Foundation for Vertebral Subluxation

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The Honorable John W. Suthers Attorney General 1525 Sherman Street Denver, CO 80203

RE: Chiropractors & Injectables

Dear Attorney General Suthers,

The Foundation for Vertebral Subluxation offers the following information in regards to the effort to add injectables into the scope of chiropractic practice in Colorado.

Proposed Rule 7 (C) provides for chiropractors, who have completed a 24 hour course of instruction, to administer a variety of legend (prescription) drugs by injection. Colorado Revised Statutes expressly prohibit chiropractors from prescribing, compounding, or administering drugs. All injectables for human use are prescription drugs. The Board of Chiropractic Examiners may only promulgate rules that are "not inconsistent with the law." Proposed Rule 7 (C) exceeds the statutory scope of practice for chiropractors in Colorado, and is therefore unlawful.

Under the Colorado Chiropractors Practice Act, chiropractors are prohibited from prescribing, compounding, or administering drugs.

Colorado Revised Statutes, Title 12, Professions and Occupations, Article 33, Chiropractors, Effective July 1, 2011, Section 12-33-118 states, in part, "Such license shall not confer upon the licensee the right to practice surgery or obstetrics or to prescribe, compound, or administer drugs, or to administer anesthetics."

The injectable products enumerated under proposed Rule 7 (C) are prescription drugs, and are not "nutritional remedial measures" under Section 12-33-102 (1.7) because they are not intended or labeled as dietary supplements for oral administration.

Colorado Revised Statutes, 12-22-102. Definitions, defines a prescription drug as follows: (30) "Prescription drug" means a drug that, prior to being dispensed or delivered, is required to be labeled with the following statement: "Caution: Federal law prohibits dispensing without a prescription.", "Rx only", or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

Under the Federal Dietary Supplement Health and Education Act of 1994 (DSHEA), a "dietary supplement" is a product that "is intended for ingestion in a form described in Section 411 C1 (B)(i)". Section 411 C1(B)(i) clarifies that "ingestion" means oral intake of the supplement. This provision specifically requires that, in order to be a "dietary supplement", rather than a "legend drug", the supplement must be one that:

"(i) [I]s intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form. . ."

The FDA states, in explaining the DSHEA, states, in part, "A dietary supplement is a product taken by mouth... The 'dietary ingredients' in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites." <u>http://www.fda.gov/Food/DietarySupplements/ConsumerInformation/ucm191930.htm</u>

The claim that because Colorado licensed acupuncturists are permitted to utilize injectable products does not mean that chiropractors may do so.

Colorado Revised Statutes, Title 12, Professions and Occupations, Article 29.5, Acupuncturists, do not expressly prohibit acupuncturists from prescribing or administering drugs.

Proposed Rule 7 (C) includes a broad array of prescription drugs, yet requires only 24 hours of instruction.

The proposed Rule 7 (C) provides for chiropractors, who have completed a 24 hour course of instruction, "to administer homeopathic and botanical medicines, vitamins, and minerals. phytonutrients, antioxidants, enzymes and glandular extracts by means of injectable procedures…"

The definition of "botanic" is: "pertaining to or derived from plants; of the vegetable kingdom."

There are many drugs, prescription and non-prescription, that are derived from plants. Examples include digitalis, morphine, cocaine, belladonna, and penicillin.

The FDA describes the difference between botanical drug products and dietary supplements as follows:

"A botanical drug product is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans.

A botanical drug product consists of vegetable materials, which may include plant materials, algae, macroscopic fungi, or combinations thereof.

A botanical drug product may be available as (but not limited to) a solution (e.g., tea), powder, tablet, capsule, elixir, topical, or injection. ..

A dietary supplement is a product taken by mouth that contains a dietary ingredient intended to supplement the diet."

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm09098 3.htm

The proposed Rule 7 (C) provides for chiropractors to administer homeopathic medicines by injection. Homeopathic medicine is highly controversial. Furthermore, only three states license homeopathic physicians (Arizona, Connecticut, and Nevada). These states require that an applicant hold a medical degree (MD or DO), complete residency training, and have specialty training in homeopathy. <u>http://www.cga.ct.gov/2010/rpt/2010-R-0315.htm</u>

To have untrained or marginally trained DCs practicing an entirely different "school of medicine" would not be in the best interests of the profession or the people of Colorado.

Persons licensed to prescribe and administer injectable drugs, such as physicians and nurse practitioners, are required to have extensive clinical training, including clinical rotations.

One does not qualify to practice medicine solely through classroom instruction.

A Nurse Practitioner candidate is already an experienced RN. In addition to classroom training, typically over 800 hours of clinical rotations are required.

For an MD or DO, the last 2 years of medical school emphasize clinical rotations, followed by a minimum of 3 years of residency training, which may involve 80 hour work weeks.

The public is not served by allowing chiropractors, or other practitioners, to bypass this process.

Hotel seminars and experience in private chiropractic practice is not comparable to hospital rotations in accredited teaching hospitals, for those wishing to practice medicine.

Proposed Rule 7 (C) conflicts with the statutes regarding scope of chiropractic practice.

Section 12-33-107. Board powers, states, in part:

"(1) The board is authorized to and shall:

(a) Adopt, promulgate, and from time to time revise such rules and regulations not inconsistent with the law as may be necessary to enable it to carry out the provisions of this article;"

Proposed Rule 7 (C) is inconsistent with Colorado Revised Statutes, Title 12, Professions and Occupations, Article 33, Chiropractors, Section 12-33-118 which states, in part, "Such license shall not confer upon the licensee the right to practice surgery or obstetrics or to prescribe, compound, or administer drugs, or to administer anesthetics."

Please consider the foregoing as efforts to implement Rule 7 C move forward.

Sincerely,

The Foundation for Vertebral Subluxation