

DIETICIANS

**Submitted by
The Colorado Department of Regulatory Agencies
Office of Policy & Research
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I. INTRODUCTION

The Department of Regulatory Agencies has evaluated the proposal for regulation submitted by the Colorado Dietetic Association. Pursuant to the Colorado Sunrise Act, C.R.S. 24-4-104.1, the applicants must prove the benefit to the public of their proposal for regulation according to the following criteria:

1. Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety or welfare of the public, whether the potential for harm is easily recognizable and not remote or dependent on tenuous argument;
2. Whether the public needs, and can be reasonably expected to benefit from, an assurance of initial and continuing professional or occupational competence;
3. Whether the public can be adequately protected by other means in a more cost-effective manner.

II. METHODOLOGY

The applicants submitted responses to the sunrise application questions. Previous submissions of documentation and literature were brought forward for this 1993 review. The Department of Regulatory Agencies met with the applicants to discuss the proposal for regulation. The Department also contacted every state that has implemented regulation of dietitians or nutritionists or that have significantly amended such regulation since Colorado's previous sunrise review of this profession in 1990. Inquiries regarding complaints against practitioners were made of the Colorado Attorney General's Consumer Protection Office and the Consumer Protection Division of the Colorado Department of Health. Recent actions by the Federal Food and Drug Administration to improve its regulation are examined.

III. BACKGROUND

The Colorado Dietetic Association has applied for regulation under the Colorado Sunrise Act in 1985, 1989, 1990 and now in 1993. The sunrise reports prepared pursuant to the prior applications are available for review upon request. These applications for regulation are part of a general movement of the American Dietetic Association and its state affiliates to pass laws in each state regulating the practice of dietetics and nutrition. Currently, twenty-nine states have adopted some form of regulation in this field.

The Colorado Dietetic Association has over 1,000 members, 879 of which are registered dietitians. Membership in the Colorado Dietetic Association is obtained through membership in the American Dietetic Association. There are an additional 92 registered dietitians in Colorado who are not members of the ADA or the CDA. According to the Colorado association, "the term 'registered dietitian' or the initials "RD" signify a person who has been certified by the Commission on Dietetic registration (CDR) of the American Dietetic Association. The CDR is a regular category A member of the National Commission for Health Certifying Agencies. There is no single association in Colorado that represents nutritionists who are not "registered dietitians".

Terminology and scope of practice.

This application requests the restriction to certain persons certified by the state of Colorado, of the terms dietitian and nutritionist and other related terms. Therefore, it is important to note the distinction between these terms at the outset. For the purposes of this report, a "registered dietitian" will mean a person who has been certified as a registered dietitian by the Commission on Dietetic Registration. In addition, the term "dietitians" shall also refer to any person who is a member of the American Dietetic Association.

Dietitians consider themselves to be nutritionists. This is because the practice of dietetics involves, "the integration and application of principles derived from the sciences of nutrition, biochemistry, physiology, food management and behavioral and social sciences to achieve and maintain peoples' optimal health through the provision of nutrition care services." Dietitians characterize their approach to nutrition as a scientific approach based on scientifically tested and validated concepts.

The universe of nutritionists, however, is much broader than the subset represented by dietitians. Where dietitians would state that they are also nutritionists, all nutritionists are not dietitians, either by the definition used in this report or by general practice within the industry. This fact is also reflected in the different laws adopted by the states which have chosen to regulate dietitians. Some states regulate both dietitians and nutritionists. Other states regulate only dietitians. Finally, a person using the title nutritionist in the United States today runs the gamut from a person who holds a degree as a Ph.D. in Food Science and Human Nutrition from a major university all the way to one who has no formal training and makes nutritional recommendations which have no proven scientific foundation.

The applicants define the practice of dietetics/nutrition as the integration and application of scientific principles of food, nutrition, biochemistry, physiology, management, and behavioral and social sciences to achieve and maintain health of people. The applicants stress that nutritionists/dieticians are the only professional group specifically educated and trained in the sciences of food and nutrition.

This knowledge base is applied by the dietitian/nutritionist in a variety of functions. Some

examples provided by the applicant of the functions of dietician/nutritionist are:

1. assessing the nutritional needs of individuals in groups;
2. establishing priorities, goals, and objectives that meet nutritional needs and are consistent with resources and constraints;
3. providing nutrition counseling in health and disease;
4. developing, implementing, and managing nutrition care systems; and
5. evaluating, making changes in, and maintaining appropriate standards of quality in food and nutrition care services.

The dietician/nutritionist may serve in a variety of settings. He or she may be a member of a health care team. In such a setting, as is pointed out in the 1993 application, the dietician/nutritionist is usually supervised by a physician. A dietician/nutritionist may serve unsupervised in health care facilities, being responsible for food service systems management. Also, dieticians/nutritionists may be employed in a variety of corporate settings advising wellness programs, or providing other consultations, including the operation of food service systems.

IV. THE PROPOSAL FOR REGULATION

The 1993 proposal for regulation is essentially the same made in the 1990 application. If this proposal were implemented, the practice of dieticians and nutritionists in Colorado would not be subject to state oversight but the use of certain titles and terms would be prohibited.

The Colorado Dietetic Association is requesting that the legislature regulate both dietitians and nutritionists in Colorado by passing a law which will restrict the use of the following titles:

1. "licensed dietitian"
2. "licensed nutritionist"
3. "nutritionist"
4. "dietitian"
5. "dietician"
6. "certified dietitian"
7. "certified nutritionist"
8. "nutrition counselor"

9. "nutrition consultant"
10. "L.N."
11. "L.D."
12. "C.N."
13. "C.D."
14. "N"
15. "D."

The applicants are also requesting title protection for any other facsimile of the foregoing terms which might imply or indicate that a person is a certified nutritionist or certified dietitian. Under this proposal, the indicated titles would be reserved to those persons who possess certain educational and experiential qualifications and who then become certified by the state of Colorado.

In order to accomplish these regulatory goals, the applicants propose that the following be established as the minimum requirements for certification.

- 1) Completed a baccalaureate, master's or doctoral degree in human nutrition, foods and nutrition, dietetics, nutrition education, food systems management, or public health nutrition from a college or university accredited by the North Central Association of Colleges and Universities or another regional accrediting agency recognized by the Council on Postsecondary Accreditation and the U.S. Department of Education: Middle States, New England, Northwest, Southern, and Western Associations of Schools and Colleges; AND
- 2) Completed not less than 900 hours of a planned, continuous, preprofessional work experience in nutrition/dietetic practice under the supervision of a) a nutritionist/dietician licensed or certified by the State of Colorado or another state or b) a registered dietitian (certified through the Commission on Dietetic Registration).

Up to the specified time (possible 6 months to 1 year) after the passage of the proposed legislation, the following may be certified: Persons who

- 1) Have completed a master's or doctoral degree in human nutrition, foods and nutrition, dietetics, nutrition education, food systems management, or public health nutrition from a college or university accredited by the North Central Association of Colleges and Universities or another regional accrediting agency recognized by the Council on Postsecondary Accreditation and the U.S. Department of Education: Middle States, New England, Northwest, Southern, and Western Associations of Schools and Colleges; AND
- 2) Can present sufficient proof that they have completed at least three years of continuous, full-time work experience in nutrition/dietetics.

The applicants have expressed their willingness to pursue flexible, cost-saving approaches to implementing regulation. However, the Department of Regulatory Agencies believes that in order to accomplish the above objectives, certain fundamental regulatory components need to be in place. Included in such a regulatory scheme would be a board or other regulatory authority to verify credentials of applicants, certify or deny certification to applicants, and to remove certification from practitioners (which would include disciplinary provisions, due process and legal appeals).

V. ARGUMENTS FOR REGULATION

As with any title protection regulatory scheme, the average citizen benefits by being able to tell, through a title, which practitioners are "state-approved" and which are not. The applicants expect that the overall quality of nutrition care of Coloradans will improve with this regulation in place because consumers would have a means of identifying appropriately-trained nutrition professionals.

Without state licensure of dietitians, consumers will not be able to distinguish between persons, such as the applicants, who have received formal training in nutritional science and related fields from accredited institutions, from persons who have received little or no scientific training in the field. In Colorado today, anyone can claim to be a "certified nutritionist" or a "certified dietitian", thereby confusing and misleading the public. With the protection of the fourteen titles proposed by the applicants and the setting of standards for persons who can use those titles, the public will be able to determine which nutrition practitioners have received formal training in nutrition science from recognized colleges and universities. If the state of Colorado adopts the minimum standards suggested by the applicants, the applicants suggest that the public will be further protected because persons using the protected titles will also be required to complete a supervised internship and pass a state examination.

VI. REGULATION OF DIETICIANS/NUTRITIONISTS BY OTHER STATES

INTRODUCTION

Since the 1990 sunrise review of the need to regulate dieticians, several states have adopted new regulation. Several others have amended their legislation. This section of the 1993 report will discuss the results of regulation and amendments based on interviews conducted of the regulators in those states. Following this discussion, the findings of the 1990 survey will be presented in order to provide the nationwide scope of dietician/nutritionist regulation.

The primary findings of the interviews conducted with states implementing new regulation or significantly amending previous regulation follow:

- 1) Consumer complaints are virtually non-existent. Complaints are received from practitioners and tend to be complaints of unlicensed or unregistered practice.
- 2) No states have disciplined a dietician or nutritionist for acts or omissions deemed to be harmful to the public.
- 3) Almost all of the states implementing new regulation have had difficulty establishing meaningful, accepted exemptions to the licensing or registration law.
- 4) Several states have increased state regulation; beginning with registration or certification and later increasing regulation to full licensing programs.

States that recently adopted regulation for dieticians/nutritionists

1. **New York** (1991). Regulation was placed with the Dept. of Education but there is nothing operating at this time. The law requires certification and establishes an advisory board, but the legislature did not allocate funding. There have been no meetings and currently there is no work to try to develop the regulatory program or to appoint a regulatory board. There have been no accomplishments in the two years since the legislation was passed.

The law provides title protection and establishes educational requirements, but does not prevent anyone from practicing.

2. **Illinois** (1991). Regulation placed with the Dept. of Regulation. Law requires licensing but there is no regulation in place yet. Some dieticians and nutritionists are battling over a variety of issues.

3. **North Carolina** (1990). Regulation here is administered by the Board of Dietetics and Nutrition. State licensing has been in effect for one year. There is no grandfather period and not many exemptions. There was opposition by other health care professionals for dietitians and nutritionists to receive licensure, but now they work together and the political difficulties seem to have been ironed out. North Carolina is considering making the LDN a requirement for all other healthcare professionals in hospitals, to be placed in the job description (for those individuals who are licensed in other areas). The North Carolina requirements essentially follow the ADA requirements for Registered Dietitian and the state will automatically license those registered with the ADA.

North Carolina experiences some problems with continuing education. Now, the state accomplishes continuing education compliance through the American Dietetic Association. North Carolina reports that its regulation is working well. They have about 1300 dietitians and nutritionists in the state. Approximately 700 are licensed, 100 didn't renew, and the rest are probably not in practice according to North Carolina officials.

Regarding complaints against licensees, the state has about 20 "concerns" to review. Of particular interest, all of the complaints were lodged by other practitioners against unlicensed people.

4. **Rhode Island** (enacted 1988, implemented 1991). The Office of Professional Regulation within the Rhode Island Department of Health administers the licensing of dietitians and nutritionists.

The state began with certification and amended the law to require licensure. There have been no substantive complaints.

Rhode Island is still in the grandfather period until November of 1993. This is causing a lot of problems according to spokespersons. Implementation was delayed because it was difficult to reach agreement on defining the scope of practice. As a result, the statute was amended several times.

The board is very active and has drafted rules and regulations, will create exams, publish a newsletter and carry out other projects. They basically respond to advertisements and perform their own inquiries.

States that have amended previous regulation

1. **Kansas** Kansas has received several complaints but has had difficulty following up on them because of too many exemptions to the state's licensing statute. Licensing authorities report that the statute is problematic and there are efforts to go back to the legislature to make additional amendments. There are some concerns about amending the statute because there were a lot of protests in the first round of legislation.

The program administrator reports that the state follows the ADA guidelines. There have been significant problems with the statutory grandfathering period of one year.

Kansas regulators have had about ten complaints and have followed up on all of them, only to find that in each instance, save one, the practitioner qualified under an exemption in the statute. There was one legitimate claim involving title protection.

2. **Louisiana** Initial regulation consisted of title protection but it was later decided that in order to protect the public, the scope of practice must be defined. Therefore, Louisiana now licenses dietician-nutritionists. The state currently has one complaint. There have been no malpractice complaints. The state reports "not much action taken over all." Louisiana reports that it has been very difficult to deal with exemptions to the statutory requirements. The licensing agency states that complaints may be low because regulation is new and consumers are not aware of the new program.
3. **Maine** Initial regulation was registration, but the law was amended to require licensure in 1987. Registration requirement passed in 1985 and was implemented around 1986. There have been six complaints since 1988. All of the complaints allege unlicensed practice. There has been one complaint in 1993, which also was a title protection issue. Maine only licenses dietitians.
4. **Maryland** Regulation began with the licensure of dietitians and was amended to add nutritionists. Since 1989, the state has received several complaints regarding exemptions. There have been four complaints in 1993. All but one involve title protection issues and the state has never revoked a license or taken other serious action against a licensee.

5. **North Dakota** The state licenses ADA registered dietitians (nutritionist regulation is voluntary). The North Dakota law provides a great number of exemptions and this has been problematic. It appears that virtually anyone can practice as long as they are not practicing therapeutically. The state has received a small number of complaints recently, all dealing with title protection. The administrator believes regulation is a wasted effort and a waste of money. North Dakota relies heavily on ADA criteria for licensing.

A summary of regulation in the remaining states taken from the previous sunrise report is attached to this report as Appendix A.

VII. PUBLIC HARM

The 1993 application for regulation relies upon essentially the body of evidence demonstrating harm to the public in Colorado that was submitted for the 1990 review. The Department's conclusions concerning these examples are unchanged. Therefore, the relevant discussion from the 1990 sunrise report is updated and summarized in this section.

INTRODUCTION

The applicants have submitted a considerable volume of material to show the threat to the public from the unregulated practice of nutrition. The information can be divided generally into two categories. First, the applicants have submitted sixteen case studies of "nutrition mismanagement in Colorado." These case studies are reproduced and further discussed below. Second, the applicants have submitted documents from the federal government, journals, magazines and other recognized authorities which indicate potential sources of harm to the public due to alleged health fraud and nutrition quackery.

These studies and the responses to them by the Department were included in the previous sunset report. The Department discussed the issue of harm to the public with the applicants as part of this 1993 review. The applicants contend that the documentation submitted previously is illustrative of actual and potential harm to the public. Based on that position, the applicants did not provide additional case studies for this review. Therefore, the original case studies are presented in this 1993 update.

Applicants' Case Studies of Nutrition Mismanagement in Colorado. The following brief case studies regarding 16 actual cases of harm or potential harm to Colorado citizens were provided by the applicants in order to support their claim that regulation of dietitians in Colorado is needed to protect the public. If the legislature were to create a state board or other regulatory vehicle for the purposes of certifying dietitians, as requested by the applicants, these types of complaints might be brought to the board for hearing or referral. Therefore, it is important to review the claims involved in each case and to consider whether other existing agencies of government might already have jurisdiction to deal with these matters.

In reviewing these case studies, it is important to note the following:

1. No dietitian is implicated as causing harm in any of the case studies.
 2. In each case, the "patient" freely sought out the advice, service or product offered by the practitioner or salesperson in question.
 3. In each case, the "patient" was free to accept or reject the advice, service or product offered by the practitioner in question.
 4. In each case, where the "patient" felt that either physical or financial harm had been done, the "patient" had the option of filing a complaint in civil court. This includes the right to sue in Small Claims Court where attorneys are not admitted and the filing fee is reasonable.
- * The case studies below are reproduced as submitted by the applicants, however, the "case notes" are submitted by the author and are found after every case in bold type.

CASE I - METRO AREA

PATIENT: Female in mid-40's

COMPLAINTS PRESENTED TO PRACTITIONER IN QUESTION: Liver cancer

PRACTITIONER/SALESPERSON: Health Food Store Owner

TREATMENT PRESCRIBED: *Wheat grass tonics, Wheat grass enemas, both
grown in "Blessed dirt"

*Excessive numbers of vitamin and mineral supplements

*Enzymes

*Kelp

*Eat only pulverized raw liver

MONETARY COST: \$300-\$400/month on supplements (patient unemployed mother)

RESULTS: Death (The urine of people taking kelp tablets has been found to contain raised concentrations of arsenic, a poison and a possible cancer-causing agent). Patient refused conventional treatment until she could not endure the pain any longer. The treatment prescribed could not help this patient and possibly lowered her quality of life even with death imminent.

CASE NOTES: CASE I.

Practitioner/salesperson in this case violated the Colorado Cancer Cure Control Act, C.R.S. 12-30-101 et. seq. Any treatment of cancer not recognized as effective is prohibited by the Board of Health under this Act. It is unlawful for any person other than a licensed physician, licensed osteopath or licensed dentist to diagnosis, treat or prescribe for the treatment of cancer. Any other persons than those named are precluded from treating cancer. Initial violations are misdemeanors; third and subsequent violations are class 6 felonies.

CASE 2 - BOULDER

PATIENT: 29 year-old male

COMPLAINTS PRESENTED TO PRACTITIONER IN QUESTION: Renal insufficiency: high blood pressure. (Patient moved to Colorado from Florida to take "special treatment" to avoid dialysis.)

practitioner/SALESPERSON: "Self-Proclaimed Nutritionist"

DIAGNOSIS METHODS USED: Lab analysis including blood work

TREATMENT PRESCRIBED: *Macrobiotic diet, including some foods high in potassium and phosphorus
*(Practitioner claimed no dialysis needed with this treatment)

POSSIBLE HARM: High potassium and phosphorus intake could have caused hyperkalemia and even death if continued. Death would have resulted had the patient not begun kidney dialysis.

RESULTS: Patient became so ill, was hospitalized 9/88 in a Chronic dialysis unit. Now on hemodialysis awaiting a kidney transplant.

CASE NOTES: CASE 2.

The practitioner/salesperson in this case has violated the Colorado Medical Practice Act by practicing medicine without a license. The Colorado Medical Practice Act, C.R.S. 12-36-101 et. seq. defines the practice of medicine to include suggestion, recommendation, diagnosing or prescribing for the treatment or prevention of disease. In this case, the patient was clearly suffering from a renal insufficiency and high blood pressure and had, in fact, "moved to Colorado from Florida to take special treatment to avoid dialysis." Clearly, the practitioner/salesperson in this case knew that the patient had a serious medical problem and that the diagnosis performed and treatment prescribed constituted practicing medicine without a license. The Colorado Medical Board already has jurisdiction over this type of violation. Violations range from class 2 misdemeanors to class 3 felonies, depending on severity and repetition of offense.

CASE 3 - METRO AREA

PATIENT: Adult female

COMPLAINTS PRESENTED TO PRACTITIONER IN QUESTION: General "ill-feelings" for 1-2 years including always tired, under a lot of stress, sinus infection, and spastic colon

PRACTITIONER/SALESPERSON: Health Food Store Salesperson

DIAGNOSTIC METHODS USED: None

TREATMENT PRESCRIBED: *Megadose of Vitamin A ((Nutralite Double X ultimate supplement (Vitamin A 15,000 IU), Beta Carotene, Vitamin A 25,000 IU x 9 daily, Atzine (Vitamin A 10,000 IU x 24 daily)) = 480,000 IU Vit. A daily

*Also other vitamin supplements

RESULTS: Hypervitaminosis A. Severe generalized hair loss over entire body: 70%+ loss of scalp hair, 40%+ of brows and lashes, 50%+ of arm hair. Dry skin, follicular hyperkeratosis, increased yellow color in palms. The amount of Vitamin A prescribed 60 times the Recommended Dietary Allowance adult women for Vitamin A intake (RDA is 8000 IU).

CASE NOTES: CASE 3

Falsely representing the use of benefits of products and services through any medium of communication violates the Colorado Consumer Protection Act, C.R.S. 6-1-101 et seq. Foods, including vitamins and supplements are products or goods. (C.R.S. 6-1-102(5.5)) The Colorado Department of Health Consumer Protection Division may also have jurisdiction over complaints in this case, particularly if the products used were in any way altered or misbranded. Since this occurred in the metro area, it is possible that the Consumer Protection Office of the District Attorney for the First Judicial District would also have jurisdiction to take action on this case.

CASE 4 - PUEBLO

PATIENT: 7 year-old female

COMPLAINTS PRESENTED TO PRACTITIONER IN QUESTION: Patient had strep throat 7 times in 7 months

PRACTITIONER/SALESPERSON: Licensed Health Care Practitioner

DIAGNOSIS: Need to build patient's Immune system (Practitioner diagnosed patient without examining her)

TREATMENT PRESCRIBED: *For 15 days patient on Formula 100 (Vitamin C 1500 mg plus Bioflavonoids, Hesperidin, Rutin, Acerola) - 6 per day and Formula 14 ((Vitamin A 18,000 I.U., Vitamin D 400 I.U., Vitamin E 100 mg., Vitamin C 150 mg., Folic Acid 0.4 mg., Vitamin B-1 25 mg., Vitamin B-2 25 mg., Niacinamide 200 mg., Vitamin B-6 25 mg., Vitamin B-12 25 mag., Pantothenic Acid 125 mg., Paba 37.5 mg.) - 6 per day
*For next 31 days patient on Calcium Lactate tablets - 1 per day, Thymex (Vobine Thymus Cytosol Extract) - 1 per day, and Cataplex A-C-P (Food complex with vitamin A and C) - 2 per day.

RESULTS: Complete hair loss on arms, legs, and scalp; 50% hair loss from eyebrows

CASE NOTES: CASE 4

The practitioner in this case is indicated to be a licensed health care provider. Therefore, the regulatory board which has licensed the practitioner in question already has jurisdiction to investigate this kind of complaint.

CASE 5 - BOULDER

PATIENT: 7 year-old female (same as previous case)

COMPLAINTS PRESENTED TO PRACTITIONER IN QUESTION: Hair loss

DIAGNOSTIC METHODS USED: Saliva sample

DIAGNOSIS: Mercury and Arsenic poisoning
Worms

TREATMENT PRESCRIBED: Homeopathic pills taken for 2 weeks

PRACTITIONER/SALESPERSON: "Holistic Healer"

RESULTS: Continued hair loss (see case 4)

CASE NOTES: CASE 5

Due to the fact that the practitioner in question diagnosed an ailment and prescribed a treatment for it, this case amounts to the unlicensed practice of medicine and is

actionable by the Colorado Medical Board.

CASE 6 - METRO AREA

PATIENT: 37 year-old female

COMPLAINTS PRESENTED TO PRACTITIONER IN QUESTION: Stomach - indigestion
- gas - constipation; depression; intolerance to heat or cold; vaginal infections

PRACTITIONER/SALESPERSON: Self-Proclaimed "Nutritionist"

DIAGNOSTIC METHODS USED: Complete blood profile - 3 times, urinalysis

DIAGNOSIS: Candidiasis

TREATMENT PRESCRIBED: *Patient followed a very low carbohydrate diet
(put on a "Yeast diet")

*Several vitamin supplements and other natural
products

*Vaginal pak

MONETARY COST: Approximately \$1,300

RESULTS: Patient believes she became anorexic because of dietary recommendations
practitioner prescribed from 2/86 to 4/86; Patient hospitalized 5/86 (after seeing
practitioner) with anorexia nervosa: patient's weight from 105 to 87 pounds;
11/88 - hospitalized again with eating disorder, patient now skeptical about
candidiasis.

CASE NOTES: CASE 6

**Once again, the practitioner in this case has violated the Colorado Medical Practice Act
and is subject to an action for practicing medicine without a license.**

CASE 7 - METRO AREA

PATIENT: Adult male

COMPLAINTS PRESENTED TO PRACTITIONER IN QUESTION: Kidney failure - on
kidney dialysis treatments

PRACTITIONER/SALESPERSON: "Nutritionist"

DIAGNOSTIC METHODS USED: Hair analysis

DIAGNOSIS: Aluminum toxicity

TREATMENT PRESCRIBED: *Follow "special diet" - to cure renal failure

*Numerous supplements: Chlorophyll, "Core-level
kidney" (vitamin, mineral), "Anti-Fatigue" (vitamin C, B
complex with licorice root), "Livah" - liver cleanser.

POSSIBLE HARM: Chlorophyll - no known nutritive or therapeutic value.

"Core-level kidney" - vitamin and/or mineral toxicities.

"Anti-Fatigue" - Excessive Vitamin C - nausea, abdominal cramps, and diarrhea; interference

with medical regimens; vitamin C interferes with anti-clotting agents; withdrawal reaction (when discontinue large dose). Excessive B complex - niacin toxicity includes niacin flush, heartburn, nausea, vomiting, diarrhea, ulcer activation, liver malfunction, low blood pressure, fainting. Thiamin toxicity may cause a nervous system hypersensitivity reaction. Excessive Vitamin B6 may cause severe impairment of the sensory nerves. Genuine locirice can cause potassium loss and retention of water and salt. "Livah" - no known nutritive value. Patient still believes "special diet" may cure his renal failure, which could be fatal if he discontinued his kidney dialysis treatments.

CASE NOTES: CASE 7

In this case, no physical damage apparently resulted from the treatment. Therefore, it would be difficult for the "patient" to make a claim against the practitioner, since most cases require that harm has been committed. It is further interesting to note that the patient still believes that the "special diet" in question may cure his renal failure. Against such a belief, regulatory law can accomplish little. However, this case would also amount to the illegal practice of medicine and a complaint would lie before the Colorado Board of Medical Examiners.

CASE 8 - PUEBLO

PATIENT: Adult male

COMPLAINTS PRESENTED TO PRACTITIONER IN QUESTION: 5 previous heart attacks. very resistant high blood pressure; current gallbladder disease; large mass in bladder; chronic headaches; and back pain.

PRACTITIONER/SALESPERSON: Multi-level Marketing Salesperson

DIAGNOSTIC METHODS USED. ANALYSIS ON "Nutra-check machine" (see under C. products and services being promoted in Colorado)

DIAGNOSIS: Problems with circulation, stomach, pancreas, and gall bladder

TREATMENT PRESCRIBED: *Supplements which included vitamin C, vitamin E, protein, and zinc

*Salmon oil

*Digestive aids

*Lippo-Active 40 Uni Pack

*Animal organ extractives

POSSIBLE HARM: Excessive Vitamin C - nausea, abdominal cramps, and diarrhea; interference with medical regimens; vitamin C interferes with anticlotting agents; withdrawal reaction (when discontinue large doses). Excessive Vitamin E - interferes with antocoagulant therapy. Increased protein intake may cause dehydration, hypertrophy of the liver and kidneys, and possibly lead to renal failure. Excessive zinc - anemia; heart muscle degeneration; diarrhea; vomiting; decreased calcium and copper absorption; fever; elevated white blood cell count; renal failure; raised LDL; lowered HDL; muscular pain and incoordination; nausea; exhaustion; dizziness; drowsiness; reproductive failure. Excessive salmon oil - a high-fat diet increases the risk of coronary heart disease. Digestive aids - no

known nutritive value. Lippo-active 40 Uni Pack - product content unknown to author. Animal organ extractives - if contain liver, heart, etc. cholesterol content very high (not appropriate for patient with heart disease).

RESULTS: According to the patient, animal extractives made him "deathly ill".

CASE NOTES: CASE 8

The "patient" in this case clearly has a serious medical history which was made known to the practitioner. Because the practitioner engaged in diagnosis and treatment and because harm apparently resulted as well, this would be a good case for action under the Colorado Medical Practice Act.

CASE 9 - BRUSH

PATIENT: 43 year-old female

COMPLAINTS PRESENTED TO PRACTITIONER IN QUESTION: Allergies; Depression; and Asthma

PRACTITIONER/SALESPERSON: "Nutritionist" with degree from Donsbach University, an unaccredited institution in California. Donsbach was convicted of practicing medicine without a license (Calif. 1979) and charged with and paid fines for numerous health fraud activities in several states (California, Illinois, and New York). In 1987, Donsbach University was renamed the International University for Nutrition Education (see Appendix D: "The Unhealthy Alliance").

DIAGNOSTIC METHODS USED: A pendulum was used to tell the patient what to take

DIAGNOSIS: Candida Albicans

TREATMENT PRESCRIBED: *A chelation therapy treatment (supply \$90 per mo.)

*Garlic

*Hydrogen peroxide by mouth

*Chlorophyll

*Megadoses of vitamins A and E

*Also put on a diet high in saturated fats to "kill" the candida

RESULTS: Bladder problems

Urinary tract burning

Extreme headaches

MONETARY COST: \$700 to \$900

CASE NOTES: Case 9

Allergic and asthmatic conditions are medical conditions of which the practitioner in this case was made aware. Because the practitioner made a diagnosis and prescribed a course of therapy, this case would also be a violation of the Colorado Medical Practice Act. There may also be an action under the Colorado Consumer Protection Act for consumer fraud.

CASE 10 - METRO AREA

PATIENT: 72 year-old male

COMPLAINTS PRESENTED TO PRACTITIONER IN QUESTION: Prostate cancer, patient previously had surgery for treatment

PRACTITIONER/SALESPERSON: "Nutritionist"

TREATMENTS PRESCRIBED: *Macrobiotic diet
*Vitamin and food supplements
*Bile
*Predigested Protein

MONETARY COST: \$240/every 4-6 weeks (\$35/per consultation, usually by phone)

POSSIBLE HARM: Financial and time loss due to unnecessary treatment, previous orchidectomy probable cause of improved health. Oral ingestion of a bile produce is of no benefit physiologically. Pre-digested protein has no value over eating foods containing protein. No enzyme deficiency was noted or tested.

CASE NOTES: CASE 10

In this case there was no physical harm, although financial harm appears to have been done to the "patient". The patient's best recourse here is an action in damages against the practitioner/salesperson in Small Claims Court.

CASE 11 - METRO AREA

Patient: Adult female

COMPLAINTS PRESENTED TO PRACTITIONER IN QUESTION: Four bypasses (single bypass in 1980 and triple bypass in 1986)

PRACTITIONER/SALESPERSON: "Clinical Nutritionist" at a Health Food Store

DIAGNOSTIC METHODS USED: Live cell analysis

DIAGNOSIS: Abemia

TREATMENT PRESCRIBED: *Fish oil capsules containing 150 mg each of eicosapentaenoic and docosahexaenoic acid
*Iron with B vitamin supplements

RESULTS: PATIENT DID NOT TAKE SUPPLEMENTS ON THE ADVICE OF A POST GRADUATE NUTRITIONIST WHO OVERHEARD THE INTERVIEW IN A HEALTH FOOD STORE

POSSIBLE HARM IF RECOMMENDATIONS HAD BEEN FOLLOWED: One potential side effect with fish oil supplements is an increased tendency to bleed, of particular concern to a heart disease patient on anticoagulant drugs. Excessive iron ingestion causes tissue damage, especially to the liver, and infections are likely, because bacteria thrive on iron-rich blood. The ingestion of massive amounts of iron can cause sudden death. Excess B vitamins complications can be found under Case 7 Results.

CASE NOTES: CASE 11

Although no harm was caused to the "patient" in this case, the Colorado Board of Medical Examiners was made aware of the incident and responded in a letter dated January 25, 1988, by indicating that, "the services provided by this organization appear to constitute the practice of medicine, as much as diagnoses are apparently rendered on the basis of live cell analysis." Therefore, a complaint before the Colorado Board of Medical Examiners would be appropriate.

CASE 12 - BOULDER

PATIENT: Adult female

COMPLAINTS PRESENTED TO PRACTITIONER IN QUESTION: High blood cholesterol, leg cramps

TREATMENT PRESCRIBED: *Olive oil and toasted sesame oil should be used instead of margarine

*Should cut down on red meats and increase cold water fish or use fish oil capsules.

*(MaxEpa or Omega 3-2 capsules daily)

*Should use lecithin powder, 1-3 T, daily for cleansing.

*Also beneficial in "cleansing" the body: lemon in water, greens with high chlorophyll content, sprouts.

*Hawthorne tea berries beneficial for cholesterol problems (\$4.89/lb. and they rotted within 3 days.)

*Garlic seems to help cholesterol problems.

*Guar Gum should be put in juice or water and taken quickly before it gels. This binds up cholesterol and takes it out of the body.

*For leg cramps, calcium, magnesium, potassium, and Vitamin E were recommended.

*Avoid aluminum.

PRACTITIONER/SALESPERSON: Self-Proclaimed "Nutritionist" at a Health Food Store

POSSIBLE HARM: Possible vitamin and mineral toxicity with excessive intake. Also a financial loss from unnecessary supplement recommendations. Excess lecithin can cause not only short-term discomforts such as stomach distress, sweating, salivation, and anorexia, but also long-term health hazards from disturbance of the nervous and cardiovascular systems.

CASE NOTES: CASE 12

The "patient" in this case suffered only economic harm. No diagnosis was performed and all of the information given and treatments prescribed are not dangerous unless engaged in to excess. It is likely that no complaint would lie in this case.

CASE 13 - BOULDER

PATIENT: 17 year-old female

COMPLAINTS PRESENTED TO PRACTITIONER IN QUESTION: Acne and fatigue

PRACTITIONER/SALESPERSON: Self-Proclaimed "Nutritionist" from Health Food Store

DIAGNOSIS: Symptoms due to stress

TREATMENT PRESCRIBED: *Megafood tablets (eat once each day) or Country Life\ or Complete Nutritional System brand supplements

*Eat 3 meals per day, use lots of sea weed in her diet and increase fruits and vegetables.

RESULTS: Individual did not take supplements on the advice of her mother (a R.D.)

POSSIBLE HARM: Vitamin toxicity from excessive vitamin intake. Also a financial loss from unnecessary supplement recommendations.

CASE NOTES: CASE 13

Although all of the information and products provided may have had no benefit, no physical harm was done and a complaint such as this would likely be dismissed in court or before a regulatory board.

CASE 14 - DENVER

PATIENT: 12 year-old male

COMPLAINTS PRESENTED TO PRACTITIONER IN QUESTION: Type 1 Diabetes (Juvenile Diabetes)

PRACTITIONER/SALESPERSON: Licensed Health Care Practitioner

DIAGNOSTIC TESTS PERFORMED: Acupuncture and Applied Kinesiology

DIAGNOSIS: Type 1 Diabetes, allergies to all animal fats, wheat, milk and peanuts causing elevated blood sugars.

TREATMENT PRESCRIBED: *Diet excluding all animal fats, wheat, milk and peanuts to control blood sugar. Daily vitamin supplements. Monthly acupuncture and applied kinesiology treatments.

HARM: At the time reported, the patient's hemoglobin A1C was 13 indicating poor diabetic control.

POSSIBLE HARM: Uncontrolled diabetes can lead to diabetic ketoacidosis, coma and death. Acupuncture, applied kinesiology and food allergies have no scientific basis in the diagnosis or therapeutic treatment of diabetes. Blood tests indicate the dose of insulin may need to be increased. But family may continue to trust practitioner, allowing unorthodox treatment instead of increasing insulin dose. An excessively restrictive diet could lead to nutritional deficiencies including calorie deficit.

CASE NOTES: CASE 14

Because the practitioner in question was a licensed health care practitioner, a complaint to the licensing board in question would be appropriate.

CASE 15 - LONGMONT

PATIENT: 11 year-old male

COMPLAINTS PRESENTED TO PRACTITIONER IN QUESTION: Foot pain

PRACTITIONER/SALESPERSON: Licensed Health Care Practitioner

DIAGNOSIS: "Patient not handling sugar well and it was collecting in his foot"

TREATMENT PRESCRIBED: *A sugar-controlled diet and whole food enzymes.

POSSIBLE HARM: Unnecessarily restrictive diet of particular concern in growing children. Could potentially lead to nutrient deficiencies. Enzyme supplements unproven, family spending money unnecessarily. Oral ingestion of enzymes has extremely limited therapeutic use. Enzymes are proteins and like any other protein they are degraded when exposed to the stomach's acidic environment.

CASE NOTES: CASE 15

Once again, because the practitioner in this case was licensed, a complaint to the appropriate licensing authority should be actionable. Discipline of the practitioner would be problematic, however, since no actual harm was done.

CASE 16 - LOVELAND

PATIENT: 45 year-old female

COMPLAINTS PRESENTED TO PRACTITIONER IN QUESTION: Premenstrual Syndrome

PRACTITIONER/SALESPERSON: Herb Specialist/Colonic Irrigationist

TREATMENT PRESCRIBED: *Diet avoiding dairy foods. Herbs and other supplements including Vitamin C (2000 mg), Ca-C, Cornsilk Blend, Dragon Eggs, Barage Seed Oil, Florazymes.

POSSIBLE HARM: Financial harm from purchasing unneeded supplements. Possible allergic reactions.

CASE NOTES: CASE 16

Because the practitioner in question did not presume to diagnose a medical problem and because the foods and supplements recommended are all readily available over the counter, this complaint would probably be unsuccessful. In an action for financial harm, the "patient" would have to show that the products purchased either harmed her or did not perform as promised. Since the monetary damages in cases such as this are usually small, proving that the treatments prescribed are not of some assistance in relieving premenstrual syndrome would require a scientific analysis which is probably prohibitively expensive.

VIII. CONCLUSION

The Department of Regulatory Agencies is not convinced that the harm to the public by dietitians and nutritionists is of such magnitude that additional state regulation is required at this time.

Consumers can make informed choices.

Some proponents for regulation argue that consumers will be misled in an unregulated marketplace. One result may be that a consumer will avoid contact with a doctor while pursuing "alternative therapies." This concern may be unfounded. A January 28, 1993 Special Article appearing in the New England Journal of Medicine reported that such unconventional therapies are more commonly used in addition to conventional therapy. In fact, consumers who use unconventional therapies are more likely to see a medical doctor than an alternative provider, states the Special Article.

A recent Denver Post article estimated that 75 million Americans supplement their diets with vitamins and herbs. The numbers of complaints or problems by consumers is not significant when compared to numbers of consumers who use these products.

Results of regulation in other states does not support the argument to regulate in Colorado.

Indeed, this is supported by contact with other states that have chosen to regulate in this area. Complaint activity is low in general and the few complaints that have been received involve use of a restricted title. These types of complaints are generally made by other practitioners and not by the public.

The experience of the states that have chosen to join other states that regulate dietitians and nutritionists (29 total) has been one of few complaints. There is no reason to expect that the Colorado experience will be any different if it chooses to regulate dietitians and nutritionists.

In fact, Colorado did pass related legislation amending the Colorado Consumer Protection Act to include false claims concerning educational degrees. The Department has been unable to determine whether any consumer has actually used this provision to seek damages from a dietician or nutritionist.

Although Colorado citizens are free to make their own choices about nutrition, Colorado law provides protection or remedy in specific, harmful instances. Aside from a direct action in the civil courts, Colorado consumers are protected by the following:

1. COLORADO CONSUMER PROTECTION ACT. Falsely representing the use or benefits of products or services through any medium of communication violates the Colorado Consumer Protection Act. (C.R.S. 6-1-101, et. seq.) Foods including vitamins and supplements, are products or goods. (C.R.S. 6-1-102(5.5)) Such violations also include falsely representing an associational affiliation of a practitioner. In addition, the Colorado Dietetic Association was successful in further amending this Act in 1990 to include false claims concerning educational degrees. (C.R.S. 6-1-105) As previously stated, successful prosecution by consumers under the Colorado Consumer Protection Act can result in the payment of triple damages and the award of the plaintiff's attorney fees.
2. COLORADO CANCER CURE CONTROL ACT. As previously mentioned, any treatment of cancer not recognized as effective by the Board of Health is prohibited by the Colorado Cancer Cure Control Act. (C.R.S. 12-30-101 et. seq.) It is unlawful for any person other than a licensed physician, licensed osteopath, or licensed dentist to diagnose, treat or prescribe the treatment of cancer.
3. FACILITIES REQUIREMENTS. In order to receive funding from the Department of Health and Human Services, certain health care facilities are required to employ or contract for consultation by dietitians who are qualified to be registered dietitians. As indicated previously, since most dietitians work in institutional settings, the job requirements of those institutions already require that persons qualified to be registered dietitians fill those positions.
4. Finally, as previously indicated, the Colorado Department of Health Consumer Protection Division is already active in this area and is perhaps one of the best equipped, although most underused, state agencies having jurisdiction in this area.

In conclusion, this report has found no convincing evidence of harm being caused to Colorado consumers by the operation of dietitians, either in private practice or in institutional settings. Cases of harm or potential harm related to nutritional practice by other persons, licensed and non-licensed, are few compared with the numbers of nutritional decisions made by Colorado consumers. Such cases are being handled adequately by the numerous available authorities already in place with jurisdiction to handle those problems. The passage of a title protection act as requested by the applicants would serve only to restrict the use of certain titles and would not provide any appreciable increase in consumer protection. Such laws in other states are generally weak, ineffective and poorly staffed.

Besides, the title R.D. or Registered Dietician, is already well established and internationally recognized. A more effective approach from every standpoint would be to effectively enforce Colorado's existing Pure Food and Drug Law in order to assist the Colorado Department of Health in complementing the efforts of the U.S. Food and Drug Administration to address the problems in this area.

The Department recognizes the concerns of the applicant group. There is no doubt that the consumer is faced daily with a plethora of alternatives in nutrition related areas. Similarly, there is little doubt that a few consumers will make choices that are ultimately not the correct courses of action.

However, consumers bear the final responsibility to educate themselves to make better choices. Recent studies concluding that patients typically seek medical advice in addition to alternative therapies supports this contention. The Department believes that the proper role for government is to supplement this consumer education process through labeling and marketing requirements.

Therefore, the Department of Regulatory Agencies recommends no title protection, registration, certification, licensing or other regulation of dieticians/nutritionists at this time.

APPENDIX A

STATE EXPERIENCE IN REGULATING NUTRITION PRACTITIONERS

INTRODUCTION.

As the applicants have indicated, twenty-four states have passed laws regulating various nutrition practitioners. There is much that Colorado can learn from the experience of those states and the quality of the laws passed to regulate in this field. Every state that regulates nutrition practitioners was contacted and the information obtained from those contacts is set out below.

| State | Year Law Enacted | Law | Type of | Number of Licensees | Number of Activity | Complaint |
|----------------|---------------------------|-----------------------|--|----------------------------|-----------------------------|--|
| ALABAMA | 1984 Amended 10/89 | Title (License | Protection of 700) not required for persons not using restricted title) | 600 | (Potential relate to | Few complaints. Most complaints weight loss clinics, which have an R.D. consultant. |

(NOTES: This is a 3-person board which is staffed by one full-time secretary who was formerly the lobbyist for the dietitians in passing the recently amended Act. This agency is not part of Alabama state government. Licenses cost \$25.00 per year and all persons meeting R.D. standards were grandfathered under the law.)

| | | | | |
|-----------------|---|--|----------------------------|----------------------|
| ARKANSAS | 1989 (Worked for 8 yrs. to get law passed) | Mandatory Practice Act, protects "licensed dietitian" and "provisional dietitian" | 140 (350 projected) | No complaints |
|-----------------|---|--|----------------------------|----------------------|

(NOTES: Arkansas' seven member dietitian's board, (three public members and four dietitians), is not part of Arkansas state government. Regular licenses cost \$110 per year or \$125 per year for a provisional license. License by reciprocity "will cost more." Part-time secretary is only staff. No complaint authority. Complaints referred to Attorney General's Office.)

| State | Year Law Enacted | Law Title | Type of protection | Licenses | Number of Activity | Complaint |
|---|-------------------|---------------------------------|--|---------------------|--|---|
| CALIFORNIA | 1982 | Title | protection for term "dietitian" and term "registered dietitian." | No state See notes. | All are program. ADA, CDA, or Attorneys. | referred to local District 142 complaints filed with California Dietetic Assoc. from 1985-1988. Only 1 case involved a dietitian. |
| (NOTES: California's law allows "private agencies or institutions" to grant the right to use the restricted titles. Dietitians are no longer regulated by any government agency in California. A bill to strengthen this law was introduced in February of 1988 but was subsequently withdrawn by its sponsor, Senator Kopp, after a negative sunrise review by the legislative unit of the California Division of Consumer Services.) | | | | | | |
| FLORIDA | 1988 | | practice protection titles, licenses dietitian, nutritionist and nutritionist counselor protected. | 2,100 | 5 complaints, | "none serious". |
| (NOTES: This is a council under the Florida Board of Medicine. Nutrition practitioners employed before 1988 were grandfathered. There are 13 exemptions under the law. "Only the educated ones are becoming licensed, others are not," according to Program Administrator.) | | | | | | |
| GEORGIA | 1984 Amended 1989 | "Licensed dietitian" protected. | | 740 | "Quiet" | |
| IOWA | 1985 | Title | protection | 673 active | Few Complaints licenses. | {4 complaints in 171 inactive 1989, no disciplinary actions} |

| State | Year Law Enacted | Law | Licensees | Number of Activity | Complaint |
|--|-------------------------|--|-----------------------|---------------------------|--|
| KANSAS | 1988 | Practice and title protection ("Dietitian" and "licensed dietitian" protected. | 0 | | None |
| (NOTES: This program is staffed by one F.T.E. and is just about to begin licensing. The law contains "20 to 30 exemptions.") | | | | | |
| KENTUCKY | 1988 | Title protection. (lifetime license, no renewals) | 150 potential) | (600 | None |
| (NOTES: Persons are licensed as "certified nutritionists". This is a five member board with one public member; no complaint power; no grandfather clause; standard license costs \$50.) | | | | | |
| LOUISIANA | 1987 | Practice protection ("licensed dietitian/nutritionist" or any form are protected titles.) | 800 | 15 in 1990, 1/2 | regarding weight loss clinics, balance due to licensing, not due to harm. |

(NOTES: Weight loss clinics must consult with a dietitian; ADA standards are used throughout the statute.)

| State | Year Law Enacted | Law | Type of | Licensees | Number of Activity | Complaint |
|--------------------|--|---------------------------|--|------------------|---------------------------------|-------------------|
| MAINE | 1985 (Registration law. 1987 (Law changed to licensure) | | Practice protection for dietitians | 350 | Few complaints | |
| (NOTES: | Board is staffed by .2 F.T.E. Law contains broad exemptions for "persons giving general nutritional related information" and for persons involved in food distribution. | | | | | |
| MARYLAND | 1986 Registration Licensing passed 1989 | Practice and title | protection | 1,200 | Few complaints regarding | practice |
| (NOTES: | Maryland has a seven member board, five dietitians and two consumer members.) | | | | | |
| MISSISSIPPI | 1986 | Title | protection | about 300 | No practice | complaints |
| MONTANA | 1987 | Title | protection | 132 | No complaints | |
| (NOTES: | This program is administered under the Montana Medical Board, which Board includes a dietitian as a member. | | | | | |
| NEBRASKA | 1988 | Title | protection "certified nutritionist" | 235 | No complaints | |

| State | Year Law Enacted | Law | Type of Licensees | Number of Activity | Complaint |
|---------------------|--|--|---------------------------------------|---|--|
| NEW MEXICO | 1989 | Practice | 100 of dietetics and nutrition | 1 complaint on | license violation |
| NORTH DAKOTA | 1986 title protection 1989 practice protection | Practice | 259 LRDs protection | 8-10 since 1986 33 Nutritionists | Very few recently |
| (NOTES: | This is another "free standing Board" which is staffed by a "1/3 time secretary.) | | | | |
| OHIO | 1986 | Practice of dietetics | 2,600 | 88 complaints; 122 cases, 2/3 | dismissed, 22 outstanding cases |
| (NOTES: | Ohio has one of the strongest regulatory programs and is further discussed below. | | | | |
| OKLAHOMA | 1984 | Title | 500 | 5 or 6 in the | last several years |
| | | protection "registered dietitian" | | | |
| OREGON | 1989 | Title | 0 | 0 (program just started) | None |
| | | protection "licensed dietitian" or "L.D." | | | |

(NOTES: **Oregon has the smallest staff of any of the states, .25 F.T.E., for this type of program.**

| State | Year Law Enacted | Law | Type of | Licensees | Number of Activity | Complaint |
|---------------------|--|------------------|--|------------------|-------------------------------|----------------------|
| RHODE ISLAND | 1989 | Title | protection | 50 | | No complaints |
| TENNESSEE | 1987 | Voluntary | registration | 150 | None (potential-1,200) | |
| (NOTES: | Tennessee grandfathered all practitioners who were active before June 30, 1988. Although Tennessee's law was passed in 1987, its rules and regulations were not in place until January of 1990. | | | | | |
| TEXAS | 1983 | | Title protection (voluntary) "registered dietitian" and "licensed dietitian" protected titles | | 2,859 | "Infrequent" |
| UTAH | 1986 | Title | protection for "dietitians" | 279 | None | |
| WASHINGTON | 1988 | Title | protection | 410 | "Quiet" | |

