prescription" for the use of ozone and herbs. I have personally experienced the effectiveness of these ingredients in colonic fluids, as have friends. They have been instrumental in dealing with such things as Candida, parasites, and heavy metal and other toxins. To the extent that the preceding are "diagnoses", they are of course never offered by CHT's, rather they are the client's self-diagnosis or the result of client/MD-initiated lab tests.

As a policing arm of the state, your duty is to "serve and protect". Apparently protection is not needed for a modality that has never experienced a client complaint in Washington. And you would not be serving at least the uninsured by enacting this proposed measure.

Thomas H. Morrin

I wanted to take the time to send you my views in regard to the Washington State Department of Health's review of purposed regulation of Colon Hydrotherapy by the Dept. of Health.

I have practiced as a licensed and registered healthcare professional for 30 years and have practiced in the state of Washington for 17 of those years. I work in conjunction with MD's, D.O.'s, DC's, ND's, acupuncturists, physical therapists, message therapists, nutritionists, and others, as well as colon hydrotherapists.

On a personal level I first researched colon hydrotherapy in New Mexico in 1981 when I had an interest due to having been diagnosed with IBS, irritable bowel syndrome. Most doctors gave nutritional recommendations and prescriptions but had not much else to offer me. I researched and found out about colon hydrotherapy and did about 6 sessions which were extremely helpful in relieving irritation to my colon and the discomfort of constipation. I self referred myself and was able to find a skilled and knowledgeable practitioner and was really glad this treatment was available to me at a reasonable cost and in a comfortable and sanitary environment.

I currently rent an office suite where an I-ACT certified colon hydrotherapist works and have observed their practice and noted how extremely beneficial this treatment is and how appreciative people are to have this therapy available. I have noticed most find out about this treatment from friends, relatives, internet searches, and through other practitioners who have had this therapy. It seems that an occasional ND or DC will refer but very few MDs and D.O.s, if at all, except with their patients request.

I attended the hearing and noted only one MD, one ND, and 2 DC's present at the meeting. They were there as representatives of the I-ACT organization only. I realize that if there was a high risk factor in this treatment that the therapist's liability insurance would reflect that, and this doesn't seem to be an issue. In my experience and observation, I see colon hydrotherapists to be very careful and steadfast in regard to safety and cleanliness. I also observe a thorough and professional manner in consultation and phone conversations. In addition, I have observed colon hydrotherapists referring clients to physicians when appropriate.

I would urge the panel to regulate the industry while continuing to make colon hydrotherapy widely and easily accessible without the necessity of physician approval and/or referral.

Thank you for your consideration.
Heidi Gould, OTR/L, CST

I have practiced colon hydrotherapy for more than 10 years as a trained and I-ACT-certified colon hydrotherapist following the guidelines received by the Review Panel from I-ACT and my own common sense. I decided, upon my own volition, to further my anatomy and physiology training by attending massage school in the State of Washington and also have attended continuing education courses (at least one) for each year that I have been in practice. These courses have included topics such as digestion, nutrition, first aid and CPR, HIV/AIDS training and body mechanics.

I have built an independent and successful practice in the City of Olympia with a large clientele that self-refer to me as well as referrals from many of the local naturopathic physicians, some acupuncturists, chiropractors, physical and

occupational therapists and nutritionists. I use FDA-registered and approved equipment, sterile and disposable speculae, and hospital-grade cleaning and disinfecting materials. My client's are never exposed to me and do their own self-insertions and clean-up of themselves. My equipment is very similar to the equipment viewed by the Panel at the hearing review. My professional liability insurance costs approximately \$175 annually.

I concur, that colon hydrotherapy should fall under the RCW 18.120.030 code with standardized guidelines and regulations. It is a procedure that can be safely administered by trained, independent practitioners such as myself. However, Washington State has a history of higher continuing education standards for the health care professions. The panel may wish to consider placing colon hydrotherapy certification within the purview of the already existing educational institutions in the state, e.g., massage schools and community colleges.

I must stress to the Panel that the days of "doctor-directed" health care and prevention are long gone—all you have to do is watch the commercials on the television during the 6:00 p.m. news to observe this. **BY FAR, MOST OF MY CLIENT'S ARE SELF-REFERRED. I urge the Panel not to take away the public's right to make their own health care and prevention choices.** Most of my clients see colon hydrotherapy as a way to prevent having to go to the doctor. Many of them have goals of obtaining and maintaining optimum health—much like people who go to the gym. I have clients who are mountaineers, scuba drivers, tri-athletes. I have other clients who believe, as I do (my brother died from colon cancer), that proper cleansing and detoxifying of the body is one way of enhancing overall health and vitality. When I deem it appropriate and/or necessary, I am the one to engage these clients and nudge them into going to see a doctor—something they may be avoiding.

I also have clients who are woefully constipated and lack proper bowel function and elimination. I have some clients under direct doctor supervision—a few who are using this procedure to avoid more invasive and long-term debilitating surgeries. I have seen clients as young as 12 and as old as 94. I have made a personal and professional decision to NOT administer the colonic to minors; I always have the parent or guardian in the room administering the procedure and communicating to the child after a thorough in-take and a discussion of other potential alternatives.

There is a CPT code for the procedure of bowel irrigation, and colon hydrotherapists should be able to bill insurances, when medically approved, for this procedure.

Thank you for the inclusion of my comments during your deliberations.
Jalene Smith, LMP
Certified Colon Hydrotherapist, I-ACT

My name is Cathleen Rogers and I have been a recipient of Colon Hydrotherapy over the past few years. In the beginning I was referred by my Naturopath to a Colon Hydrotherapist. This took place after I had some stomach pains and X-rays revealed that I was backed up to my ribcage. As far as I knew then I had no signs of this until the pain began. I was 5'5" and weighed 130 pounds. My stomach did not protrude and to look at me at that time one would not understand how this could be possible. I did not realize that I was not "regular" until this all took place.

Since having Colon Hydrotherapy I have become more regular, but most amazing is that I have much more energy, my skin has cleared up, the dark circles under my eyes are gone, my hair and nails are healthier, I am less stressed and have an over all feeling of good health which I was seriously lacking prior to be introduced to Colon Hydrotherapy.

I now am self-referred and discuss the fact that I have regular hydrotherapy session throughout the year with my Naturopath when I see her. I know when I need Colon Hydrotherapy – I can feel it in all senses. Colon Hydrotherapy is a preventative to needing to see my Naturopath and my Naturopath is happy that I take my health serious enough to listen to my body and prevent sickness from having grounds to grow.

I strongly feel that needing to obtain a referral every time one needs Colon Hydrotherapy is a waste of time and money. Health care is far to regulated and most of the time it is about making more money for the doctors or companies and not really about the patient. Some regulation as far as equipment, proper training and sanitation

make sense although the Hydrotherapist that I see is extremely knowledgeable, explained the procedure completely, is very professional and her facility is very clean. In all I am very comfortable and feel completely safe.

On a side note, I am also self-referred to a Massage Practitioner and Chiropractor.

Sincerely,

Cathleen Rogers

I am a retired federal employee and have health benefits that allow me to self refer to any specialist in my providers book. I choose to pay out of pocket for many practitioners who are not covered by my insurance. It was either my homeopath or naturopath who told me about colon hydrotherapy. I believe in setting standards for certification to weed out the bad apples and protect the consumers. I find colon hydrotherapy to be a very gentle, cleansing treatment. My alternative health care providers never hesitate to coax me to go see an MD if they think I have a condition that is not responding to their treatment. However, my MDs never suggest any alternative treatment even when they give up on me and say they can't help me. As consumers we need many choices in health care and need to do our research to be informed consumers. Please help to preserve that right of choice.

Christine Tutor

I have been under a gastroenterologist care for severe constipation since 1992. I have been treated with multiple laxatives and the latest pharmaceuticals none of which had any effect on my condition (lack of peristalsis).

In the early 90's I received colon hydrotherapy from a naturopath in Olympia but my condition did not respond well to the type of equipment use. In 2004 I began seeing a colon hydrotherapist in Olympia who used the Libbe system (gravity-fed) and my health and quality of life has improved ten-fold. I continue under the care of my gastroenterologist (Dr. Michael Schuffler, Pacific Medical Center) who approves of this avenue since it is effectively managing my symptoms and the only other option for treatment would be a subtotal colectomy which has its own complications. My doctor has also referred others to my hydrotherapist.

My colon hydrotherapy is not covered by my insurance (Premera Blue Cross) even though it is an **absolute** necessity for my health – as insulin would be to a diabetic. My monthly expenditure is approximately \$240 (\$60.00/week). I hope that someday soon the insurance companies will recognize the importance of this treatment and cover as they do other alternative treatments. I think that it is important that an individual have the right to choose the practitioner that he/she is most comfortable with – just as you would choose a chiropractor or massage therapist. Having to settle for a “preferred provider” would not be acceptable.

I believe some regulation is necessary to be sure that a therapist is properly trained and would include inspections to be sure that the equipment is maintained according to guidelines and protocols. I have absolute confidence in the professionalism of my colon hydrotherapist.

Respectfully submitted,

Kathleen Heidenreich, Educator

My name is Gloria Ross and I am a practicing Colon Hydrotherapist in the state of Washington. I received my training and certification from the Michigan School for Colon Hydrotherapy in Ithaca, Mich. I worked at the Detroit Wholistic Center and the Center for Healing Arts in Michigan prior to relocating to Seattle. I currently own my own business on Mercer Island and I work with a licensed Naturopathic Doctor in Issaquah, WA.

I received my first colonic treatment in 1984 and immediately understood the benefits to my health. It is unfortunate that most medical practitioners are not aware of the health benefits and safety of colons when administered by a properly trained and certified practitioner. I'm proud to be a Colon Hydrotherapist and I know I have helped hundreds of people, purely based on what they have told me.

As far as regulating and bringing standards to the profession I must ask you “why reinvent the wheel?” Why spend taxpayers' dollars doing what the International Association for Colon Hydrotherapy (I-ACT) has already done.

Their training and certification program includes an in-depth education in anatomy and physiology, digestion, nutrition, the history colon therapy, equipment use, professional practices and ethics. Additionally each certification candidate must have practical experience supervised by an I-ACT certified instructor.

I have been tested and certified through I-ACT and have gone on to take additional training, education, and advanced testing so that I can teach and train others in the field of colon hydrotherapy. I have trained and certified several Colon Hydrotherapists who are now employed in the state of Washington, Florida, and Michigan.

I strongly support some type of licensure in the state of Washington but it must be implemented in fairness to currently practicing Colon Hydrotherapists.

Thank you for taking my comments into consideration.

Gloria Ross

Certified Colon Hydrotherapist

P.S. I hope one chiropractor who practiced 30 years ago, with what looks like home-made equipment, does not determine the fate of an entire profession. (re: Amebiasis document)

I am so disturbed to here of WA DOH's crusade to regulate colon hydrotherapists under the guise of protecting both therapist and client. Something is definitely rotten in the state of Denmark. Why is it that this modality is being targeted and given DOH's top priority when it is not broke and doesn't need fixing?

I vehemently oppose any regulation and licensing of colon hydrotherapy, including what should or should not be put in the water used. I am a receiver of this therapy. It is an integral part of my healthcare routine. The course of treatment in a session is between me and my colon hygienist. I respectfully request that I have the freedom to choose.

Respectfully,
Paula Muth

My name is Kristi McKinney Zimmer and I am a licensed massage therapist in the state of WA since 1997. I am also an IACT certified colon hydrotherapist practicing in WA State since 1996. I have trained in colon hydrotherapy with local naturopathic physicians in Seattle, Prime Pacific Health Innovations and Bousher Institute of Naturopathic Medicine in Vancouver BC, and the International School for Colon Hydrotherapy in Kiental, Switzerland. I co-own and operate a successful health center in Seattle, WA with my husband since 2003. We employ ~ 10 people year round, 7 days a week providing colon hydrotherapy, massage, and nutrition counseling since 2003. We see up to 7 new clients a day in peak season (spring) and have strong referral networks in the ND and CAM community of Seattle and surrounding areas. We have healthy relationships with the colon hydrotherapy community around the United States including several instructor level practitioners. We are a leader in the industry and proud to serve our community with these ancient healing modalities.

I was first introduced to the idea of colon hydrotherapy in massage school. It has been instrumental for me in achieving optimum health and I have witnessed 1000's of consumers regaining health as a result of this in combination with other self healing modalities. This therapy was important in ancient times for hygiene and bowel conditioning and remains an effective tool for that purpose today. It proves to be even more important in modern times to address basic physical hygiene due to the level of pollution in our environment and consequently in our bodies. Colon hydrotherapy is effective, inexpensive, enjoyable and safe.

We receive calls on a daily basis from consumers who are looking for a provider for this therapy. They often ask about training, certification or some standard skill set that is appropriate for the provider to have in order to feel good about receiving the service. They want to make sure the water and facility are clean, the therapist is professional, and that there will be no health risk involved with receiving the therapy. We provide an extensive

explanation in order to educate the public. This is a task we gladly take on both locally and nationally because we want educated consumers that create a demand for high standards. We have those standards. For this reason I feel that state recognition and certification or licensure is a positive step forward for providers and consumers.

I have witnessed first hand the power of state licensure with massage. This recognition took a modality known for centuries for its effectiveness with many health goals and turned it into a modern therapy choice covered by insurance companies. Now consumers are educated as to what massage is, how it serves health, and who can provide it with a certain standard of care. This is progress and serves the public. The public would also be well served by the regulation and support of colon hydrotherapy. This is evident in the many letters from consumers regarding their use of this valuable therapy.

From my years of experience both performing, receiving, and teaching colon hydrotherapy I feel that this is one of the safest modalities available to the public. Its record is as flawless as massage. While there are modern factors that pose caution (ex: drugs that thin the intestinal lining) I feel that it would never cause serious harm when applied within appropriate parameters. The most discomfort I have ever witnessed has been intestinal cramping (due to the exercising of a weak colon) and nausea (a common detoxification side effect). These can be experienced up to 12 hours post session and then they quickly abate. They can also be remedied with hydrating electrolyte solutions and applied heat.

Medical prescriptions are not needed for this therapy unless a contraindication is present. It would be a crime to take a self healing tool such as colon hydrotherapy out of the hands of the public. This therapy should be available to all just like massage, acupuncture, chiropractic and other spa services. The allopathic medical community is not providing, training, or educating others about this therapy. They are not qualified to control it.

Certain herbs, electrolyte solutions, and other natural healing solutions can be extremely helpful with the effectiveness of this therapy. A list of non drug items can be drawn up in the bill to allow for these items to be infused into the water. They prove completely safe.

Lastly, the decisions made by the DOH that will determine the way this industry flourishes in WA state need to be guided by those promoting, educating and providing services in colon hydrotherapy. I believe in the goodness of people and the spirit of democracy. I also understand the fear experienced by people when they do not understand something. It is our job together to assure that ignorance does not precede experience in this situation and limit the people of this great state to a powerful health tool. Health is a fundamental birthright and I challenge you to support WA state citizens in their quest for it.

Thank you,

Kristi Zimmer, LMP, Certified Colon Therapist, Co-Owner of Tummy Temple

APPENDIX: F

**Court of Appeals Decision: Yow v.
Department of Health Unlicensed Practice Program**

**IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON
DIVISION ONE**

WASHINGTON STATE)	No. 61021-0-I
DEPARTMENT OF HEALTH)	
UNLICENSED PRACTICE PROGRAM,)	ORDER GRANTING
)	MOTION TO PUBLISH
Appellant/Cross-)	OPINION
Respondent,)	
)	
v.)	
)	
DIRK YOW,)	
)	
Respondent/Cross-)	
Appellant.)	

Appellant, the Department of Health, has moved for publication of the opinion filed in this case on October 13, 2008. The

No. 61021-0-I/2

panel hearing the case has considered the motion and has determined
that the motion should be granted. The court hereby

ORDERS that the motion to publish the opinion is granted.

Dated this _____ day of December 2008.

FOR THE PANEL:

Judge

IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON

WASHINGTON STATE DEPARTMENT)	No. 61021-0-I
OF HEALTH UNLICENSED PRACTICE)	
PROGRAM,)	DIVISION ONE
)	
Appellant/Cross-)	
Respondent,)	
)	
v.)	
)	UNPUBLISHED
DIRK YOW,)	
)	FILED: <u>October 13, 2008</u>
Respondent/Cross-)	
Appellant.)	

Cox, J.—The Department of Health appeals the superior court's order, which affirmed the Department's final order against Dirk Yow for the unlicensed practice of medicine except for the civil fine levied against him. We hold that the imposition of the \$444,000 fine was not arbitrary and capricious.

Yow cross-appeals. We hold that the Department had statutory authority to use a health law judge to conduct the administrative hearing. The findings of fact that Yow challenges are supported by substantial evidence. Moreover, the findings support the legal conclusions, including the decision that Yow was engaged in the unlicensed practice of medicine. Yow fails in his burden to prove beyond a reasonable doubt that a portion of the statutory definition of the practice of medicine is constitutionally overbroad. Finally, the superior court did not abuse its discretion in striking evidence Yow first proffered during his appeal to that court. We affirm in part, reverse in part, and remand.

The Department began investigating Yow for the unlicensed practice of medicine after receiving a complaint from the son of an elderly man who had 163 colonic irrigation sessions with Yow in the 11 months before he died. Based on its investigation, the Department filed a Notice of Intent to Issue a Cease and Desist Order against Yow on March 16, 2006.

Yow requested an administrative hearing to contest the charges and filed an answer to the Department's allegations. A health law judge, appointed by the secretary of the Department, presided over the hearing.

Yow, several of his former patients and students, and an expert called by

the Department testified at the hearing. According to the witnesses, colonic irrigation is a procedure by which “about 15 gallons of water” are circulated through a person’s colon over one to two hours. The “modified tap water” is pumped into the colon through the anus and rectum through the use of a six-inch long tube called a speculum, which can vary from “the circumference of a quarter to a half dollar.” The speculum is inserted one to two inches inside the body. As “part of the whole procedure,” Yow would provide various additives to the water that was circulated through the colon, including ozone, various herbs, coffee, and “micro flora and probiotics.”

Yow testified that the benefits of colonic irrigation are “anecdotal” and that the purpose is based on “many theories,” such as “colon hygiene.” He admitted that he advertised colonic irrigation as providing “hydration, decongestion, [and] aerobic supplementation.” Two articles authored by Yow and admitted into evidence show that he also offered his services to help with “prolapsed organs,” “ballooned” or “spastic” colons, “diverticula,” and constipation, among other things. Yow advertised himself as a “certified Hydrotherapist” and as an “intestinal hydropath.”

Expert testimony by Stephen Rulyak, M.D., revealed that colonic irrigation creates serious medical risks in recipients. The procedure creates a potential for colon perforation, which could result in blood stream infection, as well as a risk of electrolyte shifts and cardiac arrhythmia.

Following the hearing, the health law judge entered his Corrected

Findings of Fact, Conclusions of Law, and Final Order, concluding that Yow had engaged in the unlicensed practice of medicine. Based on evidence that Yow had engaged in the unauthorized practice of medicine for 37 months, averaging 12 work days per month, the Department imposed the statutory maximum fine of \$1,000 per day, totaling \$444,000. The health law judge also directed that Yow cease and desist his unlicensed practice of medicine.

Yow petitioned the King County Superior Court for judicial review pursuant to RCW 34.05.514. The superior court affirmed the Department's Final Order in all respects except for the fine. The court struck the civil fine "as arbitrary and capricious under RCW 34.05.570(3)(i)" and concluded that "no fine is appropriate."

The Department appeals. Yow cross-appeals.

PRESIDING OFFICER AT ADMINISTRATIVE HEARING

Yow argues that the Department's order was void ab initio because the Department lacked subject matter jurisdiction over his hearing. Specifically, he takes issue with the Department's use of "its own employee as the presiding officer," rather than assigning the case to the office of administrative hearings.

Yow improperly characterizes the question of the use of the health law judge as jurisdictional. It is not.

A tribunal lacks subject matter jurisdiction when it attempts to decide a type of controversy over which it has no authority to adjudicate.¹ A lack of

¹ Marley v. Dep't of Labor & Indus., 125 Wn.2d 533, 539, 886 P.2d 189

subject matter jurisdiction implies that an agency has no authority to decide the claim at all, let alone order a particular kind of relief.² Any party may raise the issue of lack of subject matter jurisdiction at any time.³ We review de novo a challenge to a tribunal's subject matter jurisdiction to hear a claim.⁴

The supreme court considered the meaning of subject matter jurisdiction in the context of agency adjudication in Marley v. Department of Labor & Industries.⁵ In Marley, the Department of Labor and Industries determined that Marley was not entitled to widow's benefits under her deceased husband's worker's compensation payments. Marley did not appeal this decision within the 60-day appeal period. Nearly seven years later, Marley attempted to appeal the decision, arguing that the decision was void and therefore not final and binding. The supreme court concluded that in order to show that an order is void, the party must show that the tribunal lacked jurisdiction over the party or the claim.⁶ The court concluded that the Department had broad statutory authority for subject matter jurisdiction over worker's compensation claims.⁷ The court

(1994).

² Id. at 539.

³ RAP 2.5(a)(1); Skagit Surveyors & Eng'rs, LLC v. Friends of Skagit County, 135 Wn.2d 542, 556, 958 P.2d 962 (1998).

⁴ Indoor Billboard/Wash., Inc. v. Integra Telecom of Wash., Inc., 162 Wn.2d 59, 71, 170 P.3d 10 (2007).

⁵ 125 Wn.2d 533, 886 P.2d 189 (1994).

⁶ Marley, 125 Wn.2d at 539.

⁷ Id.

refused to classify the Department's alleged errors of law as jurisdictional.⁸

Here, Yow characterizes the Department's choice of presiding officer at his hearing as an issue of subject matter jurisdiction. But his argument is more fairly characterized as an alleged error of statutory interpretation.

Determinations regarding the unlicensed practice of medicine fall within the type of controversy over which the Department has jurisdiction and the authority to adjudicate.⁹ Whether the Department's health law judge properly presided at the administrative hearing in this case is not a question of jurisdiction.

Despite Yow's contentions, the statutory scheme supports the Department's choice of presiding officer. The Department is correct in noting that the Secretary has independent statutory authority to conduct adjudications for unlicensed practice. RCW 18.130.190(2) states, in part:

The secretary [of health] may issue a notice of intention to issue a cease and desist order to any person whom the secretary has reason to believe is engaged in the unlicensed practice of a profession or business for which a license is required by the chapters specified in RCW 18.130.040.

The recipient of the notice may request a hearing to contest the charges.¹⁰ The statute then provides that all proceedings shall be conducted in accordance with the Washington Administrative Procedure Act (APA).¹¹ Under the APA, "in the

⁸ Id. at 542.

⁹ See RCW 18.130.190.

¹⁰ RCW 18.130.190(2).

¹¹ Id.

discretion of the agency head, the presiding officer in an administrative hearing shall be" the agency head, an administrative law judge from the office of administrative hearings, or, "[i]f the agency has statutory authority to do so, a person other than the agency head."¹² The Uniform Disciplinary Act (UDA), chapter 18.130 RCW, provides for such delegation by the secretary of health. The UDA defines "secretary" to mean "the secretary of health or the secretary's designee."¹³ In short, the health law judge, as the secretary's designee, was authorized to preside at the adjudicative hearing here.

Furthermore, we agree with the Department's position that RCW 18.130.095(3) does not limit the Secretary's authority with respect to unlicensed practice determinations.

UNLICENSED PRACTICE OF MEDICINE

Colonic Irrigation as Unlicensed Practice of Medicine

Yow argues that the Department erred in concluding that his colonic irrigation practice constituted the practice of medicine. We disagree.

Judicial review of a final administrative decision is governed by the APA.¹⁴ In reviewing the decision, the court applies the standards of the APA directly to

¹² RCW 34.05.425(1).

¹³ RCW 18.130.020(10).

¹⁴ RCW 34.05.

the administrative record before the agency.¹⁵ Relief from an agency decision is granted when the agency has erroneously interpreted or applied the law, the order is not supported by substantial evidence, or it is arbitrary or capricious.¹⁶

We review findings of fact to determine whether they are supported by substantial evidence.¹⁷ Substantial evidence has been defined as evidence in sufficient quantum to persuade a fair-minded person of the truth of the declared premises.¹⁸ Unchallenged findings are verities on appeal.¹⁹ The application of law to the facts is a question of law that we review de novo.²⁰

No person may practice or represent himself or herself as practicing medicine without first having a license to do so.²¹ A person practices medicine if, among other things, he or she:

- (1) Offers or undertakes to diagnose, cure, advise or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality;

....

¹⁵ Tapper v. Empl. Sec. Dep't, 122 Wn.2d 397, 402, 858 P.2d 494 (1993).

¹⁶ RCW 34.05.570(3)(d), (e), (i).

¹⁷ RCW 34.05.570(3)(e).

¹⁸ Heinmiller v. Dep't of Health, 127 Wn.2d 595, 607, 903 P.2d 433 (1995).

¹⁹ Hilltop Terrace Homeowner's Ass'n v. Island County, 126 Wn.2d 22, 30, 891 P.2d 29 (1995).

²⁰ Tapper, 122 Wn.2d at 403.

²¹ RCW 18.71.021.

(4) Uses on cards, books, papers, signs or other written or printed means of giving information to the public, in the conduct of any occupation or profession pertaining to the diagnosis or treatment of human disease or conditions the designation "doctor of medicine", "physician", "surgeon", "m.d." or any combination thereof unless such designation additionally contains the description of another branch of the healing arts for which a person has a license . . .^[22]

Whether actions constitute the practice of medicine "is dependent upon the facts and not upon the name of the procedure, its origins, or legislative lack of clairvoyance."²³

Yow has not expressly assigned error to any of the Department's Findings of Fact. He appears to challenge a portion of Finding of Fact 1.2, that he "diagnosed patients as suffering from congestion, constipation, dehydration, and prolapsed organs."

Substantial evidence supports the Department's finding. Webster's Third New International Dictionary defines "diagnose" as "to identify (as a disease or condition) by symptoms or distinguishing characteristics."²⁴ Department investigator Kozar testified that Yow said Kozar was "congested" when he went

²² RCW 18.71.011.

²³ State v. Pacific Health Center, Inc., 135 Wn. App. 149, 166-67, 143 P.3d 618 (2006) (quoting People v. Amber, 76 Misc.2d 267, 273, 349 N.Y.S.2d 604 (1973)) (holding that a health center's practice of using electrodermal testing as an instrumentality to determine or "diagnose" medical conditions in a patient and recommending and selling specific remedies to that person to address those conditions are "practices that unquestionably fall within the valid police power the legislature exercised when it regulated the practice of medicine").

²⁴ Webster's Third New International Dictionary 622 (1993).

in for an initial appointment. Geneva Tillery, a former patient of Yow's, testified that Yow told her she "had a lot of congestion," and was "passing an excessive amount of lymph at one time," and that she "had a whole lot of adhesions." Yow told Tillery to "make sure [she] was going all the time because of adhesions," and if she was not having bowel movements she should "get up here and get to me immediately" for colon irrigation. A former patient wrote an article about Yow, which stated, "Yow says almost all of his patients are chronically dehydrated and I was no exception," and that "when I first saw Dirk, he told me my transverse colon had prolapsed."

This evidence, together with the abundant inferences that one can make from Yow's literature in the administrative record, provides substantial evidence that Yow was identifying diseases or conditions by symptoms and other distinguishing characteristics. Though some of Yow's testimony at the hearing conflicted with the evidence above, the presiding officer at Yow's administrative hearing did not find his testimony credible. Credibility determinations are not subject to appellate review.²⁵

Yow also appears to challenge Finding of Fact 1.6, which found that Yow signed a prescription for colonic irrigation equipment as "Dr. Yow."

Substantial evidence in the record supports this finding. Yow admitted to signing a prescription using the title "Dr." The recipient of the prescription also testified that he signed it as "Dr. Dirk Yow." Yow questions the admissibility of

²⁵ State v. Camarillo, 115 Wn.2d 60, 71, 794 P.2d 850 (1990).

the evidence underlying this finding because it was hearsay. But RCW 34.05.452 governs the admissibility of evidence at APA adjudications and plainly permits the admission of hearsay evidence in the discretion of the presiding officer.²⁸ Yow's argument has no merit.

In arguing that colonic irrigation does not constitute a penetration of tissue, Yow also appears to challenge Findings of Fact 1.11 and 1.14. In Finding 1.11, the Department found that “[t]he procedure employed by [Yow] provides the potential for colon perforation, especially if the patient has certain diseases.” This finding is supported by substantial evidence. Dr. Stephen Rulyak, an expert in gastrointestinal diseases and conditions, testified to the risk of colon perforation as a result of the irrigation procedures done by Yow.

In Finding 1.14, the Department found that “administering a colonic or conducting a digital rectal exam is an invasive procedure.” Substantial evidence in the record supports this finding. Tillery testified that she saw Yow give a digital exam. When asked to explain what was involved in a digital exam, she said, “Well, you put on a pair of rubber gloves, client turns over on his side, and you put your index finger up their rectum.” Yow showed investigator Kozar his colonic irrigation equipment, including “a speculum, the part that goes into the rectum,” which Yow said “wouldn’t go all the way, only went so far.” Patient Brad Martin explained that he “laid flat on [his] back” on a table for the procedure,

²⁸ “Evidence, including hearsay evidence, is admissible if in the judgment of the presiding officer it is the kind of evidence on which reasonably prudent persons are accustomed to rely in the conduct of their affairs.” RCW 34.05.452(1).

"[a]nd then you just kind of roll over on your side, put one leg up a little bit, and he puts the speculum in." He further explained, "I was a little apprehensive at first, naturally, but really it was no big deal," and that after Yow inserted the speculum "there's a tube that comes through the [irrigation] machine that you can see what comes out of your colon, out of your body."

Yow also argues that the Department erred as a matter of law in concluding that colonic irrigation constitutes the unlicensed practice of medicine. We disagree.

Yow diagnosed patients as suffering from a number of diseases and conditions. He gave colonics to a patient to address chronic constipation. He conducted digital rectal exams for the purpose of determining the angle of the rectum and whether fissures exist. He professes that colonic irrigation will result in rehydration and will stimulate the liver to purge dead lymph, mucoid plaque, parasites, Candida die-off, and other accumulated toxins. He used herbs and ozone in colonic irrigations, and told one patient that the ozone "enhances the detoxification process." He routinely checked patients' abdomens to see how they felt.

Yow's procedures carry the potential for colon perforation, which could result in blood stream infection. Yow's use of herbs in his patients' colons could cause side effects such as difficulty breathing, and may result in allergic reactions. Colonic irrigation also creates a risk of electrolyte shifts and subsequent cardiac arrhythmia.

Finally, Yow signed his name as “Dr. Yow” on a prescription form for colonic irrigation equipment, which requires a physician’s prescription.

We conclude that Yow’s conduct constitutes the practice of medicine under RCW 18.71.011. The Findings of Fact demonstrate that Yow was offering or undertaking to diagnose human ailments, infirmities, and conditions by the instrumentality of colonic irrigation. He also prescribed colonic irrigation for his patients’ ailments and conditions. Though signing one’s name as “Dr.,” without more, may not constitute a violation of the plain language of the statute, Yow’s signature as “Dr. Yow” in the context of a prescription form is sufficient to meet the definition of RCW 18.71.011(4).

Yow claims that his colonic irrigation practice is exempt from the Department’s licensing scheme because it is a “self-care practice” under chapter 74.39 RCW. Yow’s argument is unpersuasive. The chapter was intended to address the state’s “chronically functionally disabled population.”²⁷ The licensing exceptions for self-directed care apply only to those who aid adults with functional disabilities living in their own homes.²⁸ The record is clear that Yow’s practices did not occur under these circumstances.

Yow asserts that the Department does not have authority to regulate colonic irrigation because it has not followed the procedures of chapter 18.120 RCW. We disagree. The express purpose of chapter 18.120 is to establish

²⁷ RCW 74.39.001.

²⁸ RCW 74.39.050, .070.

guidelines for the regulation of health professions that were not licensed or regulated prior to July 24, 1983, and those licensed or regulated health professions that seek to substantially increase the scope of practice.²⁹ As a "colonic hydrotherapist," Yow seeks to substantially increase the scope of his practice to allow for an activity currently defined by the legislature as the practice of medicine. RCW 18.120 created a legislative scheme under which an individual, such as Yow, or any health professional group or organization, can propose a bill to substantially increase the scope of their practice.³⁰ But the fact that "colonic hydrotherapy" is not licensed or regulated as a health profession has no bearing on the Department's authority to regulate the unlicensed practice of medicine. Such statutory authority is clear.³¹ RCW 18.120 does not apply here and does not preclude the Department from taking action against the unlicensed practice of medicine.

Yow claims that the Department does not have authority to regulate his colonic irrigation practice because it relied on a draft interpretive statement in adjudicating his case. This argument has no support in the record before us and we reject it.

The Department charged Yow with violating the statutes prohibiting the unlicensed practice of medicine, not with violating the terms of an agency

²⁹ RCW 18.120.010(1).

³⁰ See Gebbie v. Olson, 65 Wn. App. 533, 539, 828 P.2d 1170 (1992).

³¹ RCW 18.130.190; RCW 18.71.019.

interpretive statement. As we have explained, those charges were founded and fully supported by the record developed at the administrative hearing.

At oral argument of this case, Yow pointed to several documents in the record that he contends show that the Department took inconsistent positions in prosecuting its case against him for his unauthorized practice of medicine. We take this opportunity to explain why those documents do not support his argument.

The first document at issue is an August 11, 1996 memo regarding the unlicensed practice of colonic irrigation.³² The memo describes the Department's concerns about colonic irrigation with respect to licensed health professions, and outlines possible departmental action regarding the practice. An assistant attorney general had recently advised the Department that colonic irrigation constitutes the practice of medicine and that unlicensed persons may not perform colonic irrigations. The memo plainly states the Department's position that unlicensed persons may not legally perform colonic irrigations.

The second document is a March 11, 1998 memorandum regarding a proposed interpretative statement on colonic irrigation.³³ Again, the memo demonstrates the Department's position that unlicensed persons are legally prohibited from performing colonic irrigations. The memo's discussion of a potential ambiguity relates only to individuals who have been improperly

³² Clerk's Papers at 93-95.

³³ Clerk's Papers at 96-101.

delegated colonic therapy duties by licensed health practitioners and individuals in licensed health professions where the procedure is beyond the scope of the licensed practice. Neither of these situations applies to Yow.

In short, the Department's actions in this case are entirely consistent with the substance of each of the memorandums on which Yow attempts to challenge the decision in this case. Yow's claims are without merit.

Constitutional Arguments

Yow argues that the "prohibition against advice on human conditions" in RCW 18.71.011 is unconstitutionally overbroad on its face and unconstitutionally vague as applied to him. We disagree.

In general, "[a] person may not urge the unconstitutionality of a statute unless he is harmfully affected by the particular feature of the statute alleged to be violative of the constitution."³⁴ Moreover, "[o]ne who challenges the constitutionality of a statute must claim infringement of an interest particular and personal to himself, as distinguished from a cause of dissatisfaction with the general framework of the statute."³⁵

A statute is presumed to be constitutional, and the party challenging its constitutionality bears the burden of proving beyond a reasonable doubt its unconstitutionality.³⁶

³⁴ State v. Rowe, 60 Wn.2d 797, 799, 376 P.2d 446 (1962).

³⁵ Id.

³⁶ Madison v. State, 161 Wn.2d 85, 92, 163 P.3d 757 (2007).

Under these rules, Yow does not have standing to challenge the “advice on human conditions” portion of RCW 18.71.011 as void for vagueness as applied to him. While the Department’s initial notice to Yow cited subsections (1) and (4) of the statute in their entirety, the Department made its ultimate determination against Yow on grounds that he “diagnosed, prescribed, and treated patients by the use of colonics” and that he held himself out as a medical doctor.³⁷ Yow was not ordered to cease and desist conducting colonic irrigations based on “advising on the human condition.” The portion of the statute he challenges as vague was not applied to him.

Washington courts have given more leeway to facial challenges based on overbreadth. Because of the importance of the rights protected by the First Amendment, “the overbreadth doctrine allows a litigant to challenge a statute on its face, rather than as applied to his own facts, and have a statute invalidated for overbreadth where it would be unconstitutional as applied to others even if not as applied to him.”³⁸

A law is overbroad if it sweeps within its prohibitions constitutionally protected free speech activities.³⁹ The First Amendment overbreadth doctrine may invalidate a law on its face only if the law is “substantially overbroad.”⁴⁰ In

³⁷ AR at 248-49 (Conclusions of Law 2.5, 2.6).

³⁸ State v. Motherwell, 114 Wn.2d 353, 370-71, 788 P.2d 1066 (1990).

³⁹ Id. (citing City of Seattle v. Huff, 111 Wn.2d 923, 925, 767 P.2d 572 (1989)).

⁴⁰ City of Bellevue v. Lorang, 140 Wn.2d 19, 26, 992 P.2d 496 (2000) (quoting Huff, 111 Wn.2d at 925).

determining overbreadth, “a court’s first task is to determine whether the enactment reaches a substantial amount of constitutionally protected conduct.”⁴¹ A statute may be saved from being facially invalid on overbreadth grounds where it has been or could be afforded a narrowing and limiting instruction by a court.⁴²

Here, despite the fact that Yow was not prejudiced by the particular features of the statute that he challenges, we consider his overbreadth argument.

The constitutionality of RCW 18.71.011 has not yet been decided in Washington. In State v. Pacific Health Center, Inc.,⁴³ this court acknowledged the possibility of the statute’s overbreadth without deciding the question:

We acknowledge appellants’ concern that the statute’s plain language could allow the State to regulate many practices the legislature could not have intended to regulate, such as elementary school teachers instructing students on health and hygiene or a Pilates instructor advising a client to hold in her stomach to prevent lower back pain. But those situations are not before us.⁴⁴

In People v. Rogers,⁴⁵ the Michigan Court of Appeals addressed an overbreadth challenge to a “practice of medicine” definition very similar to ours:

“Practice of medicine” means the diagnosis, treatment, prevention,

⁴¹ Id. at 26-27 (quoting Huff, 111 Wn.2d at 925).

⁴² Broadrick v. Oklahoma, 413 U.S. 601, 613, 93 S. Ct. 2908, 37 L. Ed. 2d 830 (1973).

⁴³ 135 Wn. App. 149, 143 P.3d 618 (2006).

⁴⁴ Id. at 166.

⁴⁵ 249 Mich. App. 77, 641 N.W.2d 595 (2001).

cure, or relieving of a **human** disease, ailment, defect, complaint, or other physical or mental **condition**, by attendance, **advice**, device, diagnostic test, or other means, or offering, undertaking, attempting to do, or holding oneself out as able to do, any of these acts.^[46]

In comparison, the challenged provision of RCW 18.71.011 reads:

A person is practicing medicine if he does one or more of the following:
(1) Offers or undertakes to diagnose, cure, **advise** or prescribe for any **human** disease, ailment, injury, infirmity, deformity, pain or other **condition**, physical or mental, real or imaginary, by any means or instrumentality . . .^[47]

The Rogers court, relying on the principle that statutes may be saved from facial invalidity by judicial narrowing and limiting constructions, held that Michigan's statute was not overbroad.^[48] The court looked to a 1915 Michigan Supreme Court case, Locke v. Ionia Circuit Judge, which recognized that the "sweeping" definition of the practice of medicine "would render criminal numerous gratuitous and humane acts of relief and kindness to the suffering common amongst mankind in all ages and places."^[49] Yet the court in Locke recognized that "the police power of the State, though comprehensive, is scarce[ly] adequate to compass [sic] the possibilities of such a definition."^[50] The Michigan Court of

⁴⁶ Id. at 92 (quoting M.C.L. § 333.17001(1)(d)) (emphasis added).

⁴⁷ RCW 18.71.011 (emphasis added).

⁴⁸ Rogers, 249 Mich. App. at 101.

⁴⁹ Id. at 98 (quoting Locke v. Ionia Circuit Judge, 184 Mich. 535, 538-39, 151 N.W. 623 (1915)) (emphasis omitted).

⁵⁰ Id.

Appeals concluded that to the extent the statute, limited by judicial construction, "might reach constitutionally protected speech or conduct, the overbreadth is not substantial judged in relation to the plainly legitimate sweep of the statute."⁵¹

Further, the court concluded, "there is no realistic danger that the statute, so limited, will itself significantly compromise recognized First Amendment protections of parties not before the Court."⁵²

Here, the only portion of Washington's definition of the practice of medicine that Yow challenges is the extracted phrase "[advise] on human conditions." The word "advise" arguably has the potential to bring constitutionally-protected free speech activities into the scope of the statute. As the court pointed out in Pacific Health Center, "advising" may include practices such as elementary school teachers instructing students on health and hygiene, or a Pilates instructor advising a client to hold in her stomach to prevent lower back pain.

Notably, the legislature has already limited RCW 18.71.011 in scope by RCW 18.71.030. That statute exempts religious practices, treatment by prayer, emergency medical assistance, and domestic administration of family remedies, among many others, from the prohibitions of chapter 18.71 RCW.⁵³

To the extent that elementary school teachers instructing students on

⁵¹ Id. at 101 (citing Broadrick, 413 U.S. at 615-16).

⁵² Id. (citing City Council of the City of Los Angeles v. Taxpayers for Vincent, 466 U.S. 789, 800, 104 S. Ct. 2118, 80 L. Ed. 2d 772 (1984)).

⁵³ RCW 18.71.030.

health and hygiene or Pilates instructors advising clients could be violating the practice of medicine statutes, the statute could be limited further to avoid the constitutional problem that Yow identifies here. But it is equally clear that Yow has not demonstrated that his concerns represent “substantial overbreadth” in relation to the plainly legitimate sweep of the statute. Yow has failed in his burden to prove beyond a reasonable doubt that the statute he challenges is unconstitutional.⁵⁴

EXCLUSION OF EVIDENCE AT SUPERIOR COURT

Yow contends that the superior court abused its discretion in striking new evidence he sought to admit on his appeal from the Department’s order. We disagree.

The APA expressly limits judicial review of disputed issues of fact to the agency record, supplemented only in very limited circumstances.⁵⁵ RCW 34.05.562 provides the exception, allowing the court to take new evidence “only if it relates to the validity of the agency action at the time it was taken” and is needed to decide certain issues.

The evidence Yow sought to admit is from 2007. The Department entered its final order against Yow in December 2006. The evidence Yow sought to admit, which arose after the Department’s final order, does not “relate to the validity of the agency action at the time it was taken.” The trial court did not

⁵⁴ Madison, 161 Wn.2d at 92.

⁵⁵ RCW 34.05.558.

abuse its discretion in striking the evidence.

CIVIL FINE

The Department argues that the trial court erred in striking the fine the Department levied against Yow as arbitrary and capricious. We agree.

As discussed above, RCW 18.130.190 sets out the procedure and authority by which the secretary of health or the secretary's designee can investigate and determine whether a person is engaged in the unlicensed practice of medicine.⁵⁶ Subsection (3) gives the secretary the authority to impose a civil fine "in an amount not exceeding one thousand dollars for each day upon which the person engaged in unlicensed practice" of medicine or other professions licensed by the Department.⁵⁷

A court can reverse an agency order if the order is arbitrary or capricious.⁵⁸ Arbitrary and capricious action is "willful and unreasoning action, without consideration and in disregard of facts and circumstances."⁵⁹ Where there is room for two opinions, action is not arbitrary and capricious even though one may believe an erroneous conclusion has been reached.⁶⁰ Action taken after giving a party ample opportunity to be heard, exercised honestly and upon

⁵⁶ RCW 18.30.190; RCW 18.130.020(10).

⁵⁷ RCW 18.130.190.

⁵⁸ RCW 34.05.570(3)(i).

⁵⁹ Heinmiller, 127 Wn.2d at 609.

⁶⁰ Id.

due consideration, even though it may be believed an erroneous decision has been reached, is not arbitrary or capricious.⁶¹ Harshness is not the test for arbitrary and capricious action.⁶²

The health law judge calculated the fine against Yow in accordance with RCW 18.130.190(3), in the statutory amount of \$1,000 per day for each day that Yow engaged in the unlicensed practice of medicine during the charging period. The Health Law Judge ordered Yow to pay \$444,000 for working an average of 12 days per month (three days per week) for 37 of the 38 months in the charging period, a conservative estimate.

In Heinmiller v. Department of Health,⁶³ the supreme court found that sanctions imposed against a social worker were not the result of willful and unreasoning action where Heinmiller was given a fair hearing at which the facts were considered and she had an opportunity to present her arguments. For the same reasons, the Department's fine against Yow must be reinstated. Yow was given a fair hearing at which the facts were considered, and he had an opportunity to present his argument.

Moreover, the Department's order makes plain that the fine was the result of reasoned consideration. The health law judge noted the aggravating factors in Yow's case of "multiple occurrences, vulnerability of patients (children and

⁶¹ Id. at 609-10.

⁶² Id. at 609.

⁶³ 127 Wn.2d 595, 610, 903 P.2d 433 (1995).

senior citizens), and medical risk to patients.” The health law judge noted the mitigating factor that no evidence indicated that any patient suffered physical harm. Because Yow refused to testify as to the number of days upon which he had conducted colonic irrigations, the health law judge adopted the Unlicensed Practice Program’s fairly conservative estimate that Yow only saw patients three days per week, and that he took one month off from practice during the charging period.

Yow asserts that the rule of lenity should apply to his sanctions because the Department’s proceeding was “quasi-criminal” and the “legislative/regulatory scheme attendant with [colonic hydrotherapy]” is ambiguous. We reject this argument. Yow has not demonstrated any ambiguities in RCW 18.71.011 or 18.130.190. The rule of lenity applies only where a statute is ambiguous.⁶⁴

ATTORNEY FEES

Yow claims that the trial court erred in denying his tardy request for attorney fees under RCW 4.84.350(1). He also requests attorney fees under the same statute on appeal. We deny his requests.

RCW 4.84.350, known as the “Equal Access to Justice Act,” provides authority for petitioners to recover attorney fees from a state agency for successful court challenges to the agency’s action. Because Yow is not a prevailing party, here or below, an award of fees to Yow is not warranted.

Moreover, Yow’s petition for attorney fees at superior court was untimely

⁶⁴ State v. Jacobs, 154 Wn.2d 596, 600-01, 115 P.3d 281 (2005).

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under CR 54(d)(2).

We affirm in part, reverse in part, and remand with instructions to reinstate the \$444,000 civil fine that the Department imposed.

Cox, J.

WE CONCUR:

Selengor, J.

Becker, J.

APPENDIX: G

Applicant Rebuttal to Draft Report

(Taken directly from applicant email dated January 11, 2008)

Applicant Rebuttal to Draft Report

We appreciate the opportunity to provide comments on the draft of the Colon Hydrotherapist Sunrise Review.

Although the draft is well written, there are some errors of either omission or interpretation that cause the draft to reflect a bias that should not be present in an impartial Sunrise Review report. The report should accurately report the information provided during the Sunrise Review so the legislative body can make their decision on the bill H-3505.1/07.

The first section of the draft provides a review of “The Sunrise Review Process” and lists criteria for healthcare professions that should be regulated and the types of regulation that may be considered. There is another benefit of having a Sunrise Review as it provides the Legislative body the opportunity to identify when or if there is a bias in the Department of Health that is inconsistent with the direction of the legislative body.

The second section is an “Overview of the Proceedings”. We suggest a change on the last line of the third paragraph to read: “On December 21, 2007, the Department of Health distributed a draft report to participants and interested parties for review, followed by a ten-day rebuttal period to comment on the draft report.” Rationale: this provides the date of the draft.

The third section is a “Summary of Information”. It is in the fourth sub-section that is inaccurate in its reflection of the record. The Sub-Section entitled Colon Hydrotherapy a Medical Practice, second paragraph, “The practice of colon hydrotherapy is recognized in Washington as an instrumentality to diagnose and treat medical conditions.” This statement is inaccurate and misleads the legislative body by referring to the *State v. Pacific Health Center, Inc.*, as the rationale for colon hydrotherapy being the practice of medicine. That case was not about colon hydrotherapy, but was about an individual that held themselves out as healing medical conditions using Electrodermal Testing (EDT), not colon hydrotherapy.

There is no similarity between the two modalities.

The practice of colon hydrotherapy SHOULD NOT be recognized in Washington as a Medical Practice as the Sunrise Review Hearing documented that colon hydrotherapists do not diagnose, do not prescribe and do not treat medical conditions. Additionally, the Sunrise Review Hearing clearly documented that colon hydrotherapists do not insert any device into any orifice of the body.

In the next sentence, the Department of Health states, “Medical procedures may be performed only by an appropriately licensed health professional acting within the scope of his or her license. In Washington, colonic irrigation is within the statutory scope of practice for naturopaths, physicians, and osteopathic physicians.” This statement is not factual. This is an interpretation that shows the bias of the Department of Health. There are no laws that specifically delineate colon hydrotherapy in the scope of practice of any of those professions. The fact is that there is not a single medical school or naturopathic school in Washington that trains naturopaths, physicians, and osteopathic physicians that provides training in colon hydrotherapy.

The next lines continue to reflect the Department of Health’s bias and interpretation as they state, “These practitioners may delegate colon hydrotherapy to other practitioners under limited circumstances. When delegated, colon hydrotherapy must be in the scope of practice and training of the licensee performing the task.” There are no laws that list the services that naturopaths, physicians, and osteopathic physicians

may delegate, nor are there any laws that direct to whom it may be delegated. This is an interpretation of the Department of Health and is not consistent with current practice.

To make the point, currently, there are other class II medical devices that are routinely prescribed for patient use and that is the use of Oxygen. Patients with pulmonary or heart issues are routinely prescribed oxygen. The licensed practitioner writes the prescription, and the patient takes the prescription to a medical supply company where they are taught how to use the equipment, the patient then takes the equipment home and uses it when necessary. There is no requirement for another licensee to administer the oxygen.

The records of the Sunrise Hearing clearly establish that the therapist should have a prescription from an individual licensed by the state to purchase colon hydrotherapy equipment and supplies, however, the public was very clear that they do not want to have to get prescriptions for the procedure. In Florida, where the state certifies colon hydrotherapist, there is no requirement for prescriptions to purchase the equipment or to provide the service to the customer.

It is this interpretation by the Department of Health that screams for the legislative body to certify colon hydrotherapists. If the legislative body does not provide certification, then the result may be that the public is deprived of access to colon hydrotherapy, or they will be forced to go to a practitioner that may not be properly trained.

The last paragraph of this sub-section. For accuracy, the second line should read: "Under FDA regulations, colonic irrigation equipment is considered to be a class II medical device." Rationale: accuracy, as the FDA does not use the term colon hydrotherapy.

Under the section "Safety and Efficacy", third paragraph, second and third sentence, the Department of Health states, "Frequent treatments can result in the absorption of too much water. This can lead to electrolyte imbalances in the blood, nausea, vomiting, heart failure, fluid in the lungs, abnormal heart rhythms, or coma." This statement is not accurate as reflected in the Serum Electrolyte Study provided. The study showed that no patients experienced any clinically significant complications or complaints during or after the course of treatment. The only problem might be encountered with paraplegics that are unable to completely release their bowels.

The last line of this sub-section, "Death and serious injury have been associated with colon hydrotherapy treatment without physician involvement." is also misleading. The information we provided was from a report in New England Journal of Medicine, August 5, 1982, that there was a spread of amebiasis due to improperly cleaned equipment. It was the amebiasis that lead to the deaths, not the colon hydrotherapy session. This would not happen with appropriately trained therapists using state of the art colon hydrotherapy equipment as registered with the FDA, and disposable speculums/rectal tubes.

There have been no other documented and verified cases of death as a result of colon hydrotherapy.

In the section Findings:, we contend that colon hydrotherapy is not the practice of medicine. The colon hydrotherapist receives a prescription from a licensed practitioner, and the writing of the prescription is the practice of medicine. The colon hydrotherapist is following the directions of the licensed practitioner, the colon hydrotherapist is not practicing medicine.

The next to the last section Review of Sunrise Criteria, under the sub section, First Criterion Unregulated practice can harm or endanger health and safety, there are errors that need correction in each paragraph.

The first paragraph under the sub section, First Criterion Unregulated practice can harm or endanger health and safety, third sentence, “Patient injury or death may also occur from frequent treatments.” Is not accurate. There is no basis for that statement, in fact, it is in direct conflict with the study that was provided which found, “In spite of the considerable duration of treatment and volume of water used in our study, the subjects experienced none of the symptoms of water intoxication.”

The first paragraph under the sub section, First Criterion Unregulated practice can harm or endanger health and safety, last sentence, “Injuries and death from colon hydrotherapy have been documented.” This is misleading and should reflect that the death was from the spread of amebiasis, and that was the cause of death, not the colonic.

The second paragraph under the sub section, First Criterion Unregulated practice can harm or endanger health and safety, last sentence, “Regulation for the health professionals who administer the treatment is appropriate and necessary to protect patient health and safety.” This statement requires that the legislative body support the bill and provide certification for colon hydrotherapists “to protect the public” and is in direct conflict with the final recommendation of the Department of Health.

The third paragraph under the sub section, First Criterion Unregulated practice can harm or endanger health and safety, “Colon hydrotherapy is already regulated in Washington because it is the practice of medicine. It is within the scope of practice of physicians, osteopaths, and naturopaths. These professionals may delegate the task to other personnel if the delegatee is properly trained and has colon hydrotherapy within his or her scope of practice.” This was addressed earlier as it reflects the bias of the Department of Health. No medical school or naturopathic school in WA trains or teaches about colon hydrotherapy. Without legislation, there are no laws that preclude the practitioner from using equipment not registered with the FDA, and since the professional may delegate the task, then colon hydrotherapists must be registered or certified to perform the task. Colon hydrotherapists are the only ones that are trained and skilled in the procedure.

The fourth paragraph under the sub section, First Criterion Unregulated practice can harm or endanger health and safety, “The department concludes, therefore, that unregulated practice of the single procedure proposed for this profession can harm or endanger health and safety. This conclusion, however, does not support the need to regulate colon hydrotherapists as an independent profession. Professionals already regulated in Washington can provide this treatment.” This paragraph, once again, cries for the legislative body to certify the colon hydrotherapists. The Department of Health continues to contend that there are professionals in WA that can provide the treatment yet the only individuals that have been trained in colon hydrotherapy are unregulated colon hydrotherapists. The Department of Health has made the case that colon hydrotherapists need to be regulated under the first criterion, yet they continue to deny that fact.

The Second criterion: Public needs will benefit from an assurance of professional ability, can only be guaranteed by recommending the legislative body regulate colon hydrotherapists, yet the draft report continues to maintain that a currently licensed practitioner that may or may not have received any training is superior to a regulated profession that guarantees the therapists are trained and regulated. Regulation can guarantee that the practitioners are using FDA registered equipment and disposable speculums/rectal tubes. The department concludes the Sunrise Review does not satisfy the second Sunrise criterion, yet the exact opposite is true. The Sunrise Review showed that Public needs will benefit from an assurance of professional ability which includes appropriate training.

The Third criterion: Public protection cannot be met by other means in a cost-effective manner, has the same problem as the Department of Health continues to contend that, “the scope of practice for the

proposed profession is already regulated by other professions with established programs administered through the Department of Health. There are, therefore, other more cost effective means for providing public protection.” Yet the fact is that the current professions do not have any required training for colon hydrotherapy in any schools and the only way the legislative body can ensure that individuals that perform this valuable service are properly trained is through certification or regulation by law.

The Conclusion the department reaches is that the Sunrise Review did meet the first Sunrise criterion. Yet the draft states, “However, this criterion does not support regulation of the profession because the practice of colon hydrotherapy is already regulated in Washington.” This interpretation of current regulations is not consistent with current practices and the testimony received by the Sunrise Review process. Dr. Jacob Kornberg, Surgeon/MD provided testimony at the Sunrise Review hearing that colon hydrotherapy is not the practice of medicine and that an I-ACT certified colon hydrotherapist should be permitted to perform these services without MD supervision or further medical training. The testimony clearly shows that there are highly trained and highly skilled colon hydrotherapists that perform this service to the public. Testimony also showed that the public definitely wants to have this service available to them. Testimony showed there are no medical or naturopathic schools in Washington that train colon hydrotherapy. The only possible conclusion should be to recommend legislation.

Finally the Recommendation of the department was that the “legislature should not adopt the proposed bill establishing certification for colon hydrotherapists.” as the proposal did not satisfy the three Sunrise criteria. Yet, in their Conclusion, the department did find that the first Sunrise criterion had been met.

Bottom line: Throughout this draft, the department has attempted to interpret that colon hydrotherapy is in the scope of practice for naturopaths, physicians, and osteopathic physicians, yet there is no training available in any Washington medical school or naturopathic school that provides training on colon hydrotherapy. The colon hydrotherapists that came forward during the Sunrise Review have been appropriately trained and are using FDA registered equipment.

The Sunrise Process has determined a need for certification for this profession. The draft and the department should resoundingly recommend the legislature support the bill and enact regulation to certify colon hydrotherapists.