Provision for Adverse Events Reporting System —
– Voluntary Reporting System
–, needs updating
– Dietary Supplements / Research Plan

– 2y. contract NAS/IOM — develop a Regulatory Framework for D Supp.
Develop the ~~kintatype~~ monograph
– DS / GMP Proposal – never cleared OMB prior to Jan 21.

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Divider Title: _____

U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition

Dietary Supplements

Contents

Overview

FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products (prescription and Over-the-Counter). Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to register with FDA nor get FDA approval before producing or selling dietary supplements. Manufacturers must make sure that product label information is truthful and not misleading.

FDA's post-marketing responsibilities include monitoring safety, e.g. voluntary dietary supplement adverse event reporting, and product information, such as labeling, claims, package inserts, and accompanying literature. The Federal Trade Commission regulates dietary supplement advertising.

Recent Announcements

- Letter Regarding Review of a Health Claim that Was the Subject of the Pearson Court Decision **February 23, 2001** NEW
- Guidance on Applying the Structure/Function Rule; Request for Comments **February 22, 2001** NEW
- Letter to Manufacturers Regarding Botanicals and Other Novel Ingredients in Conventional Foods **January 30, 2001**
  - FDA Talk Paper **February 5, 2001**
- Letter Regarding a Dietary Supplement Health Claim That Was The Subject of the *Pearson* Court Decision **December 22, 2000**

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
December 1, 1995

DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994

For decades, the Food and Drug Administration regulated dietary supplements as foods, in most circumstances, to ensure that they were safe and wholesome, and that their labeling was truthful and not misleading. An important facet of ensuring safety was FDA's evaluation of the safety of all new ingredients, including those used in dietary supplements, under the 1958 Food Additive Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act). However, with passage of the Dietary Supplements Health and Education Act of 1994 (DSHEA), Congress amended the FD&C Act to include several provisions that apply only to dietary supplements and dietary ingredients of dietary supplements. As a result of these provisions, dietary ingredients used in dietary supplements are no longer subject to the premarket safety evaluations required of other new food ingredients or for new uses of old food ingredients. They must, however, meet the requirements of other safety provisions.

Signed by President Clinton on October 25, 1994, the DSHEA acknowledges that millions of consumers believe dietary supplements may help to augment daily diets and provide health benefits. Congress's intent in enacting the DSHEA was to meet the concerns of consumers and manufacturers to help ensure that safe and appropriately labeled products remain available to those who want to use them. In the findings associated with the DSHEA, Congress stated that there may be a positive relationship between sound dietary practice and good health, and that, although further scientific research is needed, there may be a connection between dietary supplement use, reduced health-care expenses, and disease prevention.

The provisions of DSHEA define dietary supplements and dietary ingredients; establish a new framework for assuring safety; outline guidelines for literature displayed where supplements are sold; provide for use of claims and nutritional support statements; require ingredient and nutrition labeling; and grant FDA the authority to establish good manufacturing practice (GMP) regulations. The law also requires formation of an executive level Commission on Dietary Supplement Labels and an Office of Dietary Supplements within the National Institutes of Health.

These specific provisions of the DSHEA are synopsized below.

DEFINITION OF DIETARY SUPPLEMENT

FDA traditionally considered dietary supplements to be composed only of essential nutrients, such as vitamins, minerals, and proteins. The Nutrition Labeling and Education Act of 1990 added "herbs, or similar nutritional substances," to the term "dietary supplement." Through the DSHEA, Congress expanded the meaning of the term "dietary supplements" beyond essential nutrients to include such substances as ginseng, garlic, fish oils, psyllium, enzymes, glandulars, and mixtures of these.

The DSHEA established a formal definition of "dietary supplement" using several criteria. A dietary supplement:

- is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.
- is intended for ingestion in pill, capsule, tablet, or liquid form.
- is not represented for use as a conventional food or as the sole item of a meal or diet.
- is labeled as a "dietary supplement."
- includes products such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision).

SAFETY

The DSHEA amends the adulteration provisions of the FD&C Act. Under DSHEA a dietary supplement is adulterated if it or one of its ingredients presents "a significant or unreasonable risk of illness or injury" when used as directed on the label, or under normal conditions of use (if there are no directions). A dietary supplement that contains a new dietary ingredient (i.e., an ingredient not marketed for dietary supplement use in the U.S. prior to October 15, 1994) may be adulterated when there is inadequate information to provide reasonable assurance that the ingredient will not present a significant or unreasonable risk of illness or injury. The Secretary of HHS may also declare that a dietary supplement or dietary ingredient poses an imminent hazard to public health or safety. However, like any other foods, it is a manufacturer's responsibility to ensure that its products are safe and properly labeled prior to marketing.

LITERATURE

The DSHEA provides that retail outlets may make available "third-party" material s to help inform consumers about any health-related benefits of dietary supplements. These materials include articles, book chapters, scientific abstracts, or other third-party publications. These provisions stipulate that the information must not be false or misleading; cannot promote a specific supplement brand; must be displayed with other similar materials to present a balanced view; must be displayed separate from supplements; and may not have other information attached (product promotional literature, for example).

NUTRITIONAL SUPPORT STATEMENTS

The DSHEA provides for the use of various types of statements on the label of dietary supplements, although claims may not be made about the use of a dietary supplement to diagnose, prevent, mitigate, treat, or cure a specific disease (unless approved under the new drug provisions of the FD&C Act). For example, a product may not carry the claim "cures cancer" or "treats arthritis."

Appropriate health claims authorized by FDA--such as the claim linking folic acid and reduce risk of neural tube birth defects and the claim that calcium may reduce the risk of osteoporosis--may be made in supplement labeling if the product qualifies to bear the claim. Under DSHEA, firms can make statements about classical nutrient deficiency diseases--as long as these statements disclose the prevalence of the disease in the United States. In addition, manufacturers may describe the supplement's effects on "structure or function" of the body or the "well-being" achieved by consuming the dietary ingredient. To use these claims, manufacturers must have substantiation that the statements are truthful and not misleading and the product label must bear the statement "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." Unlike health claims, nutritional support statements need not be approved by FDA before manufacturers market products bearing the statements, however, the agency must be notified no later than 30 days after a product that bears the claim is first marketed.

INGREDIENT AND NUTRITION INFORMATION LABELING

Like other foods, dietary supplement products must bear ingredient labeling. This information must include the name and quantity of each dietary ingredient or, for proprietary blends, the total quantity of all dietary ingredients (excluding inert ingredients) in the blend. The label must also identify the product as a "dietary supplement" (e.g., "Vitamin C Dietary Supplement"). Labeling of products containing herbal and botanical ingredients must state the part of the plant from which the ingredient is derived. If a supplement is covered by specifications in an official compendium and is represented as conforming, it is misbranded if it does not conform to those specifications. Official compendia include the U.S. Pharmacopeia, the Homeopathic Pharmacopeia of the United States, or the National Formulary. If not covered by a compendium, a dietary supplement must be the product identified on the label and have the strength it is represented as having.

Labels also must provide nutrition labeling. This labeling must first list dietary ingredients present in "significant amounts" for which FDA has established daily consumption recommendations, followed by dietary ingredients with no daily intake recommendations. Dietary ingredients that are not present in significant amounts need not be listed. The nutrition labeling must include the quantity per serving for each dietary ingredient (or proprietary blend) and may include the source of a dietary ingredient (for example, "calcium from calcium gluconate"). If an ingredient is listed in the nutrition labeling, it need not appear in the statement of ingredients. Nutrition information must precede ingredient statements on the product label.

NEW DIETARY INGREDIENTS

Supplements may contain new dietary ingredients--those not marketed in the United States before October 15, 1994--only if those ingredients have been present in the food supply as an article used for food in a form in which the food has not been chemically altered or there is a history of use, or some other evidence of safety exists that establishes that there is a reasonable expectation of safety when the product is used according to recommended conditions of use. Supplement manufacturers must notify FDA at least 75 days before marketing products containing new dietary ingredients, providing the agency with the information on which the conclusion that a dietary supplement containing the new dietary ingredient "will reasonably be expected to be safe" was based. Any interested party, including a manufacturer of a dietary supplement, may petition FDA to issue an order prescribing the conditions of use under which a new dietary ingredient will reasonably be expected to be safe.

GOOD MANUFACTURING PRACTICES (GMPs)

DSHEA grants FDA the authority to establish GMP regulations governing the preparation, packing, and holding of dietary supplements under conditions that ensure their safety. These regulations are to be modeled after current good manufacturing practice regulations in effect for the rest of the food industry. FDA intends to work with the supplement industry and other interested persons to develop GMPs and, in doing so, will seek public comment as to their scope.

COMMISSION ON DIETARY SUPPLEMENTS

The DSHEA requires the formation of a Commission to conduct a study and make recommendations on the regulation of label claims and statements for dietary supplements and procedures for the evaluation of the claims. The members of the Commission will evaluate how best to provide truthful, scientifically valid, and not misleading information to consumers so that they can make informed and appropriate health care choices. The Commission will be composed of seven members, appointed by the President, with experience in dietary supplements and in the manufacture, regulation, distribution, and use of supplements. Three members must be qualified by scientific training and experience to evaluate supplements' health benefits, and one of these must be trained in pharmacognosy, medical botany, traditional herbal medicine, or other related sciences. All Commission members and staff should be unbiased about supplement use.

On October 2, 1995, the White House announced the names of the seven individuals the President intends to appoint to the Commission. The members include nutritionists, industry representatives, a pharmacognosist, and attorneys.

The Commission will submit a final report including recommendations and legislation related to label claims for dietary supplements to the President and Congress within two years of convening.

OFFICE OF DIETARY SUPPLEMENTS

The HHS Secretary will establish an office within the National Institutes of Health to explore the potential role of supplements to improve health care in the U.S. The office will also promote scientific study of supplements and their value in preventing chronic diseases; collect and compile scientific research, including data from foreign sources and the NIH Office of Alternative Medicine; serve as a scientific adviser to HHS and FDA; and compile a database of scientific research on supplements and individual nutrients.

EFFECTIVE DATE

DSHEA's provisions for use of nutritional support statements and third-party literature became effective when the law was signed. The effective date for other labeling provisions and any FDA implementing regulations is after December 31, 1996, although manufacturers may label their products consistent with provisions of DSHEA until that date.

This document was issued on December 1, 1995.
For more recent information on Dietary Supplements

U.S. Food and Drug Administration

FDA Talk Paper

FDA Talk Papers are prepared by the Press Office to guide FDA personnel in responding with consistency and accuracy to questions from the public on subjects of current interest. Talk Papers are subject to change as more information becomes available.

T01-09
February 5, 2001

Print Media: 202-205-4144
Broadcast Media: 301-827-3434
Consumer Inquiries: 888-INFO-FDA

FDA ISSUES LETTER TO INDUSTRY ON FOODS CONTAINING BOTANICAL AND OTHER NOVEL INGREDIENTS

The Food and Drug Administration (FDA) recently issued a letter to the food industry restating the requirements of the Federal Food, Drug, and Cosmetic Act regarding the marketing of conventional foods containing novel ingredients, including botanicals. FDA is issuing this letter because of the significant growth in the marketing of foods containing these ingredients.

FDA is concerned that some botanical and other novel ingredients that are being added to conventional foods are neither approved food additives, nor generally recognized as being safe for these uses. This letter serves as a reminder to the industry of the longstanding legal requirements governing conventional food products.

In issuing this letter, FDA is also reminding manufacturers about the legal requirements regarding claims on conventional foods. The Food Drug and Cosmetic Act allows for certain claims such as:

- health claims -- a claim characterizing the relationship between a food substance and a disease or health related condition;
- nutrient content claims -- a claim characterizing the level of a nutrient in a food; and
- structure/function claims -- a claim characterizing the effect of a food on the structure or function of the body.

FDA must review health claims and nutrient content claims prior to marketing, unless the claim has been authorized by regulation or by statute under the authoritative statement notification procedure.

Manufacturers are encouraged to contact the agency regarding the regulatory status of ingredients and claims they intend to use for foods.

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
January 30, 2001

Letter to Manufacturers Regarding Botanicals and Other Novel Ingredients in Conventional Foods

Dear Manufacturer:

The Food and Drug Administration (FDA) has seen a significant growth in the marketplace of conventional food products that contain novel ingredients, such as added botanical ingredients or their extracts that have not previously been used as food ingredients. These products often bear claims to provide certain health benefits. FDA is writing to remind you about the requirements of the Federal Food, Drug, and Cosmetic Act (the Act) regarding the marketing of conventional foods containing novel ingredients, including botanicals. Of particular concern to the agency are the use of these ingredients and claims made on the label or in labeling.

Many ingredients intentionally added to a conventional food are food additives. Food additives require pre-market approval based on data demonstrating safety submitted to the agency in a food additive petition, ordinarily by the producer. The agency issues food additive regulations specifying the conditions under which an additive has been demonstrated to be safe and, therefore, may be lawfully used.

A substance is exempt from the definition of a food additive and thus, from pre-market approval, if, among other reasons, it is generally recognized as safe (GRAS) by qualified experts under the conditions of intended use. Accordingly, for a particular use of a substance to be GRAS, there must be both technical evidence of safety and a basis to conclude that this evidence is generally known and accepted by qualified experts. The technical element of the GRAS standard requires that the information about the substance establish that the intended use of the substance is safe, i.e., that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use. In addition, the data and information to establish the technical element must be generally available, and there must be a basis to conclude that there is consensus among qualified experts about the safety of the substance for its intended use. Any substance added to food that is an unapproved food additive (e.g., because it is not GRAS for its intended use) causes the food to be adulterated (Section 402(a)(2)(C) of the Act), and the food cannot be legally imported or marketed in the United States.

The FDA is concerned that some of the herbal and other botanical ingredients that are being added to conventional foods may cause the food to be adulterated because these added ingredients are not being used in accordance with an approved food additive regulation and may not be GRAS for their intended use.

Concerning label claims, the Act authorizes health claims, a claim characterizing the relationship between a substance and a disease or health-related condition, on food provided specific criteria are

met following the submission of a petition and promulgation of a health claim regulation (Section 403(r)(1)(B)). In addition, the Act authorizes health claims based on authoritative statements through a notification procedure (Section 403(r)(3)(C)).

A food bearing a health claim that is not authorized by regulation or by the Act misbrands the product under section 403(r) of the Act. Currently, the health claims that FDA has authorized by regulation are listed in 21 C.F.R. 101.72 to 101.83 and include such claims as calcium and osteoporosis, sodium and hypertension, dietary lipids and cancer, folate and neural tube defects. As a legal matter, an unauthorized health claim or a claim that suggests that a food is intended to treat, cure or mitigate disease subjects the food to regulation as a drug (Section 201(g)(1)).

Food labels and labeling may also bear authorized nutrient content claims (Section 403(r)(1)(A)). A nutrient content claim is a claim characterizing the level of a nutrient in a food. As with health claims, FDA authorizes nutrient content claims following the submission of a petition and promulgation of a regulation; the Act also authorizes nutrient content claims based on authoritative statements through a notification procedure (Section 403(r)(2)(G)). A food bearing a nutrient content claim that has not been authorized by regulation or the Act misbrands the product (Section 403(r)(1)(A)). Currently, the nutrient content claims that FDA has authorized by regulation are located in 21 C.F.R. 101.13 and 21 C.F.R. 101.54 to 101.67. Some nutrient content claims, such as "high" and "more" are defined only for substances with an established Reference Daily Intake (RDI) or Daily Reference Value (DRV). A list of nutrients with RDIs can be found at 21 C.F.R. 101.9(c)(8)(iv); nutrients with DRVs are listed in 21 C.F.R. 101.9(c)(9). Other nutrient content claims may be made for any substance, provided that the requirements of the authorizing regulation are met. For example, a manufacturer may make a statement about a substance for which there is no established RDI or DRV so long as the claim specifies only the amount of the substance per serving and does not imply that there is a lot or a little of the substance in the product.

A conventional food label or labeling may bear statements about a substance's effect on the structure or function of the body provided such statements do not claim to diagnose, mitigate, treat, cure, or prevent disease and are not false or misleading. Additionally, the claimed effect must be achieved through nutritive value.. In the preamble to the final rule governing structure/function claims on dietary supplements (65 FR 1000 at 1034; January 6, 2000), FDA stated that the agency is likely to interpret the dividing line between structure/function claims and disease claims in a similar manner for conventional foods as for dietary supplements. As a legal matter, a structure/function claim on a food that is not achieved through nutritive value, or a claim that a food will treat or mitigate disease, subjects the product to regulation as a drug under section 201(g)(1) of the Act.

Questions regarding the regulatory status of ingredients that you intend to use in your conventional foods and how to file a GRAS Notification or Food Additive Petition should be directed to Dr. George Pauli, Director of the Division of Product Policy, Office of Premarket Approval, Center for Food Safety and Applied Nutrition, HFS-205, 200 C Street, S.W., Washington, D.C. 20204. Questions regarding labeling claims for these foods should be directed to Mr. John B. Foret, Director of the Division of Compliance and Enforcement, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, HFS-810, 200 C Street, S.W., Washington, D.C. 20204.

FDA's general food labeling requirements are located in Title 21 of the Code of Federal Regulations part 101, and additional guidance can be obtained from the Food Labeling Guide that is available on the FDA web page, www.fda.gov.

Sincerely yours,

Christine J. Lewis, Ph.D.
Director
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition

February 5, 2001 Talk Paper: FDA Issues Letter To Industry On Foods Containing Botanical And Other Novel Ingredients

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This document was issued on January 30, 2001.
For more recent information on Dietary Supplements
See http://www.cfsan.fda.gov/~dms/supplmnt.html

Hypertext updated by kwg 2001-FEB-07

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
May 1997; Updated April 1999

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Overview of Dietary Supplements

What is a dietary supplement?

A dietary supplement is any product taken by mouth that contains a so-called "dietary ingredient" and its label clearly states that it is a dietary supplement.

The "dietary ingredients" in dietary supplements may include vitamins, minerals, herbs, and amino acids as well as substances such as enzymes, organ tissues, metabolites, extracts or concentrates. Dietary supplements can be found in many forms such as pills, tablets, capsules, liquids or powders. They must be identified on the label as a dietary supplement.

Where do dietary supplements fit in the priorities for FDA?

The Center for Food Safety and Applied Nutrition (CFSAN) oversees the agency's activities related to dietary supplement products. Dietary supplements are one of the high priority areas for CFSAN. The specific activities relative to dietary supplements, including ephedra, new dietary ingredients, health claims and stakeholder outreach, are described along with other Center priorities in CFSAN 1999 Program Priorities.

How are dietary supplements regulated?

The label of a dietary supplement must contain enough information about the composition of the product so that consumers can make informed choices. (The information must be presented in FDA-specified format.) The manufacturer must make sure the label information is truthful and not misleading. The manufacturer is also responsible for making sure that all the dietary ingredients in the supplements are safe. Manufacturers and distributors do not need to register with FDA or get FDA approval before producing or selling dietary supplements.

How do I report a problem or illness caused by a dietary supplement?

FDA can be contacted to report general complaints or concerns about food products, including dietary supplements. You may telephone or write to FDA.

If you think you have suffered a serious harmful effect or illness from a dietary supplement, your health care provider can report this by calling FDA's MedWatch hotline at 1-800-FDA-1088 or using the website http://www.fda.gov/medwatch/report/hcp.htm. The MedWatch program allows health

care providers to report problems possibly caused by FDA-regulated products such as drugs, medical devices, medical foods and dietary supplements. The identity of the patient is kept confidential.

Consumers may also report an adverse event or illness they believe to be related to the use of a dietary supplement by calling FDA at 1-800-FDA-1088 or using the website http://www.fda.gov/medwatch/report/consumer/consumer.htm. FDA would like to know when a product causes a problem even if you are unsure the product caused the problem or even if you do not visit a doctor or clinic.

Are advertisements for dietary supplements regulated by FDA?

No. The Federal Trade Commission (FTC) handles advertising for dietary supplements and most other products sold to consumers. FDA works closely with FTC in this area, but their work is directed by different laws.

Does FDA routinely analyze the content of Dietary Supplements?

FDA has limited resources to analyze the composition of food products, including dietary supplements. So, FDA focuses first on public health emergencies and products that may have caused injury or illness. Then products thought to be fraudulent or in violation of the law are analyzed. FDA uses the remaining funds for routine monitoring of products pulled from store shelves. FDA does not analyze supplement products before they are sold to consumers. The manufacturer is responsible for ensuring that the ingredient list is accurate and that the ingredients are safe. They are also required to make sure that the content matches the amount declared on the label.

FDA does not have adequate resources to analyze dietary products sent by consumers who want to know their content. Instead, consumers may contact the manufacturer or a commercial laboratory.

Are all ingredients required to be declared on the label?

Other ingredients in the product must be listed in the ingredient statement beneath the "Supplement Facts" panel. The types of ingredients listed there would include gelatin, sugars, starch, colors, stabilizers and preservatives.

Are there restrictions on size of the pill or how much of a nutrient can be in one serving of a Dietary Supplement?

There are no rules that limit a serving size or the amount of nutrients in any form of dietary supplements. This decision is made by the manufacturer and does not require FDA review or approval.

What kinds of claims can be made on the labels of Dietary Supplements?

As with other food products, the manufacturer can put certain claims on the product label. These

claims tell consumers about the nutritional value of the product. Claims defined by FDA to describe the nutrient content of a product, like "good source" or "high", can appear on the label if one serving meets the definition. There are specific rules as to which substances can be listed using these nutrient content claims.

Manufacturers can also put FDA-approved "health claims" on a product label. Health claims describe the connection between a nutrient or food substance and a disease or health-related condition. Claims about these diet/disease relationships can appear on the label if the content of the product meets the FDA requirements and if the claim is one of the approved health claims.

Why do some supplements have wording that says: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease"?

Certain statements may be included on the label that give the manufacturer's description of the role of the dietary supplement. These statements are not authorized by FDA. The manufacturer is responsible for ensuring that these statements are accurate and truthful. For this reason, the law says that if a dietary supplement label includes this information, it must also state that FDA has not evaluated the statement.

Where can I get information about a specific Dietary Supplement?

Manufacturers do not need FDA approval to sell their supplement products. This means that FDA does not keep a list of manufacturers or products on the market. If you want more specific information than the label tells you about the products, you may contact the manufacturer directly.

Office of Special Nutritionals, May 1997; Updated April 1999

For more recent information on Dietary Supplements
See http://www.cfsan.fda.gov/~dms/supplmnt.html

Hypertext updated by cjm/ear/kwg/dms 2001-JAN-26

U.S. Food and Drug Administration

Reporting Unlawful Sales of Medical Products on the Internet

If you find a Website you think is illegally selling human drugs, animal drugs, medical devices, biological products, foods, dietary supplements or cosmetics over the Web, please select ***one*** of the three options below to report to FDA.

If your report:

- involves a life-threatening situation due to an FDA-regulated product you purchased from a Website, call 301-443-1240 immediately. (Also contact your health professional for medical advice.)
- involves a serious reaction or problem with an FDA-regulated product, fill out FDA's MedWatch reporting form. (Also contact your health professional for medical advice.)
- for problem Websites that DO NOT involve a life-threatening or otherwise serious reaction, fill out the form below. To report e-mails promoting medical products that you think might be illegal, forward the email to *webcomplaints@ora.fda.gov*.

Any personal information you send us about yourself will be kept confidential.

Privacy Statement

Website Address (URL) You are Reporting *(required)*:

Date You Visited this Website:

Owner of Website:

Street Address of Website:

Problem or Concern about this Website *(required)*:

In case we need to contact you for more information, please provide one of the following:

First Name: Last Name:

Daytime Phone (with area code): Fax Number (with area code):

E-mail Address:

Street Address:

City: State: Zip Code:

Submit Form Clear Form

Although FDA cannot respond to every e-mail individually, the agency will evaluate every complaint received and take suitable action.

Privacy Statement

FDA Home Page | Website Index | Buying Medical Products Online | Search the FDA Website

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Sarah E. Taylor, J.D., R.D., M.P.H.

Sarah Taylor is Of Counsel with the law firm of Covington & Burling in Washington, D.C., practicing in the areas of food and drug law, advertising law, and trade association law. Ms. Taylor has a substantial law practice devoted to the regulation of foods and dietary supplements. Prior to joining Covington & Burling in 1989, Ms. Taylor served the U.S. Congress as a Policy Analyst specializing in food and drug policy issues with the Congressional Research Service, Library of Congress from 1984-89. She also served as a clinical research nutritionist with the Mt. Sinai Hypertension Trial, Mt. Sinai Hospital/University of Minnesota, Minneapolis, MN, 1983-84.

Ms. Taylor has published numerous articles in professional journals on the promotion of food products and the First Amendment. Ms. Taylor was awarded the 2000 Burton Award For Legal Achievement for *Promoting "Functional Foods" and "Nutraceuticals" on the Internet*, published in the Food and Drug Law Journal in 1999. Her publications on related topics include *The NLEA, Health Claims, the First Amendment, and Health Claims for Foods: Present Law, Future Policy*, published in the Food and Drug Law Journal.

Sarah Taylor received her bachelor's degree in Dietetics from the University of Wisconsin-Madison in 1980 and completed her Dietetic Internship at the St. Paul-Ramsey Medical Center, St. Paul, MN in 1982. She received a Master of Public Health degree from the University of Minnesota in 1983. Ms. Taylor received her law degree from the George Washington University National Law Center in Washington, D.C. in 1989, and is a member of *The Order of the Coif.*

Her professional activities include membership in the District of Columbia Bar Association. She is a Registered Dietitian and a member of the American Dietetic Association.

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Testimony of Sarah E. Taylor, Esq.
Covington & Burling
Washington, D.C.

Before the

White House Commission on
Complementary and Alternative Medicine (CAM) Policy
March 26, 2001

Testimony of Sarah E. Taylor, Esq.*
Covington & Burling
Washington, D.C.

Before the

White House Commission on
Complementary and Alternative Medicine (CAM) Policy
March 26, 2001

Panel #4: Advertising and Marketing of CAM Products

Good Afternoon. It is a privilege for me to address the White House Commission on Complementary and Alternative Medicine Policy. Thank you for this opportunity to discuss the key issues which I believe must be considered for our policies on the advertising and marketing of CAM products to serve the public interest as we confront the continuing advances in biomedical science and communications technology which challenge our current regulatory philosophy.

My views are shaped largely by my experience as an attorney in private practice, specializing in food and drug law, advertising law, and First Amendment law for the past 12 years. A substantial part of my law practice is devoted to advising product manufacturers and marketers on the legal requirements governing the dissemination of health information and claims for CAM products through labels, labeling, advertising, internet, and other marketing materials. Most of my practice in this area concerns food and dietary supplement products, including herbal and botanical products, for which health-related claims are a central marketing focus. I advise companies on the kinds of scientific evidence required to substantiate product claims, and on formulating claims to ensure they accurately reflect the nature and weight of the substantiating evidence on which the manufacturer relies. In addition, I advise companies on setting research priorities to help fill gaps in the scientific evidence in order to solidify the scientific basis for potential product claims. In addition, I represent companies in responding to investigations and enforcement actions brought by federal and state regulatory bodies, including by presenting the substantiating evidence supporting specific claims.

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EXPANDING ENFORCEMENT OF ANTIDECEPTION AND SUBSTANTIATION LAW

While I have worked with a wide range of companies and types of marketing programs - - from small startup companies marketing a single product - - to multifaceted national marketing programs sponsored by industry groups - - it goes without saying that my experience has been with those companies who have taken the responsible step of seeking legal advice to ensure that their marketing activities conform with legal requirements. Such companies quickly learn that the requirements of current law are rigorous and impose on companies a heavy responsibility for ensuring compliance.

Much can be said about the complexities of the legal requirements imposed under the Federal Food Drug and Cosmetic Act (FD&C Act), Federal Trade Commission Act (FTC Act), and the overlapping consumer protection statutes in the 50 states. It is important, however, that in examining these complexities we not lose sight of the bottom line: current law requires all CAM products to be safe under the conditions of use, and all claims must be accurate and fully substantiated based on scientific evidence providing a reasonable basis for the specific claims made. This "tell the truth" standard is the minimum standard required by current law, and it applies uniformly to advertising and marketing materials for CAM products.

To ensure claims comply with current antideception and substantiation standards, substantial resources and technical sophistication can be required. Smaller companies, in particular, may lack the knowledge and resources necessary to ensure full compliance before entering the market. As a result, claims may be misstated or lack appropriate substantiation. It is important to recognize that the presence of unsubstantiated or inaccurate claims in the market is symptomatic of weakness in our system for enforcing current law, and not in the standards applied to the claims themselves. The CAM product market is dynamic and is populated by many new entrants and smaller companies. Accordingly, it seems important to carefully consider ways in which the enforcement of existing antideception and substantiation requirements could be expanded, and positive incentives for compliance enhanced.

Among the most sophisticated and effective "watchdogs" against deceptive claims are competitors in the marketplace. Competitors within the same product market frequently have substantial knowledge concerning the scientific evidence available to support claims. It is not uncommon for competitors to report violations to federal agencies to encourage enforcement action. Responsible companies striving to conform with legal requirements are frustrated when competitors expand their market share through marketing programs based on unfounded claims. Expanding our vision on enforcement and compliance policy to more fully engage the industry in self-regulatory activity could substantially enhance consumer protection.

DEFINING STRATEGIES FOR CONSUMER PROTECTION IN CONFORMANCE WITH "FREE SPEECH" PROTECTIONS MANDATED BY THE FIRST AMENDMENT

1. The First Amendment Mandate

While the government has broad authority to adopt regulations to protect public health and safety, its power to restrict "free speech" to advance its objectives, including by regulating the content of product labeling, advertising, internet, and other forms of commercial speech, is confined by the First Amendment.

Stated succinctly, while claims that are false or propose an unlawful transaction can be banned outright, the government otherwise cannot regulate the content of commercial speech unless it can establish from evidence that the restriction would directly alleviate a genuine harm, and the restriction is reasonably tailored to address the harm and does not overlook obvious, less burdensome alternatives.

The First Amendment presumption favoring the free flow of commercial speech encompasses health-related claims, as recognized in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999). Health claims are constitutionally protected even when the scientific validity of the potential benefit identified has not been fully established. It is sufficient that the claim be stated to communicate accurately the weight of scientific evidence that, in fact, supports the claim.

This reflects a basic constitutional principle of our democracy which protects the freedom of citizens to have access to information to make their own choices, including in matters concerning their health. This founding principle harmonizes with the philosophy embraced in the disciplines of complementary and alternative medicine and consumer "self-care."

The First Amendment principles protecting commercial speech are helpful in distinguishing regulations that provide legitimate consumer protection from those that cross into the zone of unconstitutional paternalism. The Supreme Court addressed this line drawing issue directly in Virginia Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976). The Court made clear that the alternative to paternalism

> assume[s] that . . . information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them. . . . But the choice among . . . alternative approaches is not ours to make or the [government's]. It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us. . . .

Id. at 770.

2. First Amendment Tensions in Current Regulatory Scheme

Under the FD&C Act, the regulatory requirements concerning CAM products are dictated by the classification of the product as a "food," "dietary supplement," "drug," "cosmetic," or "medical device" under the respective statutory definitions. In determining what classification applies, FDA looks to the health information disseminated by the manufacturer to determine the "intended use" of the product. For example, under current FDA policy, a dietary supplement product promoted using the advertising claim, "helps lower cholesterol levels," would be classified as a "drug," subject to NDA requirements. The same dietary supplement product advertised instead with the claim, "helps maintain normal cholesterol levels," would be classified as a "food." This dramatic change in regulatory treatment under the FD&C Act could depend on nothing more than the change of wording from "helps lower" to "helps maintain normal" cholesterol levels. For a dietary supplement product, "drug" status usually presents an impossible barrier to market entry.

Under current policy, the "helps lower cholesterol" claim would be construed as a "disease prevention" claim - - implying that the product is intended for use in the prevention of disease - - and thus qualifying as a "drug" under section 201(g)(1)(B) of the FD&C Act. In contrast, the "helps maintain normal cholesterol" claim would be construed as a "structure function" claim which is permitted under section 201(g)(1)(C) and 403(r)(6) of the act, provided the claim accurately reflects the substantiating scientific evidence.

The policies which have developed around the FD&C Act "drug" definition are difficult to fully justify on public health or antideception grounds, and have become the most significant obstacle to manufacturers attempting to include health information about CAM products in their marketing materials. This is because satisfying the antideception and substantiation requirements of the FTC Act is not sufficient to avoid an enforcement action by the FDA on the ground the claim renders the product an unapproved new drug. Beyond the FTC Act requirements, to avoid FDA enforcement, the manufacturer must be careful to avoid any use of a term that may imply a connection to a disease or health related condition - - even if the claim is true -- because to do so potentially subjects one's food or dietary supplement product to the same kind of premarket approval requirements that apply to prescription drugs. While as a technical matter, FDA approval of health claims on a case-by-case basis is an alternative to NDA approval, the "significant scientific agreement" standard limiting health claim approval was found to violate the First Amendment in Pearson, and the approved claims written by government regulators typically have limited marketing value. Such claims seem premised on the idea that formulating claims in the most scientifically precise manner will best educate consumers and prevent deception. This concept is at odds with the communication principles which drive successful marketing programs.

The severe chilling effect the "drug" definition has on the content of advertising, internet, and other promotional matter may be best appreciated by considering basic marketing principles. Fundamentally, for a marketing program to be successful, it must be effective in motivating consumers to purchase the product being promoted. This means that the content of a promotional message must be compelling to real consumers in the target population groups.

The power of a message to motivate consumer behavior relates to the degree to which the message resonates with the already established motivations of the consumer. This means that, to design an effective promotional campaign, a marketer must not only know the product benefits, but must attempt to understand the mindset of the relevant consumer population groups so that the benefits can be communicated effectively. The health messages that are most motivating to one group of consumers, may be different than those for another group - - even for the same product benefit. These differences typically reflect the distinctive health and lifestyle concerns inherent to each group, and may require market segmentation based on age, gender, or other demographic characteristics. In all cases, to be effective, marketers must have the flexibility to respond to shifting market dynamics, and to frame and reframe claims to keep them fresh and meaningful to real consumers.

On the other hand, the responsibility of manufacturers to ensure product safety merits emphasis here. CAM products typically are marketed directly to consumers as over-the-counter products. Accordingly, product safety must be established under the promoted conditions of use. Products, which by virtue of formulation or design cannot be established as safe are prohibited and cannot be lawfully marketed.

In some cases, potential safety concerns can be resolved appropriately through the disclosure of information concerning potential health risks and warning statements. This approach may apply where a CAM product is inherently safe, but may be used for health conditions that may be confused with more serious conditions requiring medical treatment. Safety issues of this kind are routinely considered as labeling is formulated for over-the-counter drug products being switched from prescription status. As a general matter, the disclosure of the pertinent health risk information and appropriate warnings are effective where such information equips the consumer to distinguish the symptoms of the more serious disease condition and obtain timely medical treatment.

The marketing of unsafe products is prohibited on several grounds including under the FD&C Act and under federal and state consumer protection laws. Notably, although proving compliance with statutory safety standards can be helpful to a manufacturer defending against a products liability action, it is well established that such compliance does not insulate a company from products liability. Companies thus remain responsible for the safety of their products, and may be held liable for harms caused by a product, even when it fully complies with statutory safety standards.

While marketing materials may be required to contain information and warnings that are necessary for safe product use, regulations which attempt to regulate product safety indirectly by restricting promotional claims raise significant constitutional concerns. The First Amendment requires that a direct connection be established between the harm the government is seeking to avert, and the restriction on commercial speech it would impose. Such a direct connection might exist when the government establishes that consumer deception is averted, for example, by banning false claims or requiring potentially misleading claims to be qualified with clarifying information. On the other hand, it would be difficult to establish the requisite connection where the speech restriction is not established to directly alleviate the harm at issue.

3. Considerations for Further Policy Development

In view of the challenges presented by the advertising and marketing of CAM products using health information and claims, future policy development is merited in the following areas:

- Expand incentives for industry self-regulation and enforcement of existing antideception and substantiation requirements for promotional claims.

- Eliminate policies restricting the dissemination of accurate, substantiated health information and claims in conformance with First Amendment requirements.

- Ensure that restrictions on the content of promotional messages can be established to directly alleviate a genuine harm to consumers, such as to prevent deceptive claims, or disclose information necessary for safe product use.

Thank you for this opportunity to present these views on the advertising and marketing of CAM products. I am pleased to respond to any questions you may have.

Promoting Functional Foods and Nutraceuticals on the Internet

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I. INTRODUCTION

The last two decades have witnessed tremendous growth in the self-care population. Many Americans take an active role in managing their health through health-promoting lifestyles and dietary patterns. The self-care population includes healthy individuals wishing to optimize health, as well as individuals that desire alternatives to conventional medical therapies.[1] It is estimated that the purchasing decisions of at least eighty percent of primary shoppers in America are influenced by the desire to manage and/or prevent a specific disease or condition, or to follow a doctor's advice.[2]

Growth in the self-care population, coupled with advancing scientific research, has fueled the demand for foods and dietary supplements that not only help ensure adequate nutrition, but are designed to provide specialized health benefits. In addition, these trends have spurred conventional food manufacturers to accentuate the health benefits offered by old, familiar food products through claims that not only focus on essential nutrients, but on other biologically active components, such as flavonoids and other phytochemicals. Foods and dietary supplements designed to provide or promote for special health benefits commonly are referred to as "functional foods" or "nutraceuticals."[3]

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[1] H.J. Burnstein, S. Gelber, E. Guadagnoli & J. Weeks, *Use of Alternative Medicine by Women With Early-Stage Breast Cancer*, 340 NEW ENG. J. MED. 1733 (1999).

[2] *See* E. Sloan, *The Top Ten Up-and-Coming Nutraceutical Markets*, NUTRACEUTICALS WORLD, Mar./Apr. 1999, at 58.

[3] The terms "functional food" and "nutraceutical" commonly are used in marketing, but have no regulatory definition. Under the Federal Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301 et seq. (1994)), "functional foods" and "nutraceuticals" are regulated as "food" or "dietary supplements" depending on their characteristics. The adequacy of this existing legal framework is a matter of some controversy. For a recent critique of the framework, see Center for Science in the Public Interest, *International, Functional Foods: Public Health Boon or 21st Century Quackery?* (visited Aug. 1, 1999) <www.cspinet.org/reports/functional_foods/index.html>. The FDCA defines "food" to mean "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." 21 U.S.C. § 321(f). The FDCA, as amended by the Dietary Supplement Health and Education Act of 1990 (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325 (codified at 21 U.S.C. § 301 note (1994)), defines "dietary supplement" as follows:

> The term "dietary supplement" — .
> (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
> (A) a vitamin;
> (B) a mineral;
> (C) an herb or other botanical;
> (D) an amino acid;
> (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(continued)

The Internet has placed an expanding volume of health information of various kinds and all levels of quality and reliability in the hands of self-care consumers. Because of the interactive nature of the Internet, consumers can be selective when looking for information to match their interests and needs. Food and dietary supplement manufacturers are responding to the demand for health information through the rapid expansion of health-oriented websites, including those promoting specific products.[4] Because of the relatively small capital outlay required to enter the market online, the Internet is attractive, particularly to start-up companies, including functional food and nutraceutical companies.

Manufacturer-sponsored health information appearing on the Internet is varied, and includes health-related claims for specific products, as well as online "white papers" and libraries housing background information prepared by the manufacturer and third parties. Health information also may be presented in interactive formats tailored to the needs of specific consumers, including questionnaires (e.g., online dietary intake analyses) and chatrooms where consumers may converse directly with doctors and scientists in "realtime." Health information may be featured on the manufacturer's own website or that of another organization. The variety of health information that consumers may access from websites featuring manufacturer-sponsored information seems limitless, especially considering the web of connections that can be traveled through hyperlinks established by the manufacturer "out" of its own site, or by others connecting "in" to its site.

The dramatic changes in health-oriented product promotions occurring in response to the growth of the self-care population and the unique access to these con-

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).

(2) means a product that

(A)

(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or

(ii) complies with section 411(c)(1)(B)(ii);

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement, and

(3) does —

(A) include an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f); and

(B) not include

(i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations have been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.

Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of this Act.

21 U.S.C. § 321(ff).

[4] While the Internet has proven a valuable tool to distribute scientific data and market health products, it also has proven to be a popular way to market products with unsubstantiated health claims. *See* C|NET news.com, *FTC Attacks Online Health Fraud* (modified June 24, 1999) www.news.com/News/Item/0,4,0-38330,00.html?st.ne.140.head~ (discussing FTC's "Operation Cure All").

sumers provided by the Internet, presents regulatory challenges and uncertainties under existing law. This article highlights key legal considerations and rules-of-thumb to guide manufacturers engaging in health-oriented Internet promotions of food and dietary supplements. These considerations are based on developments in Internet law generally, and on the existing legal framework governing food and dietary supplement labeling and advertising.

II. THE EXPANDING UNIVERSE OF ELECTRONIC COMMERCE

A. *Rate of Growth*

The Internet has expanded at an explosive rate and generated a revolution in commerce. Five years ago the term electronic commerce, or e-commerce, did not exist. Even four years ago, one industry expert predicted that e-commerce would never become popular because of the limitations of the medium.[5] Yet today, according to a report sponsored by Cisco Systems, the Internet economy accounts for over 300 billion dollars in sales, and has created over 1,200,000 jobs, and of these, over 100 billion dollars and nearly 482,000 jobs are attributable directly to electronic commerce (as distinct from revenues and jobs created by providing Internet access or other infrastructure or support services).[6] This represents a growth rate of over 174% between 1995 and 1998.[7] By contrast, the overall world-wide average economic growth rate during the same period was 3.8%.[8] Recent studies have shown that between 92,000,000 and 101,000,000 people are connected to the Internet in North America alone.[9] In 1995, barely 10,000,000 people were connected to the Internet worldwide.[10] This growth has outstripped even the most optimistic predictions. The U.S. Government Working Group on Electronic Commerce, for example, predicted that electronic commerce would not reach 300 billion dollars until sometime after the year 2000.[11]

Growth in the field of e-commerce has affected all sectors of the economy and various businesses. For example, between the first quarter of 1998 and the first quarter of 1999, small businesses sold approximately nineteen billion dollars in goods and services through their websites, with 427,000 small businesses going online within this twelve-month period.[12] Nor is consumption of Internet services limited to one gender or age group. The number of women online has grown from a fraction of the number of men online to about equal the number of men online.[13] Children also have come online in droves, and it is estimated that children in the United States will spend 1.2 billion dollars online by the year 2002.[14]

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[5] CLIFFORD STOLL, SILICON SNAKE OIL: SECOND THOUGHTS ON THE INFORMATION HIGHWAY (1995).

[6] The Internet Economy Indicators, *Features* (visited June 18, 1999) <www.internetindicators.com/features.html>.

[7] *Id.*

[8] *Id.*

[9] Nua Internet Surveys, *92 Million Adults Online in United States* (visited June 18, 1999) <www.nua.ie/surveys/?f=VS&art_id=905354968&rel=true>; Nua Internet Surveys, *How Many Online?* (visited Aug. 25, 1999) <www.nua.ie/surveys/how_many_online/index.html>.

[10] U.S. Working Group on Electronic Commerce Policy, *First Annual Report, Nov. 30, 1998* (visited Aug. 1, 1999) <www.doc.gov/ecommerce/E-comm.pdf>.

[11] *Id.*

[12] Nua Internet Surveys, *Small Businesses Sell $19 Billion Online* (visited June 18, 1999) <www.nua.ie/surveys/?f=VS&art_id=905354922&rel=true>.

[13] Nua Internet Surveys, *92 Million Adults Online in United States* (visited June 18, 1999) <www.nua.ie/surveys/?f=VS&art_id=905354968&rel=true>; Nua Internet Surveys, *Report Looks at Changing Face of the Net* (visited June 18, 1999) <www.nua.ie/surveys/?f=VS&art_id=905354784&rel=true>.

[14] Nua Internet Surveys, *Children Ready to Buy Online* (visited June 18, 1999) <www.nua.ie/surveys/?f=VS&art_id=905354955&rel=true>; Nua Internet Surveys, *U.S. Kids to Spend $1.3 Billion Online* (visited June 18, 1999) <www.nua.ie/surveys/?f=VS&art_id=905354944&rel=true>.

Over 60,000,000 Americans went online to search for medical information in 1998.[15] The Internet also has become popular among health professionals. By the end of 1998, nearly eighty-five percent of physicians in the United States were connected to the Internet either at home or at work, an increase of 875% from 1997.[16] Given this audience, it is not surprising that the health industry is investing in this ever-growing online market. A recent study estimated that the health industry will spend over $265,000,000 on Internet advertising by the year 2002; by comparison, the health industry spent an estimated $12,300,000 on Internet advertising in 1997.[17] While no online food and drug businesses were listed in the top 100 Internet companies by sales revenue (with the exception of one online supermarket), online food sales constituted a substantial volume of Internet business.[18] Over the past two years, virtual pharmacies such as <www.drugstore.com> have emerged, which carry nutraceutical and functional food products. A study sponsored by Healtheon Corporation estimated that by the year 2003, online pharmacies will account for 1.7 billion dollars in revenue.[19] The study predicts that four markets will drive the sale of health goods online: prescription pharmaceuticals, over-the-counter pharmaceuticals, nutraceuticals, and personal care products.[20]

Over the course of the past five years, the Internet has created a new economic sector. The impact of this new medium has been profound and widespread, affecting an increasing number of consumers of all demographic types in the United States and throughout the world.[21] All sectors of the economy, including the health industry, have benefited from this expansion and will increase online sales. These figures also demonstrate that the development of e-commerce is still in its infancy, with business models and investment constantly evolving. As a result, industry practitioners, including functional food and nutraceutical companies that promote their products online, must be aware both of the nature of the Internet medium and the legal risks associated with doing business online.

B. *Interactivity -- The Key to E-Commerce*

At its most basic level, the Internet is a "network of networks," a series of protocols for linking public and private networks so that they may communicate.[22] By far, the most popular application for e-commerce is the World Wide Web. Through a common series of protocols, the World Wide Web allows users to use a client program (usually called a web browser) to access information on another system (a server), download it, and display it to the end-user.[23] The information displayed usually is

[15] Nua Internet Surveys, *Sixty Million Seek Health Info Online in the U.S.* (visited June 18, 1999) <www.nua.ie/surveys/?f=VS&art_id=905354697&rel=true>.

[16] Nua Internet Surveys, *Dramatic Increase in the Number of Medics Online* (visited June 18, 1999) <www.nua.ie/surveys/?f=VS&art_id=905354889&rel=true>.

[17] Nua Internet Surveys, *Online Health Advertising Has a Rosy Future* (visited June 18, 1999) <www.nua.ie/surveys/?f=VS&art_id=905354560&rel=true>.

[18] *The Internet Economy Indicators*, *supra* note 6.

[19] Nua Internet Surveys, *Online Pharmacies Predicted to Thrive by 2003* (visited June 18, 1999) <www.nua.ie/surveys/?f=VS&art_id=905354928&rel=true>.

[20] *Id.*

[21] *See, e.g.*, Nua Internet Surveys, *Majority of Users Will Be Non-English Speakers* (visited June 18, 1999) <www.nua.ie/surveys/?f=VS&art_id=905354950&rel=true>; Nua Internet Surveys, *European Ecommerce to Top U.S. $8.6 Billion* (visited June 18, 1999) <www.nua.ie/surveys/?f=VS&art_id=905354970&rel=true>; Nua Internet Surveys, *Over 1.2 Million Russian Users at Close of '98* (visited June 18, 1999) <www.nua.ie/surveys/?f=VS&art_id=905354958&rel=true>.

[22] Thus, while it appears to an end-user (i.e., website visitor) that he or she "visits" a website, in reality, the website "visits" the end-user. This difference is important. Because "visiting" a website involves downloading information into an end-user's own system, it becomes possible for the website to download information the visitor did not request into the end-user's system or to gather information from an end-user's system without the end-user's knowledge.

referred to as a webpage. The webpage typically is part of a larger set of pages linked together called a website. As described below, current technology supports the transfer of text, graphics, audio, and video programming, either as downloadable files to be stored and played at the end-user's convenience, or as "realtime" presentations.

This technology permits an end-user to interact with the server through a graphic user interface (GUI), so that an end-user may point and click on an icon rather than writing text-based line commands. The user also may enter information through the web browser by other means, such as typing, and this information can be processed instantly by the server. Other programs allow a website owner to collect information from an end-user "visiting" a site without requesting permission from the end-user, and even without the end-user's knowledge.[24] The ease of use and the relatively instantaneous nature of the communication (limited only by the speed at which the information travels from the user to the server and the speed at which the server can process the information) allows a website to provide "realtime" communication between the website and end-users viewing the website. In addition, control of the presentation of information and "feel" of the website is in the hands of the website designer and manager, allowing a website owner/designer both to present information and to control the manner in which the end-user will receive and evaluate the information.[25]

C. *Common Internet Applications Used to Promote Functional Foods and Nutraceuticals*

The following is a list of the most common World Wide Web applications for use in e-commerce. It is not meant as an exhaustive list, but rather as a representative list of the types of applications that can be employed to promote functional foods and nutraceuticals. It should be noted that web applications are outdated quickly by the continuing tide of rapid technological development. In fact, an entire industry now exists that is devoted to web design and web technology. Computer languages, both public and proprietary, have been developed to facilitate the creation of new web-based technologies and applications (e.g., applets).

1. *Content of the Website*

A webpage provides an opportunity to present information about a functional food or nutraceutical. This information can take a variety of forms. For example, it can be information about a company or product, or general information about a class of functional foods or nutraceuticals. In addition, the company may choose to generate the information itself, to sponsor third-party research, or to present research done by others. In using third-party literature or other materials created by third parties, a company should recall that the copyright laws apply on the Internet. All of these texts or other information can be accessed through a hypertext link that may incorporate a GUI for ease of use.

Hypothetical:[26] Global Garlic, Inc., a manufacturer of garlic products and dietary supplements, could establish a website, placing a variety of materials on the site.

[24] These programs are called "cookies." Their effect on consumer privacy is discussed *infra*, part III.D.

[25] As discussed in part III *infra*, this ability raises both intellectual property concerns and consumer protection concerns.

[26] The hypotheticals included throughout this article are entirely fictitious and are intended only to assist the reader in understanding Internet technology and related legal issues in the context of specific hypothetical fact patterns. Any resemblance of the fictitious parties named in the hypotheticals (e.g., "Global Garlic, Inc.," "Allicin Alliance," "Go Garlic Diet," "Garlic Lovers," etc.) to actual companies, organizations, groups, or to any marks used by any person, is unintentional. Descriptions of scientific evidence concerning garlic and garlic products, and other facts contained in the hypotheticals likewise are fictitious and are not intended to reflect actual scientific or other evidence relating to the benefits or risks of garlic products.

Global Garlic wants to put up information about the company itself, its products, and background information on garlic and its potential health benefits. If Global Garlic is aware of important research studies on the health benefits of garlic in a research journal, the company would need to contact the authors to secure rights to publish them on the website. To make it easier for users to find what they are looking for, Global Garlic could use a picture of a bulb of garlic or other graphic enhancement as a marker for the link to information about garlic. The health information provided would be subject to federal and state regulation, as discussed in part IV *infra*.

2. *Hypertext Links*

A hypertext link (hyperlink) allows the client to connect to another file (either on the same server or on a different server) and display the new information through the web browser. This technology makes it possible to allow an end-user (website visitor) to jump to new information that may interest the end-user. It also allows the website to control the flow of information by directing the end-user through different pages (or forcing the end-user to agree to certain terms and conditions) before allowing the end-user to proceed to the desired information. Finally, the website designer can use the hypertext link to provide an end-user with information created and controlled by a third party on another website.

Conversely, the site-manager can encourage others to link back to the manager's own site. This can be done under a variety of arrangements. In some cases, the manager will pay for the privilege of having a link from someone else's site to the manager's site, frequently, advertisements. At other times, the manager of the site may charge for allowing someone to connect to their site. This practice is harder to enforce because it is impossible to tell directly when someone is linking to a site. A website owner also may encourage those visiting the site to establish links back to gain free publicity. Finally, the site owner may agree to a cross-linking agreement, wherein two websites agree to link to each other or join links in a group of sites.

Hypothetical: Returning to Global Garlic, Inc., the company could pay to place a link on a webpage sponsored by the publishers of the "Go Garlic Diet," which would amount to an advertisement on the webpage for Global Garlic. Global Garlic could try to secure free advertising for its products by asking the publishers of the "Go Garlic Diet," in turn, to link to the Global Garlic site (perhaps utilizing a distinctive company logo). If Global Garlic finds an interesting article on the American Society of Garlic Lovers' (Garlic Lovers) webpage, Global Garlic, could try to arrange a cross-linking agreement under which Global Garlic would direct visitors seeking "more information on garlic" to Garlic Lovers' website with Garlic Lovers directing those seeking to buy garlic supplements to Global Garlic's website.

3. *Framing*

When using a hypertext link to provide an end-user with information from another site, the website designer either can display the information to make it clear that the information is created and controlled by a third party, or can present the information as if it is an integral part of the designer's site. A compromise between these methods is framing, whereby, the information appears within a frame created by the website designer. This makes it clear to the end-user that the information is coming from another source, but the website designer can place information (such as the

website's company name and logo, or other features making it easier to return to the website) on the frame.

Hypothetical: Global Garlic, Inc. could establish a link to Garlic Lovers and other informational sites. The text or information from the other site, however, could appear inside a frame bearing the Global Garlic logo and buttons (graphic representations connected with hyperlinks) that would take the end-user to an order form or back to the Global Garlic site.

4. *Pop-Up Windows*

It is possible, through the use of an appropriate applet, to use a trigger that tells the end-user's web browser to open a new window. This new window acts as a webpage within a webpage displaying advertisements, related information (whether requested by the end-user or not), terms and conditions, consumer warnings, dialog boxes for interaction between the end-user and the webpage, or anything else. The pop-up window has the same functionality as the first browser window, and usually can be enlarged, minimized, or closed by the end-user in the same fashion as the main browser window.[27]

Hypothetical: Global Garlic, Inc., could set a trigger so that when website visitors click on a link for "more information about garlic," a pop-up window offering to sell Global's garlic-fortified products and dietary supplements appears in the midst of a page discussing the health benefits of garlic. Alternatively, if the visitor clicks on a hypertext link to an order form, a pop-up window could be designed to provide necessary disclaimers and disclosures. This would allow Global Garlic to provide necessary and useful information in an obvious way while leaving the visitor at the order form site.

5. *Animation, Audio, and Video Files*

A website designer can include a variety of animated effects in a webpage, causing text to flash or to dance or to display animated figures. In addition, several proprietary programs exist that allow a website to transfer audio or visual files. As a result, a website visitor can download an audio or video presentation and replay it at leisure. Technology also exists for "realtime" audio and video transmission, sometimes referred to as "webcasting." This allows visitors to hear and/or see a live event in progress, such as an interview or a proceeding.

Hypothetical: Global Garlic, Inc. could hold a conference on the benefits of functional foods fortified with garlic and garlic supplements. Global Garlic could advertise the upcoming conference on its website, urging interested parties to "tune in" at a predetermined time. At the appropriate time, website visitors could click on the link and hear experts in the field discussing garlic metabolism, intake levels, and benefits. After the event is over, Global Garlic could create a link to the file containing the digital recording so that website visitors who missed the conference could download the information and listen to it at their leisure.

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[27] Some websites, however, (notably pornographic sites and sites that use a famous name in a deceptive fashion) construct their applets so that a new window launches whenever the end-user tries to move off the website or close the window. This makes it very difficult for the end-user to get away from undesired content without closing and restarting the browser.

6. *Mailing Lists, Chatrooms, Virtual Communities, and Other Forms of Group Interaction*

Web technology has the capacity to create common "communities of interest" among visitors to the website. This brings visitors back repeatedly, allowing the website operator to present visitors with the desired information multiple times.[28] It also can generate new content that can be archived and displayed on the site (e.g., common questions and answers). The regular addition of new material to a website is important in encouraging repeat visits. The ability to create communities is critical in the success of a website. Indeed, at least one study has found that word-of-mouth is the most important factor in the continued success of a website.[29]

The simplest way to create an interactive community is to compile a mailing list. Individuals subscribe to the list, post messages, and mail them to the mailing list addresses. The mailing list program then distributes the message to all list subscribers. A website also can offer to host a mailing list for regular visitors or subscribers,[30] which generates new traffic and greater participation by subscribers in the website.

Chatrooms create a personal experience for website visitors. In a chatroom, a predetermined number of individuals can communicate simultaneously, so that a "realtime" conversation can occur. The conversation can be monitored by the website sponsor, so that the discussion can be confined to predetermined parameters. The same technology can be used to make scientific experts or celebrities available to respond to questions presented by participants. This also can be structured in the form of an online interview, where an unlimited number of participants can watch the conversation between the interviewer and the expert, and individuals can e-mail questions.

Taking this philosophy further allows the creation of "online communities," such as GeoCities® and iVillage®, for example. Both companies host websites and chatrooms organized around specific themes. GeoCities® hosts the website and chatrooms of others without charge, and groups them together in theme "neighborhoods" under such names as "Athens" (themes of education, poetry, and philosophy), "Capitol Hill" (politics), "Enchanted Forest" (for children), and "Area 51" (science fiction).[31] The iVillage® site advertises itself as "the women's network on the Internet," and organizes chatrooms and experts around special interest channels such as "astrology.net," "parent soup," and "travel."[32]

Hypothetical: Global Garlic, Inc. could encourage site visitors to visit its chatrooms. Some of the chatrooms could be oriented around general themes where people "who recognize the importance of garlic in their lives" can chat with people with a similar interest. Other rooms could be organized around specific themes, such as "family health and garlic." Global Garlic could arrange to have a famous garlic researcher available to answer questions about garlic and garlic supplements every Tuesday from ten p.m. until eleven p.m. in the "emerging food research" chat area. These chat sessions could be archived with links to a special area of the site. Global Garlic also

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[28] *See* Robert D. Hof, Seanna Browder & Peter Elstrom, *Internet Communities*, BUS. WK., May 5, 1997, at 64.

[29] *See* Nua Internet Surveys, *Word of Mouth Drives Ecommerce* (visited June 20, 1999) <www.nua.ie/surveys/?f=VS&art_id=905354929&rel=true>.

[30] An example of this sort of promotion can be found at <www.deja.com>, a webpage that allows users to create "personal communities."

[31] *See* Yahoo!, *GeoCities* (visited Aug. 1, 1999) <geocities.yahoo.com/home/>.

[32] *See* iVillage.com: The Woman's Network (visited Aug. 1, 1999) <www.iVillage.com>.

could choose to sponsor webpages in iVillage® discussing the benefits of garlic to women's health, or in some other virtual community. The sponsored pages could be advertised on Global Garlic's own site, with a link to the virtual community site.

7. *Search Engines and Keywords*

A search engine employs an algorithm to search for a string of words or a subject. The engine sends out queries, analyzes the information returned, and presents a list of hypertext links that will take the visitor to the webpages that best respond to the request. Search engines can be limited to the website, or can be used to search the entire web for information. Alternatively, if certain requests are common, the website can employ a system known as keywords. When the visitor enters a keyword (either in a field marked keyword or using some combination of keys to indicate that the word typed is a keyword), the webpage either will move the visitor to a predetermined webpage, or provide a list of webpages connected by hypertext links. These devices help website visitors find the information they want without requiring them to search the entire website.

Hypothetical: Over time, the Global Garlic site could accumulate sufficient information to become very large and difficult to navigate. If a visitor to the website were looking for specific information, this could prove frustrating and diminish the value of the site. The problem could be addressed by providing a search engine to allow the visitor to track down specific information (e.g., garlic toxicity). Alternatively, entering the keyword "toxicity" might take the visitor to a page with relevant information, or to a neighborhood devoted to discussions of garlic issues.

8. *Cookies and Information Gathering*

A cookie is an applet that a website downloads onto a visitor's hard-drive. Cookies can track what sites are visited, how long the visitor remains on a page, what products a visitor orders, and other information about the visitor's Internet browsing habits. The cookie then reports the information back to the website, allowing the website operator to personalize its information display so that when the visitor returns to the website, the site will display links to information the site manager believes the visitor will find appealing. The site manager also can sell the information to others, or can use the information to send personalized e-mail advertisements.[33]

A site manager can collect information by other means. The most obvious method is to ask for information from the site visitor, possibly conditioning access to desired information on supplying personal information or rewarding the end-user for providing the information through give-aways, discounts, or other incentives. A site manager also can gather useful information simply from recording the e-mail address of every visitor.

Hypothetical: Global Garlic, Inc. could ask its visitors to fill out a form requesting information on the availability of garlic products in supermarkets and drug stores in the visitor's neighborhood, the visitor's dietary supplement purchasing habits, and on the visitor's level of education. Global Garlic could plant a cookie on the visitor's hard drive so that when the visitor returns to the site in the future, the visitor is transported directly to his or her favorite area of the site. Global Garlic also may use

[33] *See, e.g.*, Nua Internet Surveys, *E-Mail, a Powerful Marketing Tool* (visited June 18, 1999) <www.nua.ie/surveys/?f=VS&art_id=905354935&rel=true>; FEDERAL TRADE COMM'N, PRIVACY ONLINE: A REPORT TO CONGRESS (submitted June 6, 1998)

the personal information obtained to help in its direct marketing efforts. From analyzing the aggregate information collected from all visitors, Global Garlic could determine the demographics of its customer base and the general interests of its customers.

9. *Websites in Practice*

When designing a website, the spectrum of applications described above typically is utilized in combination. Through agreements with others, it is possible to expand the range of one's site and attract other visitors. For example, a company marketing vitamins might sponsor an area in an online community, such as GeoCities® or iVillage®, with a link from the sponsor's homepage to the relevant area. The same company might maintain its own library of links to favorable news items and studies. The company also may generate content by sponsoring research or issuing press releases. As there are companies online that distribute press releases online and display them on their own webpages,[34] it is possible to generate an independent source of information by creating a press release, issuing it, then linking to an organization that picks up the press release. Using visitor information, the company sponsoring the site can both personalize the experience for individual visitors (e.g., allowing individuals to go directly to a favorite neighborhood rather than forcing the visitor to navigate the site) and can update its site using aggregate data to determine customer preferences (e.g., eliminating seldom-visited or unpopular features and expanding on popular features).

While construction of websites is straightforward technically, the technology itself presents a host of legal considerations. Some of these issues are confronted by any company doing business over the Internet. For functional food and nutraceutical manufacturers wishing to promote the health benefits of their products on the Internet, however, there are specialized issues presented by the existing legal frameworks governing food and dietary supplement advertising and labeling.

III. CONSIDERATIONS PRESENTED BY EMERGING INTERNET LAW

The rapid growth of the Internet, combined with the lack of an agency to regulate Internet traffic, has fostered the myth that the Internet is an unregulated "wild west" where anything goes. In fact, this is not the case; law applicable in real space is equally applicable in cyberspace, although the Internet may create challenges for implementation.[35] Courts have made it clear that rules governing consumer protection, protection of intellectual property rights, and other state and federal laws, apply equally in cyberspace and real space.

The unique nature of the Internet, however, has created difficulties in applying law. For example, traditional concepts of jurisdiction, based on geography and the ability to control whether one will do business in a forum, are not applied easily to a global medium. Similarly, the tremendous volume of traffic, and the challenge of regulating it, has created difficulties in applying traditional rules of liability. The ease with which material protected by copyright law can be stolen and distributed to millions before the copyright holder can police its copyright effectively and the frequent

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[34] *See, e.g.*, <www.prnewswire.com>.

[35] *See, e.g.*, Interpretation of Rules and Guides for Electronic Media; Request for Comment, 63 Fed. Reg. 24,996, 24,998 (May 6, 1998) (noting that the Federal Trade Commission (FTC) has authority to apply its rules to the Internet, but soliciting comment on proper application of existing statutory and regulatory terms).

lack of provable damages, also have created concern. Finally, the ability of parties on the Internet to gather personal information without the knowledge or consent of an end-user has generated a great deal of concern among consumer groups regarding practices that are legal, but violate website visitors' reasonable expectations of privacy.

In some of these areas, notably protection of intellectual property and of liability for third-party speech, Congress has passed legislation to address the issue. In areas where industry engages in conduct of concern, such as violating website visitor privacy by gathering personal information, Congress and the Clinton Administration have invited industry to formulate responsible standards and to develop self-policing programs. If these efforts fail, however, Congress may be prompted to take action. In the area of jurisdiction and choice of law courts generally have been left to devise rules based on applying traditional common law principles and precedent to the Internet.

This article does not address the myriad issues and concerns that effect any business operating on the Internet.[36] Rather, this article addresses four areas of general applicability that are of particular importance to websites promoting the sale of functional foods and nutraceuticals: free speech, liability for third-party speech, jurisdiction, and privacy.[37]

A. *General First Amendment Protection of Internet Transmissions*

In *Reno v. American Civil Liberties Union*,[38] the Supreme Court addressed the constitutionality of the Communications Decency Act of 1996 (CDA).[39] The CDA made it illegal for anyone to transmit obscene or "indecent" material to minors. The Court found the indecency provision unconstitutional. The government argued that the lower standard of First Amendment protection that applied to broadcast media, such as radio and television,[40] should apply to the Internet. The U.S. Supreme Court rejected this argument, noting that there is "no basis for qualifying the level of First Amendment scrutiny that should be applied to this medium."[41] Both the Supreme Court and the trial court noted the tremendous value in disseminating scientific and cultural information on the Internet, and the Internet's ability to empower communication among individuals on a global scale.[42]

Following the Supreme Court's expansive extension of First Amendment principles to the Internet, courts generally have rejected all attempts to regulate the free flow of information online. For example, courts have rejected efforts by the states to pass statutes modeled on the CDA.[43] Courts similarly have held that attempts to require public libraries to install filters that screen out indecent material are unconstitutional prohibitions on speech based on content, despite the fact that the state is not required to provide Internet access through public libraries.[44] Courts have not allowed

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[36] For an excellent check-list applicable to any business, see Ron N. Dreben & Johanna L. Werbach, *Top 10 Things to Consider in Developing an Electronic Commerce Website*, COMPUTER LAW., June 1999, at 17; Walter A. Effross, *A Website Checklist*, LEGAL TIMES, Mar. 1, 1999, at S34.

[37] Specific concerns relating to the jurisdiction of the Food and Drug Administration (FDA) and FTC as regards to their special jurisdiction over labeling and advertising are addressed *infra*, pt. IV.A.

[38] 521 U.S. 844 (1997).

[39] Pub. L. No. 104-104, 110 Stat. 133 (1996).

[40] *See* Federal Communications Comm'n v. Pacifica Found., 438 U.S. 726 (1978).

[41] *American Civil Liberties Union*, 521 U.S. at 870.

[42] *See id.* at 853, 870; *American Civil Liberties Union*, 929 F. Supp. at 879-83 (opinion of Judge Dalzell).

[43] *See* American Library Assoc. v. Pataki, 969 F. Supp. 160 (S.D.N.Y. 1997) (decided under Commerce Clause).

[44] *See* Mainstream Loudoun v. Bd. of Trustees of the Loudoun County Library, 24 F. Supp.2d 552 (E.D. Va. 1998).

the government to restrict speech simply because the government's effort is directed primarily at commercial speech. In 1998, Congress passed the Children's Online Protection Act (COPA),[45] a second attempt to control the accessibility of indecent materials to minors. COPA attempted to prohibit the sale of indecent material to minors and required all commercial vendors to use age verification software before making indecent materials available. Despite the specific targeting of commercial speech and the attempt to narrow the definition of indecent material, the court found that the statute potentially prohibited dissemination of constitutionally protected speech and struck COPA down as violating the First Amendment.[46] Similarly, courts have upheld the right of consumers to use the Internet to disseminate consumer commentary in the face of an action for trademark infringement and dilution.[47]

Courts have been sensitive to First Amendment protection of information transmitted on the Internet, and have acted aggressively to protect speech on the Internet from prior government restraint. These concerns appear to be heightened where speech protected by the First Amendment is at issue, as may be the case when scientific literature is posted on websites sponsored by functional food or nutraceutical manufacturers.[48] The position the courts have taken in Internet cases generally is consistent with the trend toward extending enhanced First Amendment protection to scientific and medical information disseminated in a commercial context, including when relevant to highly regulated health products.[49]

B. *Liability for Third-Party Speech*

Because of the interactive nature of the Internet, a website manager may be concerned about material posted on its website by third parties. Concern may be for criminal or tort liability, or that a third party's posting of copyrighted material may trigger liability. Prior to the Telecommunications Act of 1996,[50] this issue remained unsettled. In *Stratton Oakmont v. Prodigy Service Co.*,[51] the court held that Prodigy could be responsible for third-party statements because Prodigy promoted itself as a "family service" exercising editorial control over unsuitable content. In *Cubby, Inc. v. CompuServe, Inc.*,[52] however, the court determined that CompuServe bore no responsibility for third-party statements because CompuServe expressly disclaimed any editorial control over content. As a result, online service providers were safest when taking no action to prevent the dissemination of offensive or tortious material.

To encourage interactive service providers to take action to prevent the dissemination of harmful material, Congress passed, as part of the Telecommunications Act of 1996, the Good Samaritan provision[53] of the CDA. The Good Samaritan provision

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[45] Pub. L. No. 105-277, 112 Stat. 2681-2728 (1998).

[46] American Civil Liberties Union v. Reno, 31 F. Supp.2d 473 (E.D. Pa. 1999).

[47] Bally Total Fitness Holding Corp. v. Faber, 29 F. Supp.2d 1161 (C.D. Cal. 1998) (permitting use of Bally's trademarked name online in context of consumer commentary).

[48] *American Civil Liberties Union*, 521 U.S. at 870. *See generally* Bernstein v. United States Dep't of Justice, 1999 WL 274111 (9th Cir. 1999) (noting that to the extent that government regulation impedes the flow of scientific information, it strikes "deep into the heartland of the First Amendment").

[49] *See* Washington Legal Found. v. Friedman, 13 F. Supp.2d 51 (D.D.C. 1998), *amended, request denied*, 36 F. Supp.2d 16 (D.D.C. 1999), *amended, summ. judgment granted, injunction granted*, 36 F. Supp.2d 418 (D.D.C. 1999) (striking down restrictions on the dissemination to doctors of medical information relevant to unapproved uses of approved drugs).

[50] Pub. L. No. 104-104, 110 Stat. 56 (1996).

[51] 1995 WL 323710 (N.Y. Sup. Ct. 1995).

[52] 776 F. Supp. 135 (S.D.N.Y. 1991).

[53] 47 U.S.C. § 230 (1994). This provision survived the Supreme Court decision striking down the indecency provisions of the CDA. *See* Elizabeth deGrazia Blumenfeld, Patrick J. Carome & Samir Jain, *Federal Immunity for Online Services — 47 U.S.C. § 230*, J. INTERNET L., Jan. 1999, at 20.

provides tort immunity to "interactive service providers" for third-party speech, even where the service provider takes or promises to take affirmative measures to prevent dissemination of tortious material. The definition of interactive service provider is sufficiently broad to include an interactive website or other interactive feature.[54]

Although the law does not provide immunity for content created by the interactive service provider, courts have interpreted this grant of immunity broadly, requiring an explicit adoption of speech to elevate a service provider to a content provider. In *Blumenthal v. Drudge*,[55] for example, America Online, Inc. (AOL) contracted with Matthew Drudge, an online gossip columnist, to provide his column through AOL.[56] AOL retained the right to make editorial changes, to store the columns in its archive, and to refuse to run a column if it so chose.[57] AOL also promoted the column to its users, by advertising the contract with Drudge in a press release and notice to customers and by establishing a keyword link to Drudge's column.[58] Despite the close relationship between AOL and Drudge, and the control AOL exerted over Drudge's column, the court held that AOL did not adopt the columnist's speech and was not a content provider.[59] The courts also have held that unsolicited third-party statements posted on a service provider's system are not adopted by the service provider.[60] Finally, courts have resisted attempts by plaintiffs to circumvent the statutory immunity by allowing plaintiffs to plead tort suits for content as breach of contract suits or negligence suits.[61]

The Good Samaritan provision of the CDA has three significant areas that remain uncovered by its broad immunity. First, as mentioned above, the act does not provide immunity for content created by the interactive service provider. Second, the act does not provide immunity from criminal charges,[62] and third, the act does not provide immunity from any violation of intellectual property rights.[63] This last issue was addressed in part by the Digital Millennium Copyright Act of 1998 (DMCA).[64] The DMCA provides immunity to interactive service providers for material posted on their system by a third party provided that: 1) the interactive service provider did not alter the material; 2) the interactive service provider has filed agent contact information for DMCA purposes with the Copyright Office of the Library of Congress; and 3) on receipt of proper notice, the interactive service provider removes the material from its system.[65] This immunity has not been tested in court.

Hypothetical: Global Garlic, Inc. would not need to worry about tort liability for third-party statements made through interactive services provided through its website (e.g., chatrooms). In addition, by following the DMCA procedures, Global Garlic could protect against liability for copyright infringement that occurs through material

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[54] *See id.* at 20-21; 47 U.S.C. § 230(c) (granting immunity to "a provider or user of an interactive computer service").

[55] 992 F. Supp. 44 (D.D.C. 1998).

[56] *Id.* at 49.

[57] *Id.*

[58] *Id.*

[59] *Id.* at 49-50.

[60] *See* Zeran v. America Online, Inc., 129 F.3d 327 (4th Cir. 1997) (service provider not liable for statement posted on online "bulletin board"), *cert. denied*, 118 S. Ct. 2341 (1998); Doe v. America Online, Inc., 718 So.2d 385 (Fla. Dist. Ct. App. 1998) (service provider not liable for statements made in chat rooms).

[61] *See, e.g., Zeran*, 129 F.3d at 332-34; Aquino v. Electriciti, Inc., 26 Media L. Rep. (BNA) 1032 (Cal. App. Dep't Super. Ct., Sept. 23, 1997). *See also* Blumenfeld, Carome & Jain, *supra* note 53, at 24.

[62] 47 U.S.C. § 230(e)(1).

[63] *Id.* § 230(e)(2).

[64] Pub. L. No. 105-304, 112 Stat. 2860 (1998).

[65] *Id.* § 202 (to be codified at 17 U.S.C. § 512).

posted on its website by a third party. Although Global Garlic still could find itself subject to criminal prosecution, the court would be required to consider the high value placed on scientific and educational speech disseminated through the Internet.

C. *Jurisdiction*

Of great concern to any company is the question of jurisdiction — where the company can expect to be "hauled into court." Because a website is accessible worldwide, a company doing business through its website — or even simply maintaining a website — could, in theory, find itself subject to universal jurisdiction. For functional food and nutraceutical companies promoting products over the Internet, jurisdictional considerations can be important in determining retail sales requirements, as well as state regulation of product promotions under state consumer protection statutes.

While there is no universal rule on jurisdiction, courts generally have been sensitive to the effect universal jurisdiction would have on e-commerce.[66] At the same time, courts do not want companies to have free reign to violate state laws or commit torts in cyberspace simply because the server maintaining the website is located outside the state. As a result, courts have attempted to strike a balance that satisfies the constitutional limitations on jurisdiction.

Only two district courts[67] have held that a purely passive website — one which does not permit the visitor to interact with the website — will subject a website operator to either the general or specific jurisdiction of the court in the forum where the website is accessible. Rather, "something more is needed" for the exercise of jurisdiction.[68] The level and nature of the contacts that provide this "something more" has varied significantly between courts.[69] One test that has gained popularity first was articulated in *Zippo Manufacturing Co. v. Zippo Dot Com, Inc.*[70] In *Zippo*, the court found that Internet activities fall into three classes along a sliding scale. On one end of the scale are cases where a party clearly does business in the forum over the Internet, such as by knowingly entering into contracts with forum residents and, therefore, jurisdiction clearly is warranted.[71] At the other end of the scale are cases with purely passive websites, where jurisdiction clearly is unwarranted.[72] In between, are cases involving interactive websites where the court must determine if the contacts are substantive enough to support jurisdiction; the court does this by examining the level of interactivity and the commercial nature of the exchange.[73] In addition, for exercise of specific jurisdiction, the harm must arise from the contact with the forum.[74]

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[66] *See, e.g.*, Smith v. Hobby Lobby Stores, Inc., 968 F. Supp. 1356, 1364 (W.D. Ark. 1997).

[67] *See* GTE New Media Servs., Inc. v. Ameritech Corp., 21 F. Supp.2d 27 (D.D.C. 1998) (the jurisdictional issue is now before the D.C. Circuit Court of Appeals on interlocutory appeal), 44 F. Supp.2d 313, 1999 WL 193891 (D.D.C.) (Mar. 29, 1999)); Telco Communications v. An Apple a Day, 977 F. Supp. 404 (E.D. Va. 1997).

[68] Panavision Int'l L.P. v. Toeppen, 141 F.3d 1316, 1321 (9th Cir. 1998).

[69] *Compare, e.g.*, Inset Sys., Inc. v. Instruction Set, Inc., 937 F. Supp. 161 (D. Conn. 1996) (passive website containing toll free number to call for orders supports jurisdiction, even without evidence that anyone from the forum actually had contacted the company from the forum state) *with* Blackburn v. Walker Oriental Rug Galleries, Inc., 999 F. Supp. 636 (E.D. Pa. 1998) (website that permitted visitors to send e-mail to website operator but had no other interactive features insufficient to support jurisdiction) *and* Millennium Entertainment, Inc. v. Millennium Music, LP, 4 Elec. Com. L. Rep. 249 (D. Ore. 1999) (BNA) (interactive website and "sporadic" contacts with forum insufficient to support jurisdiction).

[70] 952 F. Supp. 1119 (W.D. Pa. 1997).

[71] *Id.* at 1124.

[72] *Id.*

[73] *Id.*

[74] *Id.* at 1123, 1125.

The *Zippo* test presents a balanced approach that has become popular with courts.[75] *Zippo* allows companies to use the Internet for e-commerce, without fear that they will be subject to universal jurisdiction. At the same time, it holds companies accountable for specific acts within a forum that give rise to a cause of action. It also provides, in theory, a method of avoiding jurisdiction within a forum that the company finds too onerous. For example, as a precondition to allowing a visitor to view information or conclude a transaction, a website operator could require the visitor to certify that he or she is not from a particular state.[76] While no court has addressed whether such a certification will, in fact, prevent jurisdiction, it would be difficult to characterize a website that actively avoids doing business in a particular state as "purposely availing itself of the forum."[77] While a visitor to a site may lie in response to a question, courts are not sympathetic to plaintiffs that use deception as a method to establish jurisdiction.[78]

In addition, a website operator could attempt to limit jurisdiction by using a choice of forum clause. To use such a clause, the site should require an affirmative act, such as clicking "yes" on a pop-up window, as a precondition to viewing information or transacting business on the site.[79] At least one court has found such a clause enforceable;[80] in that case the parties concluded a commercial transaction and the choice of forum clause was a term of the agreement. It remains unclear, however, if such a clause would be enforced as part of the terms and conditions for viewing a website.

Hypothetical: If Global Garlic, Inc. wanted to limit its potential exposure to jurisdiction in inconvenient fora, it would have several options. Global Garlic could choose to maintain a purely passive website, such as one that permits no visitor to place orders through the website or to enter information. Such a strategy, however, would deny Global Garlic the primary advantage of a website as a marketing tool — the ability to interact with customers individually. Alternatively, if Global Garlic were aware of specific jurisdictions it wished to avoid, it could ask customers to provide geographic information (e.g., zip codes), refusing to admit customers from these jurisdictions. Global Garlic also could require customers interacting with the website to agree to a choice of forum clause, limiting jurisdiction to the forum preferred by Global Garlic.

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[75] *See, e.g.*, Cybersell, Inc. v. Cybersell, Inc., 130 F.3d 414 (9th Cir. 1997); Atlantech Distribution, Inc. v. Credit Gen'l Ins., 30 F. Supp.2d 534, 538 (D. Md. 1998) (citing other cases); American Homecare Fed'n, Inc. v. Paragon Scientific Corp., 27 F. Supp.2d 109, 113 (D. Conn. 1998); Edberg v. Neogen Corp., 17 F. Supp.2d 104, 114 (D. Conn. 1998) (harmonizing *Zippo* with *Inset Systems*); One World Botanicals Ltd v. Gulf Coast Nutritionals, Inc., 987 F. Supp. 317, 325 (D.N.J. 1997) (finding reasoning of *Zippo* "persuasive"); *Hobby Lobby*, 968 F. Supp. at 1369. *But see Telco Communications*, 977 F. Supp. at 406 (rejecting *Zippo* and following *Inset Systems*).

[76] *See* Effross, *supra* note 36, at S-34.

[77] *See, e.g.*, International Shoe v. State of Washington, 326 U.S. 310, 316 (1945); Hanson v. Denckla, 357 U.S. 235, 253 (1958); World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 297 (1980).

[78] *See, e.g., Millennium Entertainment, supra* note 69 (insufficient contacts to sustain jurisdiction where plaintiff instigated defendant's contact with forum for sole purpose of obtaining jurisdiction); *see also* Wyman v. Newhouse, 93 F.2d 313 (2d Cir. 1937) (ruling personal jurisdiction procured by fraud void); May Dep't Stores Co. v. Wilansky, 900 F. Supp. 1154, 1163-64 (E.D. Mo. 1996) (same).

[79] This mechanism is sometimes referred to as a "clickwrap" clause or license because the user "clicking" on an icon signifies assent to the terms and conditions. The name derives from the practice of software manufacturers of including license terms for use of the software, terms to which the purchaser assents by tearing off the "shrinkwrap" that covers the product packaging. *See* ProCD, Inc. v. Zeidenberg, 86 F.3d 1447, 1449 (7th Cir. 1996) (defining "shrinkwrap").

[80] Decker v. Circus Circus Hotel, 4 Elec. Com. L. Rep. 506 (D.N.J. 1999) (BNA).

D. *Privacy*

A website operator can collect personal information from a visitor without the visitors consent or knowledge, which has created concern among private citizens, regulators, and legislators regarding personal privacy.[81] Consistent with the principles set forth in the *Framework for Global Electronic Commerce*,[82] the Clinton Administration has looked to the private sector to self-regulate in the face of growing concerns about privacy.[83] Although there has been some effort by various industry groups to create voluntary guidelines,[84] the Federal Trade Commission (FTC) has expressed concern that this approach may not prove sufficient. In its June 1998 report to Congress, the FTC noted that while over ninety percent of websites surveyed collected personal information from visitors, only fourteen percent provided any notice, and only two percent provided notice by means of a comprehensive privacy policy.[85] The information collected included the visitor's name, address (both electronic and physical), social security number, hobbies, and spending habits.[86]

The FTC has expressed particular concern with websites directed at children. Nearly ninety percent of websites directed at children collected personal data from children, typically without any opportunity for parental intervention.[87] In addition, the FTC reported that many sites directed at children offered incentives for children to provide personal information about themselves, their parents, their parents' income, and their parents' and their own spending habits.[88]

In response to these concerns, Congress passed, as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act,[89] the Children's Online Privacy Protection Act of 1998 (COPPA).[90] The act forbids the operator of a website or online service "directed to children," or an operator who has personal knowledge that information is provided by a child, from storing, retrieving, or disclosing personal information without first obtaining verifiable parental consent. The regulations permit parents to withdraw consent at any time. COPPA also requires the operator to provide notice on the website that information is collected from children. The notice must include what type of information the operator collects, how the operator stores, uses, and protects the information, and must state the operator's disclosure policy. The act entitles parents to request more detailed information on what information the

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[81] *See generally* Erika S. Koster, *Zero Privacy: Personal Data on the Internet*, COMPUTER LAW., June 1999, at 7; Walter A. Effross, *Preparing, Preventing, and Parrying Public and Private Profiling*, STAN. J.L. & TECH. (Spring 1999) <www.wel.american.edu/pub/faculty/effross/homepage.html>; A. Michael Froomkin, *Flood Control on the Information Ocean: Living With Anonymity, Digital Cash, and Distributed Databases*, 15 U. PITT. J.L. & COM. 395 (1996).

[82] Issued by the Clinton Administration, July 1, 1997. The White House, *Framework for Global Electronic Commerce* (visited Aug. 1, 1999) <www.whitehouse.gov/WH/New/Commerce>.

[83] U.S. Government Working Group on Electronic Commerce, *First Annual Report* (visited Aug. 1, 1999) <www.doc.gov/ecommerce/E-comm.pdf>.

[84] *Id.*; *see also* Koster, *supra* note 81, at 13.

[85] FTC REPORT, *supra* note 33, at iii, 23-24. Recent studies suggest, however, that the situation online has improved considerably since the FTC submitted its report. *See* Federal Trade Comm'n, *FTC Chairman Robert Pitofsky's Statement in Response to Georgetown University's Internet Privacy Policy Survey* (visited Aug. 1, 1999) <www.ftc.gov/opa/1999/9905/culnan.htm> (noting that over 65% of consumer websites, accounting for nearly 99% of all consumer traffic, posted privacy policies and that 12% followed FTC's recommended best practices).

[86] FTC REPORT, *supra* note 33, at 25.

[87] *Id.* at iii-iv, 31.

[88] *Id.* at 5-6, 33.

[89] Pub. L. No. 105-277, 112 Stat. 2681 (1998).

[90] 112 Stat. 2681-2728.

operator actually has collected from their child, including the specific types of information collected and copies of any information collected. COPPA prohibits an operator from conditioning participation in a game, or entry in a contest, on a child's providing personal information, although the operator can exclude from service any child whose parents refuse to consent to the collection of personal information. Finally, the act requires the operator to develop reasonable safeguards to protect any personal information collected.[91]

Although Congress has not passed a law requiring operators of websites targeting adults to obey certain privacy rules, the FTC's Online Privacy Report identified five basic principles for collecting and managing personal information from end-users:

- Notice/Awareness — identifying to consumers what, if any, information will be collected, for what purposes it will be collected, and to whom it will be disclosed;[92]
- Choice/Consent — giving consumers options as to whether to provide personal information, and, ideally, providing a consumer with control over how the information will be used;[93]
- Access/Participation — allowing a consumer to have access to personal data collected and to make corrections;[94]
- Integrity/Security — taking reasonable steps to keep a consumer's personal data secure and to maintain it accurately; and
- Enforcement/Redress — providing a consumer with some mechanism for enforcing his or her rights.

In the health industry, privacy concerns are acute, particularly among regulators and consumers. For example, the U.S. House of Representatives' Commerce Committee recently approved an amendment to a securities bill to require that consumers affirmatively "opt in" before their medical information may be shared with affiliates or third parties.[95] In addition, businesses with operations in Europe must concern themselves with the European Union Privacy Directive,[96] which prohibits an entity in the European Union from transferring personal data to an entity in a country that provides insufficient protection for personal information. Thus, although a website operator need not comply with the FTC's suggested practices, it would be prudent to do so.[97]

Hypothetical: To resume the example, Global Garlic, Inc. may wish to collect personal information from visitors to its site, either through cookies or other means, such as questionnaires. Although nothing requires Global Garlic to formulate a privacy policy and notify consumers, it would be responsible to do so, and likely would foster good will with both consumers and regulators. This policy could, ideally, be

[91] The act also includes several safe harbor provisions and a provision requiring the FTC to conduct a new form of negotiated rulemaking with industry representatives. The FTC recently has conducted a rulemaking to implement COPPA. *See* 64 Fed. Reg. 22,750 (Apr. 27, 1999).

[92] FTC REPORT, *supra* note 33, at 7-8.

[93] *Id.* at 8-9. There are types of choice/consent regime proposed: the opt-in regime requires a visitor to make some affirmative step to consent to the collection of personal data for the stated uses; the opt-out regime requires a visitor to affirmatively prohibit the collection and use of personal information.

[94] *Id.* at 9.

[95] 4 Elec. Com. L. Rep. 522 (1999) (BNA).

[96] Directive 95/46, 1995 O.J. 281/31. The United States and the European Union are in continuing negotiations on the proper application of the Privacy Directive to U.S. corporations and citizens.

[97] In assessing the risk of collecting personal information, it should be noted that the FTC has shown its willingness to file an enforcement action under the Federal Trade Commission Act, 15 U.S.C. § 45(a), in particularly egregious cases. *See* Koster, *supra* note 81, at 11. Private rights of action may also be available. *Id.* at 9-11.

based on the FTC's five basic principles: notification/awareness, choice/consent, access/participation, integrity/security, enforcement/redress. Furthermore, if a portion of Global Garlic's website was targeted to children, or if Global Garlic maintained a separate website targeted to children, Global Garlic would be required to comply with the provisions of COPPA.

IV. REGULATORY FRAMEWORK: HEALTH-RELATED PROMOTIONS FOR FOOD AND DIETARY SUPPLEMENT PRODUCTS ON THE INTERNET

A. *Overlapping Authority of the FTC, FDA, and States*

Health-related promotions for foods and dietary supplements on the Internet are regulated by both the FTC and the Food and Drug Administration (FDA) because of the overlapping scope of their legal authorities. The FTC has broad authority under the Federal Trade Commission Act (FTC Act)[98] to prohibit "unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices. . . ."[99] The FTC Act specifically defines unfair or deceptive acts or practices to include "the dissemination or the causing to be disseminated of any false advertisement. . . ."[100] "Dissemination" encompasses distribution "by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food. . . ."[101]

Although advertising is not defined in the FTC Act, it has been interpreted broadly to include virtually "any method of attracting public attention,"[102] or to "give public notice."[103] There is no requirement that the product, manufacturer, or advertiser be named for material to be deemed advertising provided that, in the context of its use, the intended use of the material to draw public attention to a product or company can be established.[104]

The FTC's jurisdiction over advertising extends to materials that qualify as food or dietary supplement labeling subject to FDA jurisdiction under the Federal Food, Drug, and Cosmetic Act (FDCA).[105] Labeling has been interpreted broadly and encompasses some materials disseminated on the Internet.

The overlap in FTC and FDA jurisdiction has been addressed by a Memorandum of Understanding between the two agencies. Under this agreement, the FTC has assumed primary responsibility for regulating food advertising, while FDA has assumed primary responsibility for regulating food labeling.[106] Because health-related promotions of food and dietary supplements on the Internet may constitute both advertising and labeling, depending on the context of use, the FTC and FDA work together to coordinate policy development in this area.[107] Although both agencies are engaged in formal review of the unique policy issues presented by Internet promotions,[108] health-

[98] Ch. 311, 38 Stat. 717 (1914) (codified as amended at 15 U.S.C. §§ 41-64 (1994)).

[99] 15 U.S.C. § 45(a)(1) (FTC Act § 5(a)(1)).

[100] *Id.* § 52(b) (FTC Act § 12(b)).

[101] *Id.* § 52(a)(1) (FTC Act § 12(a)(1)) (emphasis added).

[102] State v. Cusick, 248 Iowa 1168, 84 N.W.2d 554, 556 (1957); Commonwealth v. Allison, 227 Mass. 57, 116 N.E. 265 (1917); McDonough v. Board of Educ., 198 N.Y.S.2d 401 (1959).

[103] People v. Montague, 274 N.W. 347 (Mich. 1937); People on Complaint of Moffitt v. Wendelken, 156 N.Y.S.2d 129, 131 (1956); Edwards v. Lubbock County, 33 S.W.2d 482, 484 (Tex. 1930).

[104] *See* GEORGE ERIC RODEN & PETER ERIC RODEN, THE LAW OF ADVERTISING §17.02 (1999).

[105] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301 et seq. (1994)).

[106] *See* 36 Fed. Reg. 18,539 (Sept. 16, 1971).

[107] FEDERAL TRADE COMM'N, BUREAU OF CONSUMER PROTECTION, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY 3 (1998) [hereinafter DIETARY SUPPLEMENTS].

[108] *See* 64 Fed. Reg. 14,156 (Mar. 24, 1999); 63 Fed. Reg. at 24,996; 61 Fed. Reg. 48,707 (Sept. 16, 1996).

related promotions continue to be regulated under the same regulations and guidelines applied to advertising and labeling disseminated through other media.

Most states also have authority to regulate product promotions under consumer protection statutes, sometimes called "baby FTC Acts." These laws authorize states to regulate deceptive advertising under standards similar to FTC standards.[109] Typically, such acts define advertising broadly enough to encompass both FTC-regulated advertising and FDA-regulated labeling on the Internet. While states may regulate food and dietary supplement advertising and some labeling matters on antideception grounds, FDA requirements concerning health claims and nutrient content claims made in labeling preempt differing state labeling requirements.[110]

B. *Advertising*

Health-related claims are permitted in food advertising, provided they are substantiated and nondeceptive. In fact, the same standards apply to structure/function claims and health claims made in advertising, even though such claims are subject to different standards when made in food labeling. The same standards apply whether promotional materials are disseminated on the Internet or through other media. The FTC standards that must be satisfied to ensure that a claim is nondeceptive and substantiated have been developed through FTC case law, and articulated in FTC policy statements.[111] In determining whether health-related claims are truthful, nondeceptive, and substantiated, the FTC considers the actual advertising claims made, the context in which they are used, and the factual evidence on which the claims are founded. In its most recent policy statement, the FTC has described its standard as a "truth-in-advertising law [which] can be boiled down to two commonsense propositions: (1) advertising must be truthful and not misleading; and (2) before disseminating an ad, advertisers must have adequate substantiation for all product claims."[112]

Advertisers are responsible for substantiating both express and implied claims. In determining what claims require substantiation, advertisers must consider the "net impression" of the advertising in view of the text, product name, and any graphic elements of the advertising.[113] The FTC has emphasized that its substantiation standard is a flexible one that depends on many factors. For claims about the efficacy and safety of foods, the FTC typically considers "all forms of competent and reliable scientific research when evaluating substantiation."[114] A central consideration in constructing health-related claims for foods and dietary supplements is that claims be written in a manner that "matches" the level and quality of scientific evidence, and takes into account the overall trend in the body of relevant scientific evidence. In some cases, qualified language is necessary to avoid overstating the strength of the scientific evidence supporting a claim (e.g., "two recent clinical studies reported" or "more research is needed . . .").[115]

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[109] *See* ROSDEN, *supra* note 104, §§ 13.06[1], 16.02.

[110] 21 U.S.C. § 343-1(a)(5).

[111] DIETARY SUPPLEMENTS, *supra* note 107, at 3; *see also* Deception Policy Statement, 103 F.T.C. 174 (1983); Substantiation Statement, 104 F.T.C. 839 (1984); Food Advertising Enforcement Policy Statement, 59 Fed. Reg. 28,388 (June 1, 1994).

[112] DIETARY SUPPLEMENTS, *supra* note 107, at 3.

[113] *Id.* at 24.

[114] *Id.* at 9, 10.

[115] *See* FEDERAL TRADE COMM'N, GENERIC COPY TEST OF FOOD HEALTH CLAIMS IN ADVERTISING: EXECUTIVE SUMMARY 5-6 (1998).

The FTC recently published results from generic copy tests aimed at evaluating consumer understanding of qualified health claims. The qualified language studied by the FTC focused on characterizing the level of scientific support for the diet-disease relationship, rather than disclosing additional dietary or other risk factors for the disease. The FTC concluded that its "research suggests that it is possible to communicate limitations in the level of scientific support for diet-disease relationships that have not yet attained significant scientific agreement."[116]

Hypothetical: For Global Garlic, Inc., this means that under the FTC advertising standards, health promotions of garlic products on the Internet may include claims concerning both proven and potential health benefits. Claims concerning the potential health benefits of garlic must be appropriately qualified to avoid consumer deception. Accordingly, the Global Garlic website might include a separate area dedicated to "emerging research concerning potential health benefits of garlic supplementation." This area might include such a claim as "two recent clinical studies in adult male campers reported that daily garlic supplementation reduced mosquito bites by 20 percent. More research is needed before any dietary recommendations can be made. . . ."

C. *Third-Party Literature*

Although FDA has the authority to regulate literature used in connection with the sale of food products as labeling, DSHEA excluded from FDA's labeling authority third-party literature used in the sale of dietary supplements.[117] The FTC has assumed responsibility for regulating these materials and will apply conventional antideception and substantiation policies to health information contained in these materials, as it does with food advertising generally.[118] In contrast, similar materials used in connection with the sale of food that do not meet the dietary supplement definition may qualify as labeling, and thus remain subject to the full range of FDA food labeling regulations. The FTC has stated:

> [a]lthough the FTC does not regulate the content or accuracy of statements made in independently written and published books, articles, or other noncommercial literature, FTC law does prohibit the deceptive use of such mate-

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[116] *Id.* at 10.

Using the following rating scale (5=very sure, 4=somewhat sure, 3=neither sure nor unsure, 2=somewhat unsure, 1=very unsure), consumers participating in the study gave the following "highly qualified" claim an average score of 2.88, slightly under 3.0, a score defined to mean that scientists were "neither sure nor unsure" of the diet/disease relationship: "Scientists have known for some time about the special health benefits of fruits and vegetables that are rich in antioxidants like vitamins A, C and E. Eating plenty of these foods can reduce the risk of certain kinds of cancer. Some medical studies are now finding that supplements containing these same antioxidant vitamins may also reduce the risk of cancer. It's too early to tell for sure. *Some recent studies have failed to show that these vitamins protect against cancer. Longer term research is needed . . .*

FEDERAL TRADE COMM'N, GENERIC COPY TEST OF FOOD HEALTH CLAIMS IN ADVERTISING 71, App. A at 24 (emphasis added). In contrast, consumers gave the following less-qualified health claim a score of 3.39, a score falling between "somewhat sure" and "neither sure nor unsure":

> Scientists have known for some time about the special health benefits of fruits and vegetables that are rich in antioxidants like vitamins A, C and E. Eating plenty of these foods can reduce the risk of certain kinds of cancer. *Some medical studies are now finding that supplements containing these same antioxidant vitamins may also reduce the risk of cancer. It looks promising, but scientists won't be sure until longer term research is completed.* In the meantime, always eat a balanced diet with 5 to 9 servings of fruits and vegetables a day. And to make sure you get the antioxidant vitamins you want, try new ACE Antioxidant Supplement.

Id. at 71, App. A at 23 (emphasis added).

[117] 21 U.S.C. § 343-2.

[118] *See* DIETARY SUPPLEMENTS, *supra* note 107, at 24.

> rials in marketing products. . . . As a practical matter, publications and other materials that comply with the elements of the DSHEA provision, particularly with the requirement that such materials be truthful, not misleading and balanced, also are likely to comply with FTC advertising law.[119]

DSHEA's third-party literature provision provides that "a publication . . . which is reprinted in its entirety, such as an 'article, chapter in a book' or an official abstract of a peer-reviewed scientific publication"[120] appearing in an article may be used in connection with the sale of a dietary supplement to consumers when the publication is:

- not "false or misleading;"
- does not "promote" a "particular manufacturer or brand of dietary supplement;"
- is "displayed or presented" with "other such items on the same subject matter, so as to present a balanced view of the available scientific information" concerning the supplement;
- kept "physically separate" from the dietary supplements themselves when displayed "in an establishment;" and
- does not have any information "appended to it."[121]

Interpretation of the third-party literature provision in the context of the Internet presents challenges in two specific areas. First, the requirement that there be no information "appended" to the literature could present a significant obstacle to manufacturers disseminating third-party literature on the Internet. DSHEA provides no definition of "appended," but the term commonly means "to add as a supplement, as at the end of a book" or "to fix to: attach."[122] Given the companion provisions in DSHEA prohibiting third-party literature promoting a "particular manufacturer or brand of dietary supplement," and requiring such literature to be kept "physically separate" from products when displayed in an establishment discussed above, the prohibition on "appended" information appears directed at the attachment of product or company logos, or other identifying information that impliedly would promote a particular company or brand of dietary supplement. To qualify under the third-party literature provision of DSHEA, it is important to present third-party literature using an Internet application that creates an electronic separation between such literature and product promotions. This separation might be achieved, for example, by presenting a library of third-party literature in a separate area of a website from product sales information in a manner that requires multiple "clicks" to travel the hyperlinks connecting the areas.

Second, in interpreting the requirement that third-party literature be presented with other materials to create a "balanced view" of the scientific information, the ability of the Internet to provide access to diverse materials must be taken into consideration. While the possibilities will continue to expand with Internet technology, two basic approaches frequently are taken. A library of balanced information accompanied by an index or bibliography may be provided on a single website. Alternatively, a network of hyperlinks can be developed to provide access to a balanced selection of literature from existing online libraries. Whether this latter approach achieves "fair balance" depends on whether the overall virtual library is constructed in a manner that gives consumers easy access to diverse information and views on the health mat-

[119] *Id.*
[120] 21 U.S.C. § 341-2(a) (DSHEA § 5).
[121] *Id.*
[122] WEBSTER'S II NEW RIVERSIDE UNIV. DICTIONARY 118 (A.H. Soukhanov & K. Ellis eds., 1994).

ter in question. For example, Global Garlic may establish a virtual library of information on the effects of garlic on serum cholesterol levels by establishing hyperlinks to online literature banks on this topic that are controlled by different scientific bodies (e.g., libraries sponsored by government, industry, and other relevant groups).

D. *Labeling*

FDA has broad jurisdiction to regulate the content of food and dietary supplement labeling. Health-related claims included in labeling are subject to different FDA requirements, depending on the class in which the claim falls.

The FDCA defines labeling to include "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) *accompanying* such article."[123] The scope of FDA authority over food labeling has been defined largely through the courts' interpretation of the term "accompanying." In *Kordel v. United States*,[124] and *United States v. Urbuteit*,[125] the Supreme Court held that no physical connection must exist between printed or graphic matter and a product for it to "accompany" the product within the meaning of the definition. In both cases, the Court held that Congress intended the material to accompany the product in the broad textual sense of explaining or supplementing the product "in the manner that a committee report of the Congress accompanies a bill."[126] The Court looked to "the interstate transaction in its entirety" to determine whether the distribution of the literature and product were part of an "integrated distribution program which renders the literature labeling."[127]

Since *Kordel* and *Urbuteit*, courts have interpreted "accompanying" broadly, to effectuate "the high purpose of the Act to protect consumers who under present conditions are largely unable to protect themselves in this field."[128] For example, courts have held that literature distributed to a customer prior to a product purchase may constitute labeling,[129] that lectures and lecture notes may constitute labeling,[130] and that the newsletter of an ostensibly independent organization, which was in fact owned by individuals involved in the manufacture and marketing of the product, may constitute labeling.[131]

Some courts have held that third-party literature written and published with no promotional intent, and that does not promote a particular product can constitute labeling when used by a vendor in connection with product sales. For example, in

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[123] 21 U.S.C. § 321(m) (FDCA § 201(m)) (emphasis added).

[124] 335 U.S. 345 (1948).

[125] 335 U.S. 355 (1948).

[126] *Kordel*, 335 U.S. at 350.

[127] *Urbuteit*, 335 U.S. at 357; *see Kordel*, 335 U.S. at 349-50.

[128] *Kordel*, 335 U.S. at 349.

[129] United States v. 110 V Vapazone, 194 F. Supp. 332 (N.D. Cal. 1961) (physical therapist acquired pamphlet from German vendor explaining use of device she bought while in Germany, then received delivery of device in United States).

[130] United States v. Hohensee, 243 F.2d 367 (3d Cir. 1957) (lectures following closely on introduction of product locally); *see also* Nature Food Ctrs., Inc. v. United States, 310 F.2d 67, 70 (1st Cir. 1962) (lecture notes sold separately at lectures extolling virtue of products might "incur liability for false labeling").

[131] United States v. Vital Health Prods., Ltd., 786 F. Supp. 761 (E.D. Wis. 1992), *aff'd sub nom.* United States v. Lebeau, 985 F.2d 563 (7th Cir. 1993) (considering newsletter published through separate corporation owned by manufacturer extolling virtues of "peroxide therapy" part of labeling of manufacturer's peroxide products); United States v. Sene X Eleemosynary Corp., Inc., 479 F. Supp. 970 (S.D. Fla. 1979) (holding separately organized "club" operated by person in close association with manufacturer and used to distribute information part of integrated scheme).

United States v. 250 Jars of U.S. Fancy Pure Honey,[132] an FDA inspector entered a health food store and asked for information on honey. The clerk directed the inspector to a book entitled *About Honey* and gave the inspector a copy of a newspaper article entitled "Eat Honey and Increase Your Vitality." The store displayed copies of the book for sale near its honey display (although in the book section of its store) and mailed copies of the newspaper article to customers on its mailing list.[133] The district court held that, although the book and newspaper article were written by independent third parties and did not advertise a particular brand of honey, the material constituted labeling within the FDCA's meaning.[134] A similar result was reached in *United States v. 8 Cartons Plantation "The Original" etc. Molasses*.[135] In that case, a health food store actively promoted a book about blackstrap molasses, prominently displayed a reprint of an article from a popular magazine about the book, and showed the book to customers who appeared interested in molasses. While the court was careful to state that the publisher may freely publish and sell the book "even in stores where 'Plantation' blackstrap molasses is sold,"[136] the court held that the store's actions in this case constituted a "distribution plan" that converted the book into labeling.[137]

By contrast, in *United States v. 24 Bottles etc. "Sterling Vinegar and Honey" etc.*,[138] a health food store sold a popular book on the virtues of vinegar and honey mixtures as folk remedies. A third party created a mixture based on the recipe in the book, which the health food store also sold. When the FDA sought to condemn the book and the mixture, the U.S. Court of Appeals for the Second Circuit held that the book was not labeling within the meaning of the statute.[139] Critical to the court's determination was the absence of an "integrated scheme" on the part of the store to promote the book and mixture together.[140] The court acknowledged that sales of the book would increase sales of the mixture, but found this did not create a sufficient nexus between the book and the mixture in the hands of the vendor to transform the book to labeling.[141]

The requirement for a nexus between literature and product also was addressed in *United States v. Alberty Food Products*,[142] where the court determined that Alberty could not satisfy the requirement that directions for use and adequate warnings appear on the labeling when the directions and warnings appeared in literature mailed to prospective customers. The court stated that "where, as here, the literature and the drugs do not have a common destination and the literature is not shipped to either a distributor of the drug or a consumer of the drug, it would be in derogation of the Act to broaden further the content of the verb 'accompany' as employed in § 201(m)(2) [of the FDCA], 21 U.S.C.A. § 321(m)(2)."[143] The court went on to limit the application of *Kordel* to "cases where the literature has the same destination as the drug, and hence will likely reach the hands of the consumer to serve the purposes for which labeling is intended."[144]

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[132] 218 F. Supp. 208, 209 (E.D. Mich. 1963), *aff'd*, 344 F.2d 288 (6th Cir. 1965).

[133] 218 F. Supp. at 209-10.

[134] *Id.* at 211-12.

[135] 103 F. Supp. 626 (W.D.N.Y. 1951).

[136] *Id.* at 628.

[137] *Id.*

[138] 338 F.2d 157, 159-60 (2d Cir. 1964).

[139] *Id.*

[140] *Id.* at 160.

[141] *Id.* at 158-59.

[142] 98 F. Supp. 23 (S.D. Cal. 1951), *aff'd sub nom.* Alberty Food Prods. v. United States, 194 F.2d 463 (9th Cir. 1952).

[143] *Id.*

[144] *Id.*

Thus, the labeling of a product need not physically accompany the product in the distribution channels. Labeling can take the form of any written or graphic matter, including matter prepared by third parties (except when the literature qualifies under the third-party literature provision of DSHEA) even when referring to a general commodity (such as honey) rather than to a specific product or brand. In interpreting the labeling definition, courts have looked not merely to the specific text or representation in question, but to the role of the information in the entire context of the sales transactions occurring in the chain of distribution. If the matter is part of an integrated scheme to promote the product, with a readily discernible nexus between product sales and the matter, the representation will constitute labeling under section 201(m) of the FDCA, and be subject to FDA food and dietary supplement labeling requirements.

The same labeling analysis would apply to printed or graphic matter appearing on the Internet. Where a textual nexus can be established between a product and printed or graphic matter appearing on the Internet, regulatory standards applicable to labeling (rather than advertising) would apply.

While it is clear that increasing the electronic distance between information and the point-of-sale reduces the likelihood that material will qualify as labeling, no bright-line rule can be articulated. Whenever Internet matter functions to "supplement or explain" a product and is part of an integrated marketing scheme to sell products, it is susceptible to regulation as labeling under existing FDCA precedents.

Hypothetical: Returning to Global Garlic, health claims concerning asserted benefits of garlic supplements in "preventing heart attack and stroke" appearing on the same page of the manufacturer's website as an online product order form would constitute labeling. Under current FDA policy, heart attack and stroke claims would be prohibited unless specifically authorized under FDA premarket approval or notification procedures for health claims.

E. *FDA Regulation of Health-Related Claims*

1. *Drug Claims*

In addition to FDA's direct jurisdiction over the content of food and dietary supplement labeling, FDA may consider health information and claims disseminated through advertising and other relevant information in determining whether such products are making drug claims, which would subject them to premarket approval under the FDCA. The act defines "drug" to include any product "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."[145] Products that are foods or dietary supplements also may qualify as drugs under this definition.

The "intended use" standard in the drug definition refers to the vendor's intent and may be determined from any relevant source of information.[146] FDA has issued regulations specifying that the intended use of a drug may be determined from sources including "expressions" of the manufacturer or the "circumstances surrounding the distribution of the article" including, "labeling claims, advertising matter, oral or written statements," and the manufacturer's knowing sale of the product for a drug use.[147]

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[145] 21 U.S.C. § 321(g)(1)(B) (FDCA § 201(g)(1)(B)).

[146] United States v. 46 Cartons . . . Fairfax Cigarettes, 113 F. Supp. 336 (D. N.J. 1953); 21 C.F.R. § 201.128. *See also*, United States v. B-Complex Cholinos Capsules, 362 F.2d 923, 926-27 (3d Cir. 1966); United States v. Vital Health Prods., Ltd., 786 F. Supp. 761, 772 (E.D. Wis. 1992), *aff'd sub nom. Lebeau*, 985 F.2d at 563; *250 Jars*, 218 F. Supp. at 211.

[147] 21 C.F.R. § 201.128.

Courts have held that disease claims made by third parties may render a product a drug if quoted with obvious approval or sponsored by the vendor.[148] In *United States v. B-Complex Cholinos Capsules*,[149] a vitamin manufacturer sponsored a radio show featuring a health expert extolling the curative power of vitamins. Although the expert never mentioned the name of the manufacturer or the product during the broadcast, but simply asserted health claims for vitamins generally, the court held that a sufficient relationship between the expert and the manufacturer existed to impute the statements to the manufacturer.[150] The court noted that the central issue was whether the statements of the expert properly demonstrated the intent of the manufacturer to have consumers perceive its vitamins as having curative powers.[151]

The circumstances in which the speech of third parties may be imputed to a food or dietary supplement manufacturer takes on particular significance on the Internet, where applications such as hypertext links, manufacturer-sponsored online chatrooms, or discussion groups make it simple to expose potential customers directly to the words of third parties. To counter the risk that the statements of third parties may be accredited to manufacturers sponsoring websites, appropriate disclaimers should be featured prominently.

Hypothetical: An appropriate disclaimer could state "Global Garlic's products are foods intended solely for dietary use and not to prevent or treat any disease or abnormal condition. Global Garlic makes no endorsement of the views expressed by chatroom visitors or on sites to which Global Garlic links, or sites which link to Global Garlic."

The drug definition only covers "articles *intended for use*" as drugs.[152] For a disease claim concerning the benefits of food or dietary supplements to render a particular product a drug, the claim must reflect the vendor's intended use of that particular article of food or dietary supplement. Generic disease claims concerning food or food constituent commodities that are sponsored by industry groups typically would not render the commodity categorically a drug. On the other hand, where generic disease claims, even for commodities, are disseminated in a way that implies an intended use of particular articles (e.g., brands) of the commodity, such claims potentially would trigger drug regulation for such articles.

Hypothetical: Rather than present generic disease claims for the garlic constituent, allicin, on Global Garlic's website, Global Garlic might choose to cosponsor a website concerning allicin as a member of the "Allicin Alliance," a garlic-oriented educational foundation composed of garlic growers and garlic product manufacturers. Such a website might discuss the emerging scientific research concerning allicin metabolism and the relationship between allicin intake and the risk of specific diseases. Provided the disease claims on the Allicin Alliance website are not connected to any specific articles of garlic or allicin product, they typically would not render any such product a drug. To help avoid the potential risk of "drug" regulation for its garlic and garlic supplements, Global Garlic thus might choose to omit any reference to its company or products on the Alliance website, and refrain from authorizing or establishing hyperlinks between the Global Garlic and Alliance websites.

2. *Health Claims*

A safe harbor exclusion from the drug definition protects food or dietary supplement products making health claims in labeling from regulation as drugs, when such

[148] *See, e.g.*, V.E. Irons, Inc. v. United States, 244 F.2d 34, 40, n.6 (1st Cir. 1957).

[149] 362 F.2d 923 (3d Cir. 1966).

[150] *Id.* at 926.

[151] *Id.*

[152] 21 U.S.C. § 321(g)(1)(B) (emphasis added).

claims either are authorized by FDA regulation under the Nutrition Labeling and Education Act of 1990 (NLEA),[153] or authorized under the premarket notification procedure established by the Food and Drug Administration Modernization Act of 1997 (FDAMA)[154] for health claims based on an "authoritative statement" of a federal scientific body (e.g., the Centers for Disease Control and Prevention).[155] A health claim is any claim "made in the label or labeling of the food which expressly or by implication . . . characterizes the relationship of any nutrient . . . to a disease or a health-related condition. . . ."[156] FDA has proposed to interpret disease claims broadly to encompass claims stating or implying that a product is intended to diagnose, cure, mitigate, treat, or prevent any deviation from a normal body function that has a "characteristic set of signs or symptoms. . . ."[157] Health claims often constitute express or implied disease prevention claims.[158]

3. *Structure/Function Claims*

In contrast to health claims, structure/function claims can be made in food or dietary supplement labeling under essentially the same standards the FTC applies to claims in advertising. Structure/function claims describe the effect of a food or dietary supplement on the structure or function of the body. These claims typically describe the role of a food in promoting normal growth and development, or characterize the normal mechanism by which these benefits occur in the body. A classic example of a structure/function claim is "calcium helps build and maintain strong bones." The FDCA requires no premarket approval before structure/function claims can be made in labeling.[159] Such claims are permitted provided they are stated in a truthful and nonmisleading manner and are substantiated by appropriate scientific evidence.[160] Under section 403(r)(6) of the FDCA, a postmarket notification must be filed with FDA when a structure/function claim is made for a dietary ingredient of a dietary supplement. No such notification requirement applies when structure/function claims are made for foods or dietary ingredients (e.g., essential nutrients) under section 201(g)(1)(C) of the FDCA.

In April 1998, FDA proposed regulations delineating the boundary between structure/function claims and drug claims.[161] The proposal states that structure/function

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[153] *Id.* § 343(r)(3)(B). Under the NLEA, Pub. L. No. 101-535, 104 Stat. 2353 (codified at 21 U.S.C. §§ 301 note, 321, 337, 343, 343 notes, 343-1, 343-1 note, 345, 371 (1994)), FDA issues regulations approving health claims satisfying the rigorous "significant scientific agreement" standard. 21 U.S.C. § 343(r)(3)(B). Under established FDA policy, claims not satisfying this standard have been prohibited. The recent First Amendment decision in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), *reh'g en banc denied*, 1999 U.S. App. LEXIS 5954 (D.C. Cir. Apr. 2, 1999), applied the commercial speech doctrine to health claims. The decision requires FDA to reconsider four specific health claims banned under this policy to determine if they can be presented in a manner that renders the claims nondeceptive (and thus protected by the First Amendment) through the use of qualifying language or disclaimers. The *Pearson* decision also requires FDA to more fully explain the "significant scientific agreement standard." 164 F.3d at 654. For a discussion of First Amendment issues presented by the NLEA health claims policy, see Edward Dunkelberger & Sarah E. Taylor, *The NLEA, Health Claims, and the First Amendment*, 48 FOOD & DRUG L.J. 631 (1993).

[154] Pub. L. No. 105-115, 111 Stat. 2296 (1997).

[155] 21 U.S.C. §§ 343(r)(3)(C), 343(r)(1)(B); *see also* 21 C.F.R. § 101.14(a)(1). FDA-approved health claims are codified at 21 C.F.R. pt. 101, subpt. E.

[156] 21 U.S.C. § 343(r)(1)(B).

[157] 63 Fed. Reg. 23,624, 23,632 (Apr. 19, 1998).

[158] 21 C.F.R. § 101.72.

[159] 21 U.S.C. § 321(g)(1)(C) (FDCA § 201(g)(1)(B)).

[160] *Id.* §§ 321(n), 343(a).

[161] 63 Fed. Reg. at 23,624.

claims may "describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function. . . ."[162] The proposal distinguishes structure/function claims from disease claims that trigger drug status and premarket approval requirements. For this purpose, the proposal defines disease to include:

> any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms, including laboratory or clinical measurements that are characteristic of a disease.[163]

4. *Claims Concerning Nutrient and Dietary Ingredient Levels*

Claims characterizing the level of nutritional constituents, including nutrients[164] and dietary ingredients,[165] in food or dietary supplements through absolute terms (e.g., "low" or "high") or comparative terms (e.g., "reduced" or "more") must comply with FDA definitions of these terms when claims appear in labeling. Claims using terms that are undefined in FDA regulations are prohibited in labeling.[166] Simple quantitative descriptions (e.g., "six grams of protein" or "100 milligrams of lycopene") that do not "characterize" the level of constituents with terms suggesting the level is beneficially high or low (e.g., "*only* 5 grams . . . .") can be used in labeling without premarket approval.[167]

To avoid consumer deception through the inconsistent use of FDA-defined terms in labeling and advertising, the FTC generally applies FDA requirements to the same terms used in food advertising. For undefined terms, the FTC considers the standards underlying FDA regulations for relevant defined terms in determining whether claims are substantiated and nondeceptive.[168] For example, the FTC probably would require foods promoted as a "great source of calcium" to conform generally with the criteria for the defined claim "high calcium" because the claims essentially are synonymous.

F. *Putting It Together: Rules-of-Thumb for Health-Related Promotions on the Internet*

Considering the substantiation and deception policies that are applied to Internet advertising by the FTC and the states, and the specialized regulatory framework currently governing labeling and disease claims on the Internet, some clear "rules-of-thumb" can help guide health-related promotions on the Internet by manufacturers of functional foods and nutraceuticals.

- At a minimum, express and implied health-related claims should be fully substantiated by appropriate scientific evidence before posting on the Internet.

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[162] *Id.* at 23,632.

[163] *Id.*

[164] 21 U.S.C. §§ 343(q)(1),(r)(1)(A).

[165] *Id.* § 321(ff)(1).

[166] 21 C.F.R. § 101.13. FDA-approved claims are codified at 21 C.F.R. pt. 101, subpt. D.

[167] *Id.* § 101.13(i).

[168] *See* FEDERAL TRADE COMM'N, ENFORCEMENT POLICY STATEMENT ON FOOD ADVERTISING 6-17 (May 1994).

- Disclaimers and qualified language should be used as necessary so that express and implied claims "match" the strength of the body of scientific evidence substantiating the claim. The substantive weight that should be given to supportive research findings should be determined in the context of the surrounding body of relevant scientific evidence using established scientific principles.
- Claims that may expressly or impliedly characterize the relationship between consumption of any food, dietary supplement or constituent and disease may appear on the Internet in one of the following ways:

(1) as part of a library of "third party literature" for a dietary supplement that presents the information in a manner that provides "fair balance" and does not promote any specific manufacturer or brand of supplement;

(2) in nonlabeling (advertising) material for a generic food or dietary supplement ingredient or constituent ("commodity") that is not connected by hyperlink or other means to information promoting any particular food or dietary supplement product;

(3) via spontaneous chatroom discussions by unsolicited website visitors where any manufacturer's endorsement of views expressed in the chatroom is prominently and appropriately disclaimed; or

(4) in labeling (e.g., point-of-purchase) material when the specific disease claim is either an approved health claim under FDA regulations or is based on the "authoritative statement" of a federal scientific body and is authorized under the FDAMA premarket clearance procedure.

- Health-related claims that do not expressly or impliedly characterize the relationship between a food, dietary supplement, or constituent and disease may be made in any Internet matter provided such claims are substantiated and nondeceptive. This includes structure/function claims and general health information (e.g., dietary guidance).
- Claims characterizing the level of nutrients, dietary ingredients or other constituents in food or dietary supplements in labeling or advertising matter should conform with FDA regulations for such claims (e.g., "low fat"). Claims that have not been defined by FDA (e.g., "great source of calcium") may be used in Internet advertising but should be used in a manner that is consistent with any relevant FDA-defined claims (e.g., "high in calcium").

V. CONCLUSION

While these rules can be applied to a broad spectrum of health-related information posted on the Internet by manufacturers of functional foods and nutraceuticals, they are neither exhaustive nor bright-line. Internet matter must be considered on a case-by-case basis to determine whether, in the context of its use, the FTC (or state) advertising standards or FDA labeling or drug standards apply to the specific information in question.

Because of the rapid scientific advances in diet/disease research, both the nature and volume of health information available to promote functional foods and nutraceuticals is expanding dramatically. Together with the explosive growth in the Internet, and the diversity of applications available to access self-care consumers, the

need for manufacturers to carefully review their Internet promotions on a case-by-case basis to ensure regulatory compliance is great.

The Internet represents an exciting new medium for transmitting health and nutrition information to consumers. Because of the relative newness of the medium and its rapid expansion, some appear to have developed a mistaken idea that the Internet is a "Wild West" where anything goes. This is not the case. While a speaker can expect to enjoy the same degree of First Amendment protection on the Internet as elsewhere, the Internet does not provide people with a license to ignore existing rules governing the advertising and labeling of products that make health-related claims. Furthermore, those using the Internet should exercise particular caution when taking advantage of the capabilities of the medium, particularly in the area of privacy.

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Soller

Divider Title: _____

R. WILLIAM SOLLER, PH.D.
Senior Vice President and
Director of Science & Technology
Consumer Healthcare Products Association
1150 Connecticut Avenue, N.W.
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Education: BS, Colby College
Ph.D., Cornell University
Graduate School of Medical Services

Dr. Soller's scientific and technical background includes academic and member company experience in pharmacology, epidemiology, risk assessment, product development and regulatory affairs. His responsibilities at CHPA include senior management, strategic planning, and oversight of standing committees and member task groups concerned with a wide array of dietary supplement and OTC drug safety, efficacy, manufacturing, packaging and labeling issues.

Dr. Soller has extensive experience working with the Food and Drug Administration and other government agencies and serves as CHPA's official Delegate to the United States Pharmacopeial Convention. Dr. Soller is a regular speaker at industry-wide and academic meetings on scientific and technical issues affecting dietary supplements and OTC medicines.

Prior to joining CHPA, Dr. Soller was Technical Director, Proprietary Drug Development at Lederle Laboratories (1985) and Vice President, Director of Scientific Affairs at Sterling Drug Inc. (1981-85). From 1974-79, he conducted research and taught pharmacology at the University of Pennsylvania School of Medicine.

Dr. Soller is a member of the American Society of Clinical Pharmacology and Therapeutics, Sigma Xi, the Drug Information Association, the New York Academy of Sciences, the Regulatory Affairs Professional Society, the American Association of Pharmaceutical Scientists, the Society for Neuroscience, and the American Society of Association Executives.

CHPA is the 120-year-old trade organization representing the manufacturers and distributors of dietary supplements and over-the-counter medicines. CHPA has over 200 members across the manufacturing, distribution, supply, research and advertising sectors of the self-care industry.

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Comments Before the White House Commission on Complementary and Alternative Medicine Policy on Information Development and Dissemination

Meeting in Washington, DC
March 26, 2001

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology
Consumer Healthcare Products Association

Mr. Chairman. Members of the Panel. Good afternoon.

I am Dr. Bill Soller, Senior Vice President and Director of Science & Technology of the Consumer Healthcare Products Association (CHPA), the 120-year-old trade organization representing the manufacturers and distributors of dietary supplements and nonprescription medicines. CHPA has over 200 members across the manufacturing, distribution, supply, research and advertising sectors of the self-care industry.

CHPA has commented on numerous aspects of the evolving regulatory framework for dietary supplements, including aspects relating to claims, advertising, promotion, adverse experience reporting, Good Manufacturing Practices (GMPs), analytical methods, among other areas of interest to our members.

I addressed the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP; hereafter, the Commission) at its March 16, 2001, Minnesota Town meeting, where I commented on the need for the Commission to support actively the appropriate funding of the Food and Drug Administration (FDA) to implement its long-range plan for dietary supplements.

I repeat this plea today, noting that last week at a hearing of the House Committee on Government Reform Mr. Joe Levitt, director of the FDA Center for Food Safety and Applied Nutrition (CFSAN), indicated CFSAN seeks appropriations of $6 million per year, starting with $3 million, scaling up in the second year to about $4.5 million, and reaching full funding in year three.

If Complementary and Alternative Medical (CAM) practitioners are concerned with quality and labeling issues affecting dietary supplements, then fiscal support to develop reasonable standardization that appropriately implement the statutory provisions of the

Dietary Supplement Health and Education Act (DSHEA) is vital to their interests, as well as those of consumers, patients, and, indeed, the industry.

I thank you for your invitation to me to return to the Commission to address the following questions pertaining to CAM information, specifically:

- Are current regulations adequate to assure consumer access and assure consumer safety?
- What are the barriers to consumers getting the information they need?
- What is the company responsibility in providing information to the consumer?
- Is the information provided to consumers accurate, adequate and useful?
- What recommendations the Commission should consider in their report to the President and Congress?

The answers to these questions should be set against the backdrop of Congress' intent in enacting DSHEA. Specifically, Congress wanted to facilitate providing consumers with products; information and education that would help promote health, and prevent disease through maintenance of healthy aspects of the structure and function of their bodies. In fact, Congress notes in the "findings" section of the Act, that "consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements." Clearly, adequate truthful information transfer is vital to meeting the intent of DSHEA.

In addition, while my answers to these questions are made primarily from a dietary supplement standpoint, the general points that I make are applicable across other CAM product categories.

Are current regulations adequate to assure consumer access and assure consumer safety?

Yes, in relation to dietary supplements, both the FDA and the Federal Trade Commission (FTC) are on record stating they have the tools and the intention to regulate such products. For example:

- On March 25, 1999, by Food and Drug Administration Commissioner Jane E. Henney, M.D. before the House Committee on Government Reform stated: "FDA has tools at its disposal to take enforcement actions against dietary supplements found to have safety, labeling, or other violations of the FD&C Act, as amended by DSHEA."

- Similarly, Ms. Jodie Bernstein, Director of the FTC Bureau of Consumer Protection, has given the Bureau's commitment to effective regulation of dietary supplements: "... FTC must and will continue to maintain an enforcement presence here, giving priority to cases that present serious safety considerations or prey on the very sick and especially vulnerable consumer." [1]

[1] Bernstein, J.: the FTC and Dietary Supplements. FDLI Conference on Substantiating Claims for Dietary Supplement Advertising and Labeling, Washington, D.C., November 13, 1997.

The Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) work together under a long-standing agreement governing the division of responsibilities between the two agencies. As applied to dietary supplements [2]: FDA has the primary responsibility for claims on the product labeling, including packaging, inserts, and other promotional materials distributed at the point of sale; FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials.

The Food and Drug Administration [3] [4] has the power to:

- Stop any company from selling a dietary supplement that is toxic or unsanitary [see Food Drug and Cosmetic (FDC) Act, Section 402(a)];
- Stop the sale of a dietary supplement that has false or unsubstantiated claims [see FDC Act, Section 403(r)(6)];
- Take action against dietary supplements that pose "a significant unreasonable risk of illness or injury" [see FDC Act, Section 402(f)];
- Stop any company making a claim that a product cures or treats a disease [see FDC Act, Section 201(g)];
- Stop a new dietary ingredient from being marketed if FDA does not receive enough safety data in advance (see FDC Act, Section 413);
- Require dietary supplements to meet strict manufacturing requirements (Good Manufacturing Practices), including potency, cleanliness and stability [see FDC Act, Section 402(g)].

The Federal Trade Commission [4] has the power to:

- Enforce laws outlawing "unfair or deceptive acts or practices" [5] and false advertisements to ensure consumers get accurate information about dietary supplements, so they can make informed decisions about these products [see Federal Trade Commission (FTC) Act, Sections 5 and 12];
- Challenge and stop advertising that is not adequately substantiated (see FTC's Deception Policy Statement and Advertising Substantiation Policy Statement);
- Investigate complaints or questionable trade practices; FTC can investigate either informally or formally, where it has strong compulsory investigative authority, including the power to require a respondent to produce documents, give testimony, or answer written questions [see FTC Act, Sections 6(a and b) and 9];

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[2] Federal Trade Commission, Bureau of Consumer Protection: Dietary Supplements: An Advertising Guide for Industry. 1998. (see www.ftc.gov)

[3] Taken from comments by Scott Bass, Esq. before Representative Dan Burton, Chairman of the House of Representatives Committee on Government Oversight, Oversight Hearing on the Dietary Supplement and Health Education Act of 1994, March 25, 1999.

[4] Soller, R. W.: Regulation in the Herb Market: The Myth of the Unregulated Industry. *Herbalgram* Feb.-Mar., 2000.

[5] An unfair trade practice is one that: causes or is likely to cause substantial injury to consumers; is not reasonably avoidable by consumers themselves; and not outweighed by countervailing benefits to consumers or competition (see FTC's Deception Policy Statement and Advertising Substantiation Policy Statement at www.ftc.gov).

- Following its own investigation, negotiate a consent order or proceed through an FTC adjudication resulting in a cease and desist order, which can be quite broad in its scope (see FTC Act, Section 5);
- Seek civil penalties for violations of cease and desist orders (see FTC Act Section 5).

Given that both FDA and FTC have the tools they need to ensure dietary supplements are safe, effective, high quality and properly labeled and promoted, it is important for the Commission to consider support of the general position that both agencies should be adequately funded to ensure that DSHEA is appropriately implemented, consistent with Congress' intent in passing the statute.

What are the barriers to consumers getting the information they need?

The following is a categorical listing of barriers and facilitators to CAM information transfer to consumers:

Barriers	Facilitators
Rogue manufacturers making unsubstantiated claims	Legitimate manufacturers making evidence-based claims
Lack of research incentives	NIH-sponsored research
Lack of a defined label warning policy within CFSAN[6]	CFSAN's grant to IOM/NAS to develop a scientific approach to DS
Too many information sources; no clear/central information authority	Health professional groups defining their roles as information multipliers
Educationally-unprepared consumers, patients, and conventional healthcare practitioners	Evidence-based CAM providers and consumer interest in visiting CAM providers
Limited base of current science	Evolving science base for CAM products
Limited standardization of CAM practitioner guidelines	WHCCAMP recommendations to the President and Congress on licensing and continuing CAM education models

What is the company responsibility in providing information to the consumer?

By law, companies must ensure that their labeling[7] and advertising is both truthful and not misleading,[8] and we believe claims made by CAM practitioners about CAM products, especially dietary supplements, should be held to the same standard.

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[6] On several occasions, CHPA has commented to FDA's Center for Food Safety and Applied Nutrition that the Center needs to articulate a clear labeling policy on when to warn. FDA has a long standing policy that has been used for consumer products, including OTC medicines and foods, which is that warnings (or decisions about product availability) should be "scientifically documented, clinically significant, and important to the safe and effective use of the product by the consumer." The importance of such a policy openly acknowledged by the Center cannot be underestimated, as it focuses public health decisions on the first hurdle, scientific documentation, as the basis for decision making. See also: [47 *Federal Register* 1982: 54754]; [53 *Federal Register* 1988: 46213]; and Soller, R.W.: When to Warn. *Regulatory Affairs Focus* Vol 2 Issue 10 Oct 97.

[7] Food, Drug Cosmetic Act; Dietary Supplement Health and Education Act of 1994 (Pub. L. 103-417).

Is the information provided to consumers accurate, adequate and useful?

Given that consumer- and patient-related labeling, advertising, and promotion must be by law both truthful and not misleading, the question is better re-framed in two parts:

- Is enforcement adequate to ensure the information provided to consumers is accurate, adequate and useful?
- Since both FDA and FTC acknowledge they have the statutory tools needed to implement the labeling and promotional provisions of the Food Drug Cosmetic Act and Federal Trade Commission Act, do FDA and FTC have the fiscal resources needed for adequately fulfilling their statute-derived enforcement functions, consistent with existing law?

Furthermore, CAM practitioners may distribute CAM-related products, including dietary supplements. It is therefore important that they be cognizant of the regulations and policies promulgated by FDA and FTC. For example, FDA has issued regulations pertaining to nutritional labeling, structure/function claims and health claims, to name two areas of specific interest.

FTC has re-issued a compilation of its policies, tailored for dietary supplement manufacturers (i.e., *"Dietary Supplements: An Advertising Guide for Industry"*). FTC notes in this policy guide, for example, that supplement marketers should ensure that anyone involved in promoting products is familiar with basic FTC advertising principles. The FTC has taken action not just against supplement manufacturers, but also, in appropriate circumstances, against ad agencies, distributors, retailers, catalog companies, infomercial producers and others involved in deceptive promotions. Therefore FTC appropriately cautions that all parties who participate directly or indirectly in the marketing of dietary supplements have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims.

FTC's D/S Advertising Guide has been supported by our Association. Our members, many of whom have also marketed medicinal products under the policies set forth in the guidance, recognize the value of this guide in helping to inform companies of FTC policies. CHPA has broadly distributed copies of the Guide to its members and held workshops with FTC officials to review it and respond to questions.

Companies complying with the law implementing regulations provide consumers with accurate and useful information on dietary supplements. Enforcement by FDA and FTC is intended to create a sufficiently broad environment of truthful and non-misleading information on consumer and professional products. Consequently, the issues are

[8] The FTC's truth-in-advertising law can be boiled down to two common-sense propositions: 1) advertising must be truthful and not misleading; and 2) before disseminating an ad, advertisers must have adequate substantiation for all objective product claims.[5] A deceptive ad is one that contains a misrepresentation or omission that is likely to mislead consumers acting reasonably under the circumstances to their detriment. The FTC's substantiation standard is a flexible one that depends on many factors. When evaluating claims about the efficacy and safety of foods, dietary supplements and drugs, the FTC has typically applied a substantiation standard of competent and reliable scientific evidence.

whether FDA and FTC have sufficient resources to fulfill their enforcement duties in this area, and whether CAM practitioners are sufficiently aware of their responsibilities in the context of promoting, for example, dietary supplements.

What recommendations the Commission should consider in their report to the President and Congress?

1. The Commission should provide a strong recommendation to the Administration to support for adequate funding for CFSAN to implement its long-range plan to regulate dietary supplements, consistent with DSHEA.

   Funding of reasonable, appropriately-targeted regulatory activities by CFSAN would help address a significant barrier to consumers getting accurate, adequate and useful information – i.e., address the practices of rogue manufacturers who ignore the statutory and regulatory framework of DSHEA.

2. The Commission should consider encouraging FTC to develop industry and practitioner guides in the CAM product arena as was developed for dietary supplements.

   Such guides are helpful to define the standard expected of industry, allowing well-intentioned manufacturers and practitioners to optimize their understanding of the ground rules.

3. The Commission should support a consistent standard for advertising and promotion of all CAM products, as explained in part herein for dietary supplements.

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BOIRON®

White House Commission on Complementary and Alternative Medicine Policy

Complementary and Alternative Medicine in Self-Care and Wellness and Information Development and Dissemination

Monday, March 26, 2001
Washington, D.C.

Presented by
Mark Land
Boiron USA

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email: mark.land@boiron.com

Table of Contents

Introduction

Mark Land currently holds the position of Technical Manager at Boiron USA's headquarters in Newtown Square, PA. In this capacity Mark is responsible for Boiron USA distribution operations and regulatory compliance. Mark has 20 years experience at Boiron and participates in the elaboration and implementation of the strategy of Boiron USA as a member of the Management Team.

We would like to thank this commission, commissioners and organizers for the opportunity to address you. We have followed with interest your work and look forward to contributing to the goals of the commission.

Company Profile

The Company

Boiron was founded in 1932 in Lyon, France. It is now a leading firm specializing in the manufacture, marketing and distribution of homeopathic medicines worldwide.

The Mission Statement

To give every physician and healthcare professional the world over the opportunity to learn about homeopathic medicines and use them in daily practice.

Facts About Boiron

- Boiron USA operates facilities in the United States near Philadelphia (Newtown Square) and Los Angeles (Simi Valley).
- Other subsidiaries in Canada, the Caribbean, Belgium, Italy, and Spain.
- 2,500 employees worldwide.
- Products sold in 61 countries.

Boiron USA

- Established in 1983
- CEO: Thierry Boiron
- Organized into three divisions:
  1. Marketing, Sales and Distribution, servicing independent pharmacies, natural-product stores, food, drug and mass market stores.
  2. Boiron Institute, providing educational services to healthcare professionals.
  3. Boiron Research Foundation, working with major research centers, such as UCLA and University of Washington.

Boiron: How To Reach Us
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www.boiron.com
E-mail: info@boiron.com

Brief History of Homeopathy in the United States

Homeopathy was developed more than 200 years ago by Samuel Hahnemann (1755-1843), a German physician. Homeopathy then developed through Europe and has been practiced in the United States for over 175 years. As early as 1834, many states established homeopathic medical societies, and by 1844 homeopathic trade associations and journals emerged in the United States. The first pharmacopeia (unofficial) was published in 1841. The first official pharmacopeia has been continuously published since 1897. There are currently numerous homeopathic medical boards, medical state societies, professional societies, and medical journals in the United States. It is estimated that $230 million worth of homeopathic medicines are currently sold in the United States each year and that 10 million Americans use homeopathic medicines.

$1.5 B worldwide dollar

Legal and Regulatory Aspects of Homeopathic Medicines

Key Points

Homeopathy is unique within the category of CAM in that manufacturers are required to comply with strict drug labeling and manufacturing regulations:

Homeopathic products are officially classified as drugs in the United States.

Homeopathic manufacturing is required to comply with GMP (Good Manufacturing Practices).

Applicable Legal Framework

Homeopathic Medicines are Stringently Regulated by FDA

Prior to the passage of the Federal Food, Drug, and Cosmetic Act, ("FDCA") in 1938[1/], key homeopathic medicines were characterized as "drugs." Congress codified this characterization in 1938, when, in passing the FDCA, it defined the term "drug" to include "articles recognized in the official United States Pharmacopoeia, *official Homeopathic Pharmacopoeia*, or official National Formulary, or any supplement to any of them."[2/] This is the definition in effect today.

In 1988 in cooperation with the homeopathic industry, FDA issued a compliance policy guide ("CPG") that set forth the agency's regulatory approach toward homeopathic medicines.[3/] A CPG constitutes a formal "advisory opinion"[4/] that the agency, and the regulated community, is obligated to follow unless or until it is amended or revoked.

The homeopathic CPG states that "[t]he FDCA recognizes as official the drugs and standards in the Homeopathic Pharmacopoeia of the United States and its supplements." Under the CPG, homeopathic medicines are subject to a broad array of

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1/ Pub L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-392 (1994)).
2/ 21 U.S.C. § 321(g).
3/ FDA Compliance Policy Guide, Sec. 400.400, (formerly CPG 7132.15).
4/ 21 C.F.R. § 10.85(d)(3).

quality control standards, much like other drugs, including significant labeling requirements, manufacturing protocols, purity benchmarks and other FDA restrictions on drug adulteration. Moreover, homeopathic manufacturers must follow stringent "good manufacturing practices" and are subject to routine FDA inspections. The homeopathic CPG also requires drug manufacturers to register with the FDA and "list" their drug products with the agency pursuant to the Drug Listing Act. Homeopathic medicines are also subject to the same type of extensive labeling and promotional restrictions generally applicable to other drug products marketed in the United States. In addition, homeopathic drug manufacturers are subject to standards imposed by the Homeopathic Pharmacopoeia of the United States (HPUS), an "official compendium" recognized by Congress under the FDCA.

It is also important to note that the Health Care Financing Administration ("HCFA"), the agency that administers the federal Medicare program, treats homeopathic medicines as "covered" items and services for which reimbursement may be made. *See* 42 U.S.C. § 1395x(t)(1); Medicare Carrier's Manual (HCFA Pub. 14-3) § 2049.1.

The classification of homeopathic products as "drugs" brings with it numerous rights and responsibilities. Homeopathic products are required to bear "adequate directions for use" as well as indications. They are required to make claims with respect to those conditions that the product may help. All claims must be consistent with the literature.

Safety of Homeopathic Medicines

Homeopathic medicines have an overall excellent safety profile owing to their lack of toxicity. They are well suited for the treatment of self-limiting conditions amenable to diagnosis by consumers, and because of their lack of toxicity, they are not contraindicated in patients taking other medications.

The majority of these medicines sold in the United States are OTC.

Research in Homeopathy

More than 100 clinical trials have yielded positive results, including research centering on effectiveness in allergy, asthma, acute diarrhea, and withdrawal from minor tranquilizers.

Because there have been many publications on the efficacy of homeopathic treatments, it has been possible to conduct synthesis studies, or meta-analyses, on these different trials.

The three meta-analyses which have already been carried out have demonstrated homeopathic medicines' efficacy over placebo.

The most recent, published in the September 1997 issue of the Lancet[5/], is based on 186 clinical trials. The authors K. Linde and W. Jonas concluded that: "the findings of our meta-analysis are not compatible with the hypothesis that the clinical effects of homeopathy are completely due to placebo."

[5/] Linde, K., Clausius, N., Ramirez, G., Melchart, D., Eitel, F., Hedges, L.V., Jonas, W.B. THE LANCET 1997; 350: 834-843.

Market Size Evaluation

Worldwide Pharmaceutical Sales	$211 billion
Worldwide Homeopathic Pharmaceutical Sales	$1.5 billion
Total U.S. Pharmaceutical Sales	$88 billion
U.S. Sales of Homeopathic Medicines	$230 million

Distribution of Homeopathic Medicines at Retail in the U.S.

Channel	% Stocking
Health Food Stores	95%
Chain Pharmacies	70%
Independent Pharmacies	30%

Consumer Use of Homeopathic Medicines in the U.S.

Eisenberg[6/]	1990	0.7% of those interviewed
Eisenberg[7/]	1997	3.4% of those interviewed

[6/] Eisenberg, D.M., Kessler, R.C., Foster, C., Norlock, F.E., Calkins, D.R., & Delbanco, T.L.. Unconventional Medicine in the United States: Prevalence, Costs and Patterns of Use, The New England Journal of Medicine, 1993; 328: 246-252.

[7/] Eisenberg, D.M., Davis, R.B., Ettner, S.L., et al. Trends in Alternative Medicine Use in the United States, Journal of the American Medical Association, 1998; 260(18): 1569-1575.

Advertising and Marketing Information of Homeopathic Medicines

Categories of Information: Product Labeling
Promotional Literature
Continuing Education Programs
Drug Information Center
Internet
Public Relations

Development of Information

At Boiron, we feel strongly that it is our responsibility as manufacturers and marketers to provide accurate and reliable information regarding the use and administration of our products. Since homeopathic products are drugs within the meaning of the Food Drug and Cosmetic Act, the guidelines for labeling content are quite clear.

As a 200 year old medical discipline, homeopathy is rich in reported treatment and research (homeopathic provings). This information is compiled in texts known as materia medicas. It is these documents that are the first step in the development of label indications for homeopathic drugs.

Thus the claims for homeopathic drugs are generally supported by a long history of safe documented use and clinical experience.

Proposed new homeopathic drugs undergo a rigorous review by the Homeopathic Pharmacopeia of the United States prior to marketing.

Internally Boiron exercises a careful review of label content and format by medical, pharmaceutical and legal experts prior to distribution.

Dissemination of Information

Product Labeling:

Labels for homeopathic medicines are required to bear adequate directions for use, indications for use and warnings. At Boiron, labels are developed and reviewed by medical, legal, marketing and technical experts.

Label information development relies heavily on the Code of Federal Regulations parts 200, 210, 330, advice issued by FDA and interpretation of the current literature.

Promotional Literature:

Promotional Literature is designed to visually acquaint the retailer, healthcare professional and consumer with the product benefits. We are not making claims in advertising and/or promotional materials other than what we state on labels.

Continuing Education Programs:

Pharmacy – Boiron Institute is an approved ACPE (American Council on Pharmaceutical Education) provider and continuing education articles are developed and written within the guidelines of the ACPE.

Medical – Professional texts and programs are written to further the knowledge of practitioners in the use of homeopathic medicines. Some are delivered in partnership with CME providers.

Drug Information Center:

Drug information personnel are instructed to provide information to consumers that are consistent with product labeling. Diagnosis and/or establishment of treatment regimens are strictly prohibited. Healthcare professionals are available to respond to inquiries from practitioners. Responses to practitioners are limited to information found in the literature.

Internet Websites:

Today the internet is one of the most productive information dissemination mediums. We recognized this by creating our own website where we provide information to consumers as well as to healthcare professionals on many topics relevant to Homeopathy and Boiron more specifically.

Public Relations:

Boiron seeks to supply accurate information consistent with product labeling and a fair and balanced interpretation of clinical results.

Barriers to Further Development of Homeopathy in the United States

Environment:

Today it is necessary to recognize that existing within the scientific medical community is a certain bias against so called CAM and more specifically as far as we are concerned, Homeopathy. The bias extends to teaching establishments like universities and also to some publishers (consumers or healthcare professionals).

We have observed a bias within the publishing community regarding homeopathy. Specifically publishers have refused to accept advertising for homeopathic products and medical journals have been reluctant to publish research articles related to homeopathic medicines.

We would like to see a more positive and constructive attitude that would allow for the proper dissemination of information. Specifically, we would welcome a more open minded approach to the benefits of homeopathic medicine in medical schools.

Research:

While the 200 year history of homeopathy is rich in clinical information, we believe the public could benefit from even greater insight into their clinical application and mechanisms of action. We would like to see more funds allocated towards this research in order to contribute to a better healthcare system; more compassionate, more economical and more effective.