



Regulatory Compliance Network.com

Supporting Natural Marketing
Compliance with FDA & FTC Regulations

Vitamin Lawyer.com Consultancy
Ralph Fucetola JD

New Jersey Notary #2398815
Attorney at Law in NJ - 1971-2006

Standard Operating Procedures - cGMP
Certification Program

Lawyering 40+ years led me to
develop critical training programs
for dietary supplement and natural
product companies, and "CAM"
advanced health care practitioners,
designed to meet FDA cGMP SOP
training requirements.

Development, Training & Deployment

[1] Therapy Not Treatment

A P.E.L. – Practical, Ethical & Legal
Vitamin Lawyer Webinar

- The distinction between licensed medicine and other health care therapies and services.

[2] This Webinar

- Presenter: Ralph Fucetola JD – 40 Years Experience
- This webinar includes:

AMA Code of Ethics Opinion 3.04
Ethics and Practice
The Forbidden Words
Medical Foods
Disclaimers
Resources

The Webinar eBook Contains all the text from these slides.

[3] Therapy, Not Treatment 1

Physicians now have a broader scope of practice.

- *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 has been replaced by a complex Code detailing the relationship between physician and patient and “alternative” practitioner.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."

[4] Therapy, Not Treatment 2

- 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.
- Since such therapies are not prescription services, members of the public may choose such services with or without the permission of their physician.

[5] Ethics and Practice

- Ethical considerations center on:
 - Informed Consent
 - Codes of Conduct
- Holistic Practitioners Code:
 1. Be Harmless.
 2. Work with Informed Consent.
 3. Work on the Whole Person.
 4. Work on Your Self.
 5. Breathe Deep!
 6. Honor Your Predecessors.

<http://www.lifespirt.org/holisticcode.html>

[6] The Forbidden Words & Federal Regulation

Reserved Medical Terms

<u>Med-Term</u>	<u>Non-Med</u>
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- | | |
|-------------|---------------------------|
| • Diagnose | Evaluate |
| • Prescribe | Recommend |
| • Treat | Therapy, Technique |
| Prevent | } |



- Mitigate } **Harmonize, Balance**
- Cure }
- Also OK
- **Stimulate**
- **Support**
- **Regulate**
- **Maintain**

1. FDA “Structure and Function Rule” - key to the forbidden words.

2. DSHEA Statutory Disclaimer:

“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.”

[7] Medical Foods – State & Federal Regulations

The 2005 Orphan Drug Act

Created New Federal Regulatory: Medical Foods

Definition:

"a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation...." Section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3))

This new regulation limits how State Medical Boards may restrict the use of “Medical Foods” and nutrition in Physician Practices.

See the Vitamin Lawyer P.E.L. Webinar:

Medical Foods and Dietary Supplements in Physician Practice.

[8] Disclaimers

- 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.
- Testimonial results within range of typicality.
- Product Warnings:
 - Keep out of reach of children.
 - Do not exceed recommended dose.
 - Do not use if outer or inner seal is broken or damaged.
- If you have a serious adverse reaction to product, discontinue use immediately, seek medical attention if necessary, and contact us.



- If you are undergoing treatment for a medical condition or if you are pregnant or lactating, consult your physician when taking this product.
- In addition to the above, you may need a Food Allergy Warning:
 “The term “major food allergen” means any of the following: (1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.”
 That warning should read: ALLERGY WARNING: contains [list allergens].
- Finally, there is a special warning for iron containing pills or capsules: “WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.”

[9] Resources - Some Useful Web Sites:

- Standard Operating Procedures Cert Program: www.SOPcertification.com
- Natural Health Options Network: www.NaturalHealthOptions.net
- 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
- LifeSpirit Seminary: www.LifeSpiritSeminary.org
- NutraSpace: www.nutraspace.com
- Roehr MicroTabs: www.BioG-MicroTabs.weebly.com

Vitamin Lawyer Web Pages:

- SOP Outline: <http://tinyurl.com/2eu6yj>
- Oversight Seal: <http://tinyurl.com/2cfoyb>

[10] eBook and Attachments

- Your eBook includes:
- The text of these slides
- Link to the special PEL Forum*
- Informed Consent Form

* An online forum where you ask me questions and share information and ideas with other PEL webinar graduates.

Join here: <http://groups.yahoo.com/group/PEL-Webinars>



- Thank you...
Practical, Ethical & Legal Webinars
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[11] 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>

www.vitaminlawyer.com

ralph.fucetola@usa.net

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[Name]
Bioenergetic Wellness Counseling
Informed Consent, Private License & Release
Energetic and Nutritional Therapies to
Balance the Body for Homeostasis

The undersigned hereby gives Informed Consent and grants a Private License to the Practitioner to provide bioenergetics, nutritional evaluation and recommendations for the undersigned as private expressive association activities.

The undersigned acknowledges that the Practitioner is not a licensed physician or dietician and does not diagnose or prescribe for medical or psychological conditions nor claim to prevent, treat, mitigate or cure such conditions, nor provide diagnosis, care, treatment or rehabilitation of individuals, nor apply medical, mental health or human development principles, but rather provides traditional ministerial counseling , bioenergetic, biofeedback, herbal and/or nutritional modalities that may offer therapeutic benefit by supporting normal structure and function.

The undersigned gives Informed Consent to the services that will be provided. The undersigned hereby releases the Practitioner from all claims and liabilities arising from the use or misuse of traditional, spiritual, mental, bioenergetics, biofeedback and/or nutritional modalities, indemnifying and holding the Practitioner harmless from all claims and liabilities therefrom whatsoever. The Practitioner reserves all rights. Permission is given to use any information about me for research and publication so long as all personal identification is masked.

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