# Ethical and Legal Considerations in CAM Practices

## Complementary and Alternative Modalities
## Advanced Healthcare

**Webinar Date: February ___, 2009**
**Sponsor: Natural Solutions Foundation**
**www.HealthFreedomUSA.org**

**Webinar Provider: www.Vital-Connections.com**

**Webinar presented by Ralph Fucetola JD**
**www.VitaminLawyer.com**
**34 Years Practicing Attorney**
**Expertise in Alternative Health Practices**

**This Webinar covers:**
**Alternative Health Practices are not the Practice of Medicine**
**Informed Consent**
**Structuring Your Practice**
**Defendable Record Keeping**
**The Forbidden Words**

***"Therapies that may benefit" are not the "Treatment of Disease"***

**This eBook Contains:**



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# 1. Introduction

**Ralph Fucetola JD**
**THE VITAMIN LAWYER.COM CONSULTANCY**
**Newton, New Jersey 07860**
**973.300.1519 – Fax: 300.5486**

February ____, 2009

**Welcome to the CAM Ethics and Legalities Webinar!**

This eBook is companion information for the Webinar.

Who is: Ralph Fucetola JD, the Vitamin Lawyer? Curriculum Vitae, see: www.vitaminlawyer.com

Graduated with Distinction from Rutgers College in 1967; graduated from Rutgers Law School in 1971. Practiced law for 34 years. I provide legal consulting services -- private and confidential, competent electronic professional advice and counsel to my Dietary Supplement and alternative healthcare modality clients, for the purpose of compliance with International, State and Federal (including FTC and FDA) requirements for communicating about the advertising and sale of dietary supplements and/or providing of advanced health care services and information.

Alternative health practices can be generally defined as traditional or other practices that are used by individuals, often for self-help, to achieve and maintain a healthy status, either on their own or complementary to standard medical care. These practices do not include the potentially dangerous use of invasive techniques and toxic drugs that are the province of licensed medicine. They do, however, include developing therapies and nonstandard approaches that are outside the scope of licensed medicine. These are sometimes referred to as "Complementary and Alternative Modalities" (CAM).

CAM health practices can be generally defined as traditional or other practices that are used by individuals, often for self-help, to achieve and maintain a healthy status, either on their own or complementary to standard medical care. These practices do not include the potentially dangerous use of invasive techniques and toxic drugs that are the sole province of licensed medicine. They do, however, include developing therapies and nonstandard approaches that are outside the scope of licensed medicine. Such approaches as Holistic Nutrition, Homeopathy, Hands-on-Healing, Magnetics, Sound Health, Energy Therapies, Biofeedback, Meditation, Breath Work, Reiki, Chi Gong, Tai Chi and Herbology are examples of complementary and alternative therapeutic practices. Traditional Chinese, Ayurvedic medicine or folk remedies and "Dr. Mom" home remedies are also examples of CAM practices.

The Webinar slideshow covers the topics listed on the next page. It makes reference to several forms that may be useful to the practitioner. These include an Informed Consent form and formats for Standard Operating Procedures (specially formatted for CAM practitioners) and a Site Use Statement for your web site, including such issues as intellectual property, copyrights, trademarks, privacy, legal disclosures and disclaimers.

Very truly yours,

Ralph Fucetola, JD


Attorney at Law in NJ – 1973 - 2006 – All Rights Reserved.

# 2. Outline of Webinar Slideshow

1. Ethical and Legal Considerations in CAM Practices

2. Ralph Fucetola JD

3. CAM Practices Webinar

4. Is it “Alternative Medicine” or Advanced Healthcare?

5. Advanced Healthcare

6. Historical Antecedents

7. Herbalists Charter

8. Therapy not Treatment

9. Informed Consent

10. Structuring Your Practice

11. Threats to Practice - Threats to Health Freedom

12. Your Internet Practice – Site Use Statement

13. Defendable Record Keeping

14. The Forbidden Words

15. Disclaimers

16. Resources

17. Thank you…

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# 3. Standard Disclaimer Format

Products and Services are not offered to diagnose or prescribe for medical or psychological conditions nor to claim to prevent, treat, mitigate or cure such conditions, nor to recommend specific products or services as treatment of disease or to provide diagnosis, care, treatment or rehabilitation of individuals, or apply medical, mental health or human development principles, to provide diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition. Therapies that may benefit are recommended based upon traditional uses and are not yet generally recognized as substantiated by competent and reliable scientific evidence. Any use of products or services is experimental and based upon your informed consent and private license.

[This Disclaimer covers a broad scope of licensed professions but may not include all licenses enforced by law in your state.]

# 4. Informed Consent Form

*[Name of Entity or Practitioner]*

## Informed Consent, Private License & Release

The undersigned hereby grants a **Private License** to the [Institute] and its Practitioners to engage in [bioenergetic and/or other natural healthcare] modalities with the undersigned as expressive association activities. **The undersigned acknowledges that the [Institute] and its agents do not diagnose or prescribe for medical or psychological conditions nor claim to prevent, treat, mitigate or cure such conditions. The [Institute] and its agents do not provide diagnosis, care, treatment or rehabilitation of individuals, nor does the [Institute] or its agents apply medical, mental health or human development principles, but rather provides bioenergetic, herbal and/or other natural healthcare modalities that may offer therapeutic benefit**. The undersigned gives Informed Consent for the services that will be provided. The undersigned hereby releases the [Institute] and its agents from all claims and liabilities arising from the use or misuse of spiritual, mental, bioenergetic and/or **other natural healthcare** modalities, indemnifying and holding [Institute] and its agents harmless from all claims and liabilities there from whatsoever. The [Institute] and its agents reserve all rights.

Date: _____

Signature_____
Name: _____
Address: _____
_____
Phone: _____

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E-mail: _____

Note: Material in [brackets] should be modified to meet the circumstances; use “Center” or “Practitioner” – “Minister” etc.

# 5. Standard Operating Procedures Format

## Professional Practice
## Standard Operating Procedures
## *Client Record Keeping and Retrieval*
## For AER Reporting and Other Purposes

1. The Practitioner normally maintains copies of all paid Invoices.

2. The Practitioner normally maintains regular back-up copies of Client database; this database shall comply with the requirements of the Fair and Accurate Credit Transactions Act for the Payment Card Industry to ensure the security of all customer (and employee) data: see www.pcicomplianceguide.org for details.

3. The Practitioner normally maintains copies of records of products ordered by the Practitioner for resale to clients.

4. The records of products ordered may generally include:

A. Records showing that the products are manufactured in accordance with the marketer's standards for the product.
B. Records showing any available QC analysis to prevent improper manufacturing, packaging, and mislabeling, if any.
C. Reasonably necessary records of claimed "serious adverse events."

5. These records shall be available upon appropriate and legally written request, to regulatory agencies, subject to the privacy rights of clients. If the client, upon notice, objects to release, the client shall have a reasonable opportunity to assert such objection.

6. Record Types

(a) The research and other records of the Practitioner are important assets. Such records include essentially all records produced by or on behalf of the Practitioner, whether paper or electronic, in the possession and control of the Practitioner. Records include, but are not limited to, such items as research notes, draft and other research or other reports, memorandum, e-mail, contracts, a case study, a computerized desk calendar, an appointment book or an expense record.

(b) The law requires the Practitioner to maintain certain types of records, usually for a specified period of time. Records should be retained for any required period of time.

(c) The Practitioner expects all employees to fully comply with any published records retention or destruction policies and schedules, provided that all employees should note the following general exception to any stated destruction schedule:

(d) "If you believe, or the Practitioner informs you, that Practitioner records are relevant to litigation, or potential litigation (i.e., a dispute that could result in litigation), then you must preserve those records until Legal Advice determines the records are no longer needed. This exception supersedes any previously or subsequently established destruction schedule for those records. If you believe that exception may apply, or have any question regarding the possible applicability of that exception, please contact the Practitioner."

(e)From time to time the Practitioner establishes retention or destruction policies or schedules for specific categories of records in order to ensure legal compliance, and also to accomplish other objectives, such as preserving intellectual property and cost management. Several categories of documents that bear special consideration are identified below. While minimum retention periods are suggested, the retention of the documents identified below and of documents not included in the identified categories should be determined primarily by the application of the general guidelines affecting document retention identified above, as well as any other pertinent factors. Some of these categories may not apply to a specific Practitioner and are intended to be general information only.

(f1) Tax Records. Tax records include, but may not be limited to, documents concerning payroll, expenses, proof of deductions, business costs, accounting procedures, and other documents concerning the Practitioner's revenues. Tax records should be retained for at least six years from the date of filing the applicable return.

(f2) Employment Records/Personnel Records. State and federal statutes require the Practitioner to keep certain recruitment, employment and personnel information. The Practitioner should also keep personnel files that reflect performance reviews and any complaints brought against the Practitioner or individual employees under applicable state and federal statutes. The Practitioner should also keep all final memoranda and correspondence reflecting performance reviews and actions taken by or against personnel in the employee's personnel file. Employment and personnel records should be retained for six years.

(f3) Board and Committee Materials. Meeting minutes should be retained in perpetuity in the Practitioner's minute book. A clean copy of all Board and Committee materials (such as IRB or Peer Review materials) should be kept for no less than three years by the Practitioner.

(f4) Press Releases/Public Filings. The Practitioner should retain permanent copies of all press releases and publicly filed documents under the theory that the Practitioner should have its own copy to test the accuracy of any document a member of the public can theoretically produce against the Practitioner. All filings with government agencies, such as the FDA and FTC, must be permanently retained unless Practitioner counsel directs their destruction in writing.

(f5) Legal Files. Legal counsel should be consulted to determine the retention period of particular documents, but legal documents should generally be maintained for a period of ten years.

(f6) Marketing and Sales Documents. The Practitioner should keep final copies of marketing and sales documents for the same period of time it keeps other corporate files, generally three years.

(f7) An exception to the three-year policy may be sales invoices, contracts, leases, licenses and other legal documentation. These documents should be kept for at least three years beyond the life of the agreement.

(f8) Development/Intellectual Property and Trade Secrets. Development documents are often subject to intellectual property protection in their final form (e.g., patents and copyrights). The documents detailing the development process are often also of value to the Practitioner and are protected as a trade secret where the Practitioner:

(i) derives independent economic value from the secrecy of the information; and
(ii) the Practitioner has taken affirmative steps to keep the information confidential.

(f9) The Practitioner should keep all documents designated as containing trade secret information for at least the life of the trade secret. Such documents should generally be marked, “Confidential.”

(f10) Contracts: Final, execution copies of all contracts entered into by the Practitioner should be retained. The Practitioner should retain copies of the final contracts for at least three years beyond the life of the agreement, and longer in the case of publicly filed contracts.

(F11) Electronic Mail: E-mail that needs to be saved should be either:

(i) printed in hard copy and kept in the appropriate file; or
(ii) downloaded to a computer file and kept electronically or on disk as a separate file.

The retention period depends upon the subject matter of the e-mail, as covered elsewhere in this policy.

(g) Except as provided in this Policy statement, notes, drafts and documents (including electronic copies) that no longer provide relevant information about Practitioner activities should be scheduled for destruction in an orderly manner, so that, for example, paper copies that are destroyed cannot be reassembled, generally by shredding and then trashing same. Electronic storage media should be reformatted or physically destroyed.

## 7 Compliance

(a) The Practitioner complies with the EU Directive on Privacy and Electronic Communications (Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002) and does not process the data referred to in paragraph 1 of the Directive except to the extent and for the duration necessary for services or marketing, if the subscriber or user to whom the data relates has given his/her consent.

(b) Insofar as information collected by the Practitioner may be covered by the Health Insurance Portability and Accountability Act (HIPPA), all such information is maintained as Confidential in strict conformity with HIPPA rules. In such case, the person to whom such information pertains may obtain copies upon written request in conformity with the requirements of HIPPA.

## 8. Practitioner Product Sales Record Keeping (in detail):

1. The Practitioner shall maintain copies of all Order Invoices as shipped.

2. The Practitioner shall maintain regular back-up copies of its Order database.

3. The Practitioner shall maintain copies of records of all products ordered by the Practitioner for resale to customers.

4. The records of products ordered shall generally include:

A. Records showing that the dietary supplements are manufactured consistently as to identity, purity, quality, strength, and composition (Practitioner may rely on manufacturer records in this regard).

B. Records showing analysis to prevent superpotent, subpotent, wrong ingredient, drug contaminant, other contaminant (e.g., bacteria, pesticide, glass, lead), color variation, tablet size or size variation, under-filled containers, foreign material in a dietary supplement container, improper packaging, and mislabeling, if any (Practitioner may rely on manufacturer records in this regard).

C. Records showing the steps taken to reduce risks associated with dietary supplements that are contaminated with harmful or undesirable substances such as pesticides, heavy metals, or other impurities or are not properly labeled to accurately describe what they contain (Practitioner may rely on manufacturer records in this regard).

D. Records of all claimed "adverse events" and the referral thereof to independent third parties to determine if such events are "serious" and should be reported; such records should include the determination whether the event was "serious" and the steps taken to report it. A "serious adverse event" is defined by law as: "The term "serious adverse event" is an adverse event that-- (A) results in-- (i) death; (ii) a life-threatening experience; (iii) inpatient hospitalization; (iv) a persistent or significant disability or incapacity; or (v) a congenital anomaly or birth defect; or (B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A)."

5. These records shall be available to Practitioner, and upon appropriate written request, to regulatory agencies, subject to the privacy rights of customers.

6. All AERs required to be reported shall be reported on FDA Medwatch Form 3500A: http://www.fda.gov/medwatch/SAFETY/3500A.pdf or shall be referred to Manufacturer for reporting.

7. According to FDA, the submission of an AER "will not be construed by FDA as an admission that the dietary supplement involved caused or contributed to the adverse event being reported." See: AER FAQs: http://www.cfsan.fda.gov/~dms/dsaergui.html

Name of Practitioner: _____

Office Address : _____

Prepared by Ralph Fucetola JD
www.siteusestatement.com
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# 6. Site Use Statement Format

**[Name]**
**PRIVACY & SITE USE STATEMENT**
**[www]**
**Index of Web Page**


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**- If you purchase any services or products through the web site, you acknowledge that you have done so with informed consent, and you hereby Privately License the provider to provide such products or services.**

- To the best knowledge of the [Organization], food products offered (including Dietary Supplements) comply with the Food Allergen Labeling and Consumer Protection Act of 2004 (Title II of Public Law 108-282) - http://www.cfsan.fda.gov/~dms/alrgact.html.

- This Organization is in compliance with the terms of the Dietary Supplement and Non-Prescription Drug Consumer Protection Act of 2006 and will make all required Adverse Event Reports (AER).

- To the best of the knowledge of the [Organization], none of our products are classified as “CAM” (Complementary and Alternative Medicine) Products and they are not labeled with claims to treat disease.
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**Privacy Statement**

**We have created this privacy statement in order to demonstrate our firm commitment to privacy.** The following discloses our information gathering and dissemination practices for our associated web sites.
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This site maintains a privacy policy in conformity with Section 22575(b).

This site complies with the EU Directive on Privacy and Electronic Communications (Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002) and does not process the data referred to in paragraph 1 of the Directive except to the extent and for the duration necessary for services or marketing, if the subscriber or user to whom the data relates has given his/her consent.

Insofar as information collected by the Organization may be covered by the Health Insurance Portability and Accountability Act (HIPPA), all such information is maintained as Confidential in strict conformity with HIPPA rules. In such case, the person to whom such information pertains may obtain copies upon request in conformity with the requirements of HIPPA.

Please see our information Disclaimers, above.
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**This site has security measures in place to protect the loss, misuse and alteration of the information under our control.** We use secure server technology to ensure none of your private information is intercepted by outside parties. It is the responsibility of the user to ensure their browser is capable of using this technology. We are not responsible for the results of sabotage, changed regulations and laws or other causes beyond our control.

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This site gives users the following option for removing their information from our database to not receive future communications; you can send email to [email] and put "Remove" in the subject line.

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This site gives users the following option for changing and modifying information previously provided by contacting us: by email to [email address] and put "Correct" in the subject line.

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# 7. Webinar Slideshow Text

**1. Ethical and Legal Considerations in CAM Practices**

Complementary and Alternative Modalities
Advanced Healthcare

**2. Ralph Fucetola JD**

**3. CAM Practices Webinar**

- Webinar presented by Ralph Fucetola JD
- 34 Years Practicing Attorney
- Expertise in alternative practices
-
- This Webinar will cover:
  - Alternative Healthcare Practices are not the Practice of Medicine
  - Informed Consent
  - Structuring Your Practice
  - Your Internet Practice
  - Defendable Record Keeping
  - The Forbidden Words

“Therapies that may benefit” are not the “Treatment of Disease”

**4. Is it “Alternative Medicine” or Advanced Healthcare**

- Alternative health practices can be generally defined as
- Traditional or other practices
- that are used by individuals, often for self-help,
- to achieve and maintain a healthy status,
- either on their own or complementary to standard medical care.

- These practices do not include the potentially dangerous use of invasive techniques and toxic drugs that are the province of licensed medicine.
- They do, however, include developing therapies and nonstandard approaches that are outside the scope of licensed medicine. These are sometimes referred to as "Complementary and Alternative Modalities" (CAM) or Advanced Healthcare.

**5. Advanced Healthcare**

- Includes developing therapies
- and nonstandard approaches
- that are outside the scope of licensed medicine.
- Such approaches as
  - Nutrition, Homeopathy, Hands-on-Healing, Magnetics, Sound Health, Energy Therapies, Biofeedback, Meditation, Breath Work, Reiki, Chi Gong, Tai Chi and Herbology are examples of complementary and alternative therapeutic practices.
  - Traditional Chinese, Ayurvedic medicine or folk remedies and "Dr. Mom" home remedies are also examples of CAM practices.
  - These practices aim, in the words of Philip J. Hodes, PhD., at "more efficient physiological integration and function of the human organism, leading to optimal wellness."

**6. Historical Antecedents**

Herbalists Charter - Part of our Common Law
An Act of Henry the Eighth in the 33rd Reign Year - 1542

**7. Herbalists Charter**

- To protect the "alternative practitioners" of the time from the newly licensed physicians
- Provides Freedom from "**suit, vexation, trouble, penalty, or loss of their goods...**"
- Never repealed

http://home.earthlink.net/~lifespirit23/herbcharter.htm

**8. Therapy not Treatment**

- Code of Medical Ethics of the American Medical Association acknowledges an independent use of the term "therapy."
- The original Hippocratic Oath, with its injunction to "Do no harm." has been replaced by a complex Code detailing the relationship between physician and patient and "alternative" practitioner.
- "Treatment which has no scientific basis" remains condemned (Opinion 3.01)
- Opinion 3.04 allows physicians to "refer" a patient "for therapeutic or diagnostic services to another physician, limited practitioner or any other provider of health care services permitted by law to furnish such services, whenever he or she believes that this may benefit the patient."
- Thus, unscientific "treatment" is distinguished from "health care services permitted by law."
- "Treatment" -- which means the use of standard medicine and surgery to "cure" disease -- is distinguished from other health care services (therapies) which need only meet the lesser "may benefit" standard.
- While physicians "prescribe" treatments for disease, therapies that may benefit may be subject to "referral" thereby further indicating the distinction.
- Thus, for example, Dietary Supplements that support normal structure and function to support therapeutic outcomes can be seen to complement licensed medicine, but not to be held to its strictures, nor limited in its practice to licensed physicians. Moved up
- Since such therapies are not prescription services, members of the public may choose such services without the permission of their physician.

**9. Informed Consent**

- Based on common practices and international law encoded in the Declaration of Helsinki
- The undersigned client hereby grants a Private License to the Human BioAcoustic Research Practitioner to engage in Human BioAcoustic and/or nutritional consultation with the undersigned as expressive association activities. The undersigned acknowledges that the Practitioner is not a licensed medical doctor. The undersigned has been advised to seek the services of a physician if any medical condition is suspected.
- The terms of a standard Informed Consent:
- The undersigned acknowledges that the Practitioner does not diagnose or prescribe for medical or psychological conditions nor claim to prevent, treat, mitigate or cure such conditions, to provide diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition.
- The Practitioner does not provide diagnosis, care, treatment or rehabilitation of individuals, nor does the Practitioner apply medical, mental health or human development principles, but rather provides [modality] and/or nutritional consultation that may offer therapeutic benefit the individual. Any nutrients or traditional remedies recommended may be obtained from any provider of such products.
- The undersigned gives Informed Consent for the [modality], nutritional or other consultation and services that will be provided. The research information developed by the Practitioner may be used for research and publication with personal identification removed.

Please see the standard Disclaimer and standard Informed Consent in the Webinar eBook.

**10. Structuring Your Practice**

- Forming a Company: www.lifespirit.org/vitalaw_coform.htm
- Check with your homeowners insurance agency for a professional home office rider.
- Standard Operating Procedures – SOPs

  Please see the standard SOPs in the Webinar eBook.

**11. Practitioner SOP Outline – Part 1**

1. Records of paid invoices
2. Back-up copies of client database compliant with the Fair and Accurate Credit Transactions
3. Records of products ordered for resale
4. Product order records
A. Records manufacture in accordance with marketer's standards
B. Records showing available QC analysis to
C. Reasonably necessary records of claimed "serious adverse events"
5. Record availability/client notice

**12. Practitioner SOP Outline – Part 2**

6. Record Types
(a) Research and other records
(b) Record retention periods
(c) Stated destruction schedule
(d) Litigation exception
(e) General categories for destruction schedule
(f1) Tax Records
(f2) Employment Records/Personnel Records
(f3) Board and Committee Materials
(f4) Press Releases/Public Filings
(f5) Legal Files
(f6) Marketing and Sales Documents
(f7) An exception to the three-year policy
(f8) Development/Intellectual Property and Trade Secrets
(i) Independent economic value; and
(ii) Affirmative steps to keep information confidential.
(f9) Retention of documents marked "Confidential"
(f10) Contracts
(F11) Electronic Mail
(g) Notes, drafts and documents that no longer provide relevant

**13. Practitioner SOP Outline – Part 3**

7. Compliance
(a) Compliance with EU Directive on Privacy
(b) HIPPA compliance
8. Practitioner Product Sales Record Keeping (in detail)
1. Copies of all Order Invoices as shipped
2. Maintain regular back-up copies of its Order database
3. Maintain copies of records of all products ordered
4. The records of products ordered shall generally include
A. Records showing that manufacture consistent with the cGMPs
B. Records showing analysis of identity
C. Records showing risk reduction steps
D. Records of all claimed "adverse events"
5. Availability of the records
6. All AERs required to be reported
7. Construal of AER report

## 14. Threats to Practice - Threats to Health Freedom

- 2007, Congress awards FDA for its failures by increasing its power. This was done through Sen. Kennedy's FDA "enabling act"
- Health Freedom movement gets the "DSHEA product savings clause" 1011 added to the bill.
- 2008 FDA asked for public comments whether the 1011 savings clause applies to section 301(11) of the act, that gives FDA authority to ban foods that are being studied for use as "treatment of disease."
- A prior "Citizens Petition" from a pharmaceutical company is used by FDA as the excuse to ban a specific form of B6 (Pyridoxamine) to negate the 1994 NNFA Grandfather List of Dietary Ingredients for DSHEA and open all supplements to similar bans is introduced.
- Comments are sought on the idea that FDA can ban any nutritional product it likes from interstate commerce despite specific legislative prohibition preventing the FDA from doing so for products covered under DSHEA...
- In Europe, the EFSD meets to discuss maximum permitted levels (MPLs) of nutrients ...
- Based on another one of those "citizens petitions" from favored "consumer" groups, EPA has expressed its intention to ban topical nano silver...
- FDA seeks to eliminate all nutrients and objects from health use which have had any study about them published of any sort whatsoever - this is the ultimate import of the dangerous section 301(11) of the act.
- FDA/CODEX seek to eliminate all nutrients which have not had met an artificial "significant scientific agreement" standard that violates DSHEA's commercially reasonable standard of "competent and reliable scientific evidence."
- This is the state of Health Freedom in 2009 - and on it goes…
- Read more at: http://www.healthfreedomusa.org/?p=1956

## 15. Your Internet Practice – Site Use Statement

- Internet Presence – Risk / Benefit
- Using Language on the Internet
- Metatags and Hidden Text
- Third Party Links
- Quoting Copyright Materials
- Using Images
- SUS – Site Use Statement

Please see the standard SUS in the Webinar eBook.

## 16. Defendable Record Keeping

- 1. The Practitioner normally maintains copies of all paid Invoices.
- 2. The Practitioner normally maintains regular back-up copies of Client database.
- 3. The Practitioner normally maintains copies of records of products ordered by the Practitioner for resale to clients.
- 4. The records of products ordered may generally include:
- A. Records showing that the products are manufactured in accordance with the marketer's standards for the product.
- B. Records showing any available QC analysis to prevent improper manufacturing, packaging, and mislabeling, if any.
- C. Reasonably necessary records of claimed "serious adverse events."
- 5. These records shall be available upon appropriate and legally written request, to regulatory agencies, subject to the privacy rights of clients. If the client, upon notice, objects to release, the client shall have a reasonable opportunity to assert such objection.
- 6. The research and other records of the Practitioner are important assets.
- The law requires the Practitioner to maintain certain types of, usually for a specified period of time. Records should be retained for any required period of time.
- From time to time the Practitioner establishes retention or destruction policies or schedules for specific categories of records. The retention period depends upon the subject matter of the e-mail, as covered elsewhere in this policy.
- Except as provided in this Policy statement, notes, drafts and documents (including electronic copies) that no longer provide relevant information about Practitioner activities should be scheduled for destruction in an orderly manner, so that, for example, paper copies that are destroyed cannot be reassembled, generally by shredding and then trashing same. Electronic storage media should be reformatted or physically destroyed.
- (7) The Practitioner complies with the EU Directive on Privacy and Electronic Communications (Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002) and does not process the data referred to in paragraph 1

of the Directive except to the extent and for the duration necessary for services or marketing, if the subscriber or user to whom the data relates has given his/her consent.

- Insofar as information collected by the Practitioner may be covered by the Health Insurance Portability and Accountability Act (HIPPA), all such information is maintained as Confidential in strict conformity with HIPPA rules. In such case, the person to whom such information pertains may obtain copies upon written request in conformity with the requirements of HIPPA.

Please see the standard SOPs in the Webinar eBook.

### 17. The Forbidden Words & Federal Regulation

| | |
|---|---|
| • Diagnose<br>• Prescribe<br>• Treat<br>• Prevent<br>• Mitigate<br>• Cure | **1. FDA "Structure and Function Rule"**<br><br>**2. DSHEA Statutory Disclaimer:**<br><br>"These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease." |

### 18. Disclaimers

Does not diagnose or prescribe for medical or psychological conditions nor does it claim to prevent, treat, mitigate or cure such conditions. Researchers do not provide diagnosis, care, treatment or rehabilitation of individuals, nor apply medical, mental health or human development principles.

Please see the standard Disclaimer in the Webinar eBook.

### 19. Resources

- Some Useful Web Sites:
  - Vitamin Lawyer.com Consultancy: www.VitaminLawyer.com
  - Site Use Statement: www.SiteUseStatement.com
  - Natural Solutions Foundation: www.HealthFreedomUSA.org www.NaturalSolutionsFoundation.org
  - Institute for Health Research: www.inhere.org - www.advancedhealthwiki.com

Web Pages:

- SOP Outline: http://tinyurl.com/2eu6yj
- Oversight Seal: http://tinyurl.com/2cfoyb
- Advanced Healthcare Web Ring: http://tinyurl.com/5d6489

### 20. Thank you…

I hope this Webinar has been useful. You can find more information at my blogs:
http://vitaminlawyerhealthfreedom.blogspot.com
http://vitaminlawyerarchives.blogspot.com

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