The Free Speech About Science Act

A White Paper

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The Science Free Speech Act

I. Executive Summary

"*Of all discoveries and opinions, none may have exerted a greater effect on the human spirit than the doctrine of Copernicus [which was censored and suppressed by the governments of the day].*" (Goethe)

From the earliest medical texts, the healing properties of foods have been recognized. (Chi Po's *Yellow Emperor's Classic of Internal Medicine*)[1]

Since ancient times food has been utilized not simply to satisfy hunger but also to provide healing. Our grandmother's chicken soup to treat a cold; Coca-cola, ginger ale, or saltine crackers for an upset stomach; and Cherry juice for gout. The anecdotal information gathered from cultural anthropology has at times led to scientific progress.

In 2000, a University of Nebraska study concluded: "With the cold and flu season just around the corner, Americans may welcome news about a published, well-controlled research study that says chicken soup may contain a number of substances, including an anti-inflammatory mechanism, which could ease the symptoms of upper respiratory tract infections."[2]

It has thus taken 700 or more years for modern science to investigate and confirm the reports of countless grandmothers and of Jewish physician Moshe ben Maimonides about the health benefits of chicken soup.

It appears that a disconnect has developed over time between the desires of American consuvers and the actions of the Federal government with regard to the free flow of legitimate scientific research about food and dietary supplements. Consumers desire accurate, helpful and not-misleading information based on peer-reviewed scientific literature. The People desire to receive this information from all sources including the Government, the health care provider, as well as the food industry–both manufacturer and distributor of the foods including dietary supplements purchased. The Federal government has restricted this flow of information between industry and consumer. For example:

In 1993, the U.S. Food and Drug Administration (FDA) rejected the 1992 findings and recommendation of its sister agency, the Centers for Disease Control and Prevention (CDC), regarding folic acid. It instead promulgated a rule in early 1993 prohibiting the food industry from making claims concerning the relationship between the consumption of folic acid by women of child bearing age and the prevention of Neural Tube Defects such as Spina Bifida. A Senate Committee reprimanded the FDA for this restrictive action and concluded: "*...Undoubtedly many children suffered from preventable neural tube defects as a result of FDA's delay in authorizing health claims based on the 1992 CDC recommendation.*"[3]
The FDA in 1993 also rejected a request by industry to inform the public about the beneficial relationship between the consumption of foods and dietary supplements containing omega-3 fatty acids and reduced risk for coronary heart disease (CHD). They would continue this obstruction of flow of information until 2001 when, after extensive litigation, they would approve this claim: *"Consumption of omega-3 fatty acids may reduce the risk of coronary heart*

disease. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive."[4] Many within the food and supplement industry as well as the general public have long alleged that the FDA favors the conventional medicine (i.e., pharmaceutical approach) to wellness over complementary and alternative medicine approaches that focus on diet, supplementation and lifestyle. With that in mind, the decade long refusal of the FDA to allow a health claim for fish oils and omega-3 fatty acids is most troubling given that in November 2004, the FDA announced its approval of the drug application of Reliant Pharmaceuticals Inc. for Omacor® as a prescription drug. This product is omega-3-acid ethyl esters[5] and is approved to lower very high triglyceride levels in adult patients. Only 2 clinical trials are noted on the approved label. The 2 studies included a total of 84 patients and lasted 6 and 16 weeks.[6] Given the totality of the evidence previously provided to the FDA on omega-3 fatty acids in foods and dietary supplements (and rejected), the threshold for a drug approval seems disproportionately lower. The cost to taxpayers both out of pocket and through government programs is more than $190/month for the drug while a month's supply of the dietary supplement omega-3 is less than $15/month.

More recently, in 2005, the FDA sent warning letters to more than 20 orchards and other marketers of cherry products. The FDA took issue with the following statements on the Orchard's website: "...Sweet, juicy, delicious cherries are in season now through August and research shows they can help you: safeguard against cancer...relieve aches and pains...." The FDA also took issue with the orchard providing links to other websites that provided information about the health benefits of cherries, "In addition your website includes links to other websites including www.scienceagogo ....which include claims that cherries can treat or prevent various diseases....these claims cause your product to be a drug....because this product is not generally recognized as safe and effective as labeled it is also a new drug.... a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA). FDA approves a new drug on the basis of scientific evidence submitted by a drug sponsor to demonstrate that the drug is safe and effective....Failure to promptly correct these violations may result in enforcement action without further notice. Enforcement action may include seizure of violative products, injunctions against the manufacturers and distributors of violative products, and criminal sanctions against persons responsible for causing violations of the Act."[7]

Keep in mind that the US Government has funded research into the health benefits of cherries and the US Department of Agriculture's (USDA) website reports that scientific evidence supports the health benefits of cherries. According to the USDA, consuming cherries may reduce painful arthritic inflammation and lessen the severity of cardiovascular disease and cancer.

Few on Capitol Hill today will recall that in the 1950's, the FDA jailed, and then actually burned the books and research papers of psychiatrist Wilhelm Reich. The FDA also burned the papers of other scientists such as Dr. Royal Lee whose work has been validated by subsequent scientific researchers (see Part III). During the 1960s the FDA, in overt actions to stop the flow of information about the science supporting the therapeutic benefits of food including dietary supplements, prevented health food store owners from selling any books on nutrition if they sold dietary supplements:

"Throughout the 1950s and 1960s, the FDA brought hundreds of court actions against nutrition manufacturers for making health-related claims for their products.... The FDA actively prosecuted vitamin retailers that sold vitamins and other supplements in conjunction with books or pamphlets that extolled their use. It was illegal, for example, for a health food store to sell vitamins and books extolling the virtues of vitamins. The FDA justified such practices, which many considered to be a violation of the First Amendment, under the theory that literature that was sold near a product was thereby converted into a product label, and if health claims were made in the literature, then the product had to be regulated as a drug...."[8]

This disconnect between the desires of consumers and the actions of the Government are due in part to modern medicine's increased reliance on drugs and a decreased focus, particularly in the United States during the mid-20th century, on foods for their therapeutic benefits. The post-World War II "Better Living through Chemistry" mindset led to the definition of "drug" in laws pertaining to the regulation of foods and drugs and their labeling. The core of the drug definition through which the FDA restricts the flow of information is 21 U.S.C. 321: "...articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man...."

The bottom line for the FDA is that, in order for food or supplement makers to make any health claims or even refer to any scientific research, they must subject their product to the drug approval process. But unlike drugs, food and supplements are natural products which cannot be patented. Drug manufacturers are only able to spend up to a billion dollars for FDA approval because their products are patented.

It is widely acknowledged that both foods and drugs have the potential for therapeutic benefit. Individuals when provided adequate and accurate, science-based information have the opportunity to improve their health status. The FDA has on at least one occasion agreed, although its actions continue to block the free flow of scientific information. "Research demonstrates...that consumers are more likely to respond to information concerning the health benefits of consuming particular conventional foods and dietary supplements if the information identifies, with specificity, the health benefit associated with the product..... Experts indicate that these messages help consumers in selecting foods that are likely to contribute to overall health….Decisions by individual consumers that are based on accurate scientific information about the likely benefits of food choices will improve public health."[9]

The manufacturers and distributors of foods including dietary supplements have often desired to share scientific information about the benefits or potential benefits of specific foods or ingredients in dietary supplements, but have been prevented by Federal regulators. Barriers to the distribution of valid scientific literature have been created over time by the existing regulations or interpretations of legislation by the Government. There has been some progress in rectifying these regulatory barriers. However, there is more to be done to ensure that the U.S. does not go down the mistaken road of censoring science and improve the health literacy of Americans relative to the therapeutic benefits of foods including dietary supplements.

In recent history, the Congress has offered several legislative fixes to improve the flow of scientific information about food and supplements. These are outlined in Appendix A. Further

the Courts have addressed several failures of the FDA to correctly enforce the law. This is covered in Appendix B.

The sharing of science, a free speech concern, has been abridged by the current limitations within the laws of both the Food and Drug Administration (FDA) and Federal Trade Commission (FTC). This restriction on speech is having a deleterious effect on the public health.

The following background report has been prepared for the use of Legislators, their staff, and policy makers in understanding the important opportunity that this legislation offers to protecting free speech and our nation's future as a leader in science as well as the health and well being of the people that make up this great nation.

Scientific inquiry is an ongoing and evolving process in which evidence is built over time regarding a hypothesis. The process of scientific inquiry into foods, nutrition, and health has vastly benefited the American public. Science is always a work in process. Former FDA Commissioner, Dr. Mark McClellan said, "the evidence available from science about what people can do to improve their health often is unsettled."[10]

A recent example of this 'unsettled science' is the consumption of coffee and diabetes. Coffee is one of the most consumed beverages in the world. We have decades of research for instance on the benefits and risks associated with drinking coffee. Twice within the span of a few months in 2007, reports with very different outcomes were reported in the media. First the media reported on a study which found that the regular consumption of coffee was beneficial in preventing Type 2 diabetes. A few months later the headlines seemed to flip-flop and warned that coffee consumption was bad for a diabetic because blood sugar spiked in another study done at Duke University.

Because of the existing regulatory framework, the public is denied access to an explanation that the first study was a large study of more than 7,800 people conducted as a follow up to the National Health and Nutrition Examination Study. This found for individuals under the age of 60 drinking brewed coffee (in moderate amounts on a regular basis) was beneficial for reducing the chances of getting diabetes.[11] The public is also denied access to the explanation that the second study conducted at Duke University was focused on caffeine and utilized tablets of caffeine equal to four cups of coffee given to 10 patients over three days and found that blood sugar rose by about 8% after taking the pills as well as after meals.

Media outlets typically report very little information and then only general information. If coffee manufacturers or distributors are restricted from providing what many would deem a valuable public service because they are not allowed under the current regulatory framework of the Federal government from doing so, then the public has not been well served.

The promotion of science in the use of foods including dietary supplements for the prevention and treatment of disease is important. The sharing of this information from all available sources including industry is an important public service. Not all reporting of science information by industry should be considered marketing a health claim.

Under the current 'drug mentality' any product whether it is coffee, cranberry juice, a vitamin C tablet, or water, if it might be used to cure, treat, mitigate or prevent a disease, becomes by definition a 'drug.' Even though coffee, cranberry juice, Vitamin C in tablet form, and water have been in common use for decades or centuries, if a scientist independent of a manufacturer conducts and publishes studies about the benefits of any of these common food products in the prevention or treatment of a disease, and if a manufacturer or distributor of food products distributes this science, the product then becomes an 'unapproved drug' under the FDA interpretation. A further barrier to the free flow of science information is the issue of whether the information constitutes a new claim for the product. If the science materials shared are considered marketing materials by the FDA, including information shared on a manufacturer's website, are not substantial enough to meet the FTC bar of substantiation, the company may also be prosecuted for false or misleading advertising and be subject to marketing restrictions and heavy fines. This bar of substantiation assumes drug-like trials which can cost hundreds of millions of dollars. Natural foods and supplements cannot be patented, so no business can pay for a drug-like approval process.

It is time to address this Government intrusion on the free dissemination of scientific research and the public's rights to both science free speech and the pursuit of happiness through good health. The passage and implementation of slight modifications to the law put forward in the "Free Speech About Science Act" will offer a dramatic opportunity to support science and to expand health literacy in relation to foods.

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II. The Importance of Free Speech About Science for Health

"The health of the people is really the foundation upon which all their happiness and all their powers as a state depend." (Benjamin Disraeli, British Prime Minister)

It is estimated that up to 85% of illness in America is a direct result of lifestyle decisions. In general, decisions about tobacco use, alcohol consumption, physical activity and diet have more to do with the state of someone's health over time than medicine. Seventy percent of deaths each year in the United States are premature and a result of lifestyle.

Accurate, science based information about nutrition is a cornerstone to any approach to improved health. As such, the truthful and documented delivery of scientific information from all sources, government, academia, industry, and individuals should be unfettered except for national security concerns.

"Allowing more truthful health claims for food and dietary supplements is likely to benefit both consumers and competition - better-informed consumers are better able to make healthier choices." (FTC to the FDA) [12]

According to a recently released survey conducted by HealthFocus International, more than 75 percent of grocery shoppers choose foods and beverages for specific medical purposes at least some of the time...."[F]ood shoppers are beginning to put into action what they have learned

about functional benefits of foods....there are clear indications that shoppers are currently using foods to complement medical treatment and for prevention."[13]

Historically, federal authorities have a track record of abridging the free flow of scientific information about nutrition by blocking the distribution of scientific information regarding nutrition between businesses and their customers or penalizing such actions by recategorizing foods and dietary supplements as drugs. The sharing of literature prepared by someone else, such as a scientific study published in the peer-reviewed literature should not be restricted in any form or fashion by the U.S. Government as long as it does not pose a national security risk. It is highly unlikely that science focused on the health benefits of foods including dietary supplements will pose a national security risk.

A. Information, Health and the Constitution

The Constitution empowered the Congress to "promote the progress of science." Within the Declaration of Independence, our Founding Fathers held certain Truths to be 'self-evident,' "among these Life, Liberty and the Pursuit of Happiness."

For many the pursuit of happiness goes hand-in-hand with health. Thomas Jefferson in hundreds of letters portrays this very ideal by providing in closing remarks a wish for health and happiness.[14]

At no time more so than now is maintaining the freedom to distribute science information more important. There is a growing consensus that the U.S. health care system is in crisis.

B. Current State of Our Health

In February 2005, the Government Accountability Office (GAO) issued a report to Congress entitled, "21st Century Challenges Reexamining the Base of the Federal Government."[15]

This report included the following key points:

- The U.S. health care system is in crisis.
- Between 1992 and 2002, overall health care spending rose from $827 billion to about $1.6 trillion; it is projected to nearly double to $3.1 trillion in the following decade.
- The United States now spends over 15 percent of its gross domestic product on health care—far more than other major industrialized nations.
- One of the fastest-growing segments of health care in both the public and private sectors is prescription drugs.
- Health care spending has shifted from the individual to the taxpayer. In 1962, 46 percent of point of service costs was born by the individual, dropping to 14 percent by 2002.
    - Today, Medicare and Medicaid's combined share of the federal budget—at 20 percent—has more than doubled in the last 2 decades.

- DOD's health care spending has gone from about $12 billion in 1990 to about $26 billion in 2003.
- VA's expenditures have also grown—from about $12 billion in 1990 to about $24 billion in 2003.

According to the Centers for Disease Control and Prevention (CDC):

Chronic diseases—such as heart disease, cancer, and diabetes—are the leading causes of death and disability in the United States. Chronic diseases account for 70% of all deaths in the U.S., which are 1.7 million each year. These diseases also cause major limitations in daily living for almost 1 out of 10 Americans or about 25 million people. Although chronic diseases are among the most common and costly health problems, they are also among the most preventable. Adopting healthy behaviors such as eating nutritious foods, being physically active, and avoiding tobacco use can prevent or control the devastating effects of these diseases.[16]

In 2007, the Milken Institute issued a ground-breaking study reporting that the annual economic impact of the most common chronic conditions in the U.S. exceeded $1 trillion. According to the study, seven chronic diseases – cancer, diabetes, hypertension, stroke, heart disease, pulmonary conditions and mental illness – have a total impact on the economy of $1.3 trillion annually. The Institute predicts that of this $1.1 trillion represents the cost of lost productivity.[17], [18]

More than fifty percent of the United States population has one or more chronic condition. According to the National Center for Health Statistics:

Heart Disease is the number 1 killer of both men and women in the United States.

- Approximately 12% of the adult population have diagnosed heart disease (specifically, 25.6 million noninstitutionalized[19] adults)
- 10% of nursing homes residents have diagnosed heart disease (165,100)

Stroke is the third leading cause of death in the United States

- More than 150,000 people die in the United States from stroke each year.
- Approximately 2.4 % of the US adult non-institutionalized population has suffered a stroke (5.4 million).

Hypertension has been diagnosed in 29% of the US population over age 20.

- Approximately 7.9% of deaths in the US are a result of hypertension (23,076).
- 30% of nursing home residents have been diagnosed with hypertension (481,800).

Cancer is the second leading cause of death in the United States.

- Approximately 7.4% of noninstitutionalized adults in the US have been diagnosed with cancer. (16 million).[20]

- 5.8% of nursing home residents have been diagnosed with cancer (146,700).

Diabetes affects approximately 10% of the U.S. population over age 20.

- 7.2% of the adult US population have been diagnosed with diabetes
- Another 2.9 % of the adult population likely have undiagnosed diabetes
- 17% of nursing home residents have been diagnosed with diabetes (279,000)
- Diabetes is the 6th leading cause of death in the US

C. Preventing Disease Through Lifestyle

Preventive medicine means education, empowerment and personal responsibility. (C. Everett Koop, MD, ScD, - Former Surgeon General of the United States).

In 2008, according to the Centers for Disease Control and Prevention, more than 90 million Americans are living with chronic disease. Seventy-five percent of the $1.4 trillion that the United States spends on medical care each year is for the treatment of chronic conditions.

As of 2003, the United States spent 15% of the gross domestic product on health. This is much higher than any other country. The Acting Surgeon General, Rear Admiral Steven K. Galson, M.D., M.P.H. stated, "*Health spending per capita in the United States is much higher than in other countries. This cannot be sustained over the long term. Right now, we have it backwards. Our health system is focused on treatment instead of prevention. We must place more emphasis on prevention. Keeping people healthier longer reduces the cost of care and can contribute to a longer life.... Everyone has a role to play. Everyone here can help spread the message. However, health literacy -- the ability of an individual to access, understand and use health-related information and services to make sound health decisions -- is also important. All of us - government, educators, and health care professionals - need to work together to improve health literacy.*" [21]

A February 2008 search in the National Library of Medicine's PubMed database found the following references to foods and dietary supplements in the prevention or treatment of disease. These studies, only a very small sample of the available science on nutrition (foods and dietary supplements), would prove beneficial to the public. However, the current regulatory framework has created significant barriers to their distribution by those who manufacture or distribute foods.

- A randomized clinical trial of magnesium in alcohol withdrawal symptoms found that Magnesium (Mg) might decrease the risk of death from alcoholic liver disease.[22]
- Parkinson's disease (PD) is one of the most common neurodegenerative diseases. Recent epidemiological studies suggest that caffeine, one of the major components of coffee, has a protective effect against developing PD. A laboratory study from Japan found that caffeine offered a measure of cytoprotection.[23]
- A study in Japan of women over the age of 60 found that the regular consumption of green tea was common factor in women with significantly higher bone mineral density. Higher bone mineral density is important in the prevention of osteoporosis.[24]

- A study conducted by Vanderbilt University found that the consumption of legumes (peanuts, soybeans, etc.) reduces the risk of developing Type 2 Diabetes.[25]
- A German clinical trial concluded that blackcurrant juice could support the treatment and metaphylaxis of uric acid stone disease and that cranberry juice could be useful in the treatment of brushite and struvite stones as well as urinary tract infection.[26]

In the 2006-2007 *Annual Report of the President's Cancer Panel Report*, the following was provided:

> *"In 2007, over a half million more Americans will lose their battle with cancer. Tragically, nearly two-thirds of these deaths could have been prevented through changes in lifestyle."*

Among the information provided in this report:

- A four-year, population-based, double-blind, randomized trial found that among nearly 1,200 postmenopausal women, participants who received 1,100 IU of vitamin D (an amount sufficient to increase serum vitamin D levels) along with a calcium supplement had a 60 percent lower incidence of all cancers compared with the placebo group. The vitamin D effect was determined to be independent of any effect of calcium.
- Some epidemiologic studies suggest that increasing levels of plasma lycopene (a carotene found in large amounts in tomatoes) may reduce prostate cancer risk."[27]

A leading cause of blindness in older Americans is Age-related macular degeneration (AMD). The Foundation of the American Academy of Opthamalogy recommends that Patients with intermediate AMD in one or both eyes and patients with advanced AMD in one eye only or vision loss due to AMD in one eye should consider taking antioxidants plus zinc on a daily basis. The dosages used in Age Related Eye Disease Study (AREDS) were as follows: vitamin C, 500 mg; vitamin E, 400 IU; beta-carotene, 15 mg (approximately 25,000 IU vitamin A); zinc 80 mg as zinc oxide; and copper, 2 mg, as cupric oxide. Copper should be taken with zinc because high-dose zinc is associated with copper deficiency anemia..."[28] The NIH considers this recommendation credible enough to provide a link to it through MedLine Plus.[29]

In June 2002, the Consumers for Responsible Nutrition (CRN) reviewed more than a decade's-worth of the most scientifically-significant studies measuring the health benefits of multivitamins and other nutritional supplements, including antioxidants (vitamins C and E), calcium, long chain omega-3 fatty acids (fish oils), vitamin D, vitamins B-6 and B-12, and folic acid issued the report, *The Benefits of Nutritional Supplements*.[30] Findings in the report include:

- If all women of childbearing age used multivitamins with folic acid, it should be possible to reduce the current incidence of neural tube birth defects like spina bifida by as much as 70%.
- The routine use of multivitamins and mineral supplements by the elderly could improve immune function and thus reduce infectious disease, potentially cutting in half the total number of days they are sick.

- Supplementation with calcium and vitamin D could reduce the rate of hip fracture among older people by at least 20%–meaning 40,000 to 50,000 fewer hip fractures each year in the United States–for an average annual savings of $1.5 to $2 billion.
- The potential cost savings of a prevention-oriented approach to health and diet are tremendous. A 1997 analysis predicted that if the occurrence of cardiovascular disease, stroke and hip fracture were delayed five years, total U.S. health care cost savings could equal $89 billion annually.
- While the addition of a multivitamin would benefit most people, different additional supplements should be chosen based on the specific lifestage, gender or lifestyle of the individual. For example, though calcium is generally important for all men and women, it is particularly critical for children building bone mass and elderly people seeking to preserve it.

In January 2004, the Lewin Group published, *A Study of the Cost Effects of Daily Multivitamins for Older Adults*.[31] In detailing the purpose of the study, the group stated: "In recent years, an important priority of the Federal Government and other large health care payers and providers has been health promotion and disease prevention for the elderly. Epidemiological evidence from varied published sources indicates that a significant number of older adults fail to get the amounts and types of food necessary to meet essential energy and nutrient needs. Physiological, psychological and economic changes in the later years can contribute to poor nutrition among older adults, with deficiencies of vitamins and trace elements observed in at least one third of the elderly. This study provides estimates of the costs and potential savings that could result from older adults' use of a daily multivitamin."

The Lewin study focused on the Medicare population aged 65 years and over and certain high-risk disease conditions in this population that may be mediated by multivitamins, including coronary artery disease (CAD), colorectal cancer, diabetes, osteoporosis and prostate cancer. The Lewin Group also examined the effect of daily multivitamin use on immune function in older adults, specifically as it relates to infections prevalent among aged Medicare beneficiaries. Among the study's key findings:

- The estimate of five-year (2004-2008) potential savings resulting from reduction in the relative risk of coronary artery disease and improved immune functioning and subsequent reduction in infection through providing older adults with a daily multivitamin is approximately $1.6 billion.
- The evidence strongly indicates that daily use of multivitamins by the elderly is nearly risk-free and is potentially associated with significant health improvements. Based on the available evidence regarding risks and benefits, we concur with other researchers that use of daily multivitamins by the elderly has the potential for conferring substantial benefits to any public health initiative.

In September 2004, the Lewin Group published a second report regarding the cost savings and health benefits for five Dietary Supplements: Calcium, Folic Acid, Omega-3 Fatty Acids, Glucosamine and Saw Palmetto.[32] Their review concluded:

- **Calcium:** The estimate of the five-year (2005-2009) net savings in hospital, nursing facility, and physician expenditures resulting from a reduction in the occurrence of hip fractures among those over age 65, through daily intake of 1200 mg of calcium with vitamin D is $13.9 billion. Approximately 734,000 hip fractures could be avoided over the five year period.

- **Folic Acid:** If just 10.5 million women of childbearing age began taking 400 mcg of folic acid daily, approximately 600 fewer babies would be born with neural tube defects per year, saving as much as $321,853,000 as a result. Taking into account the very low cost of the supplement, $1.3 billion in lifetime medical costs could potentially be saved over the next five years.

- **Omega-3 Fatty Acids**: Recent studies have shown that omega-3 fatty acids can have beneficial effects on cardiovascular disease (CVD), and Lewin's review found consistent evidence that omega-3 fatty acids help reduce deaths from CVD. The research literature contains many promising studies concerning the health benefits of omega-3 fatty acids for a wide number of chronic conditions (e.g., depression, renal disease, rheumatoid arthritis and asthma).

- **Glucosamine:** Glucosamine has been shown to have anti-inflammatory effects and is believed to repair and maintain cartilage. Recently the use of complementary and alternative therapies in the treatment of osteoarthritis has become more widespread, and particular interest has focused on glucosamine.

- **Saw Palmetto**: Preliminary findings on the effectiveness of saw palmetto for alleviating the symptoms of benign prostatic hyperplasia (BPH) indicate that use of the herb yields slight to moderate improvement in symptoms for men with this chronic urinary syndrome.

D. The Importance of Information for Wellness

As Dr. Galson has suggested, everyone has a role to play in spreading health-related information. This has not been the thinking of some regulators and sadly, consumers and manufacturers of foods have had to fight the Federal government repeatedly to maintain a free flow of scientific information.

The human body by design constantly seeks to return to a state of wellness. This process of seeking a state of balance is known as homeostasis. In homeostasis, body levels of acid, blood pressure, blood sugar, electrolytes, energy, hormones, oxygen, proteins, and temperature are constantly adjusted to respond to changes inside and outside the body, to keep them at normal levels.[33] A cornerstone of natural approaches to health and wellness is supporting the body through nutrition, stress management, and physical activity in order to allow the body's innate self-healing abilities to thrive.

"Nutritional medicine involves therapeutic application of dietary and nutritional modifications to re-establish bodily harmony. During the 20th century, an explosion of scientific findings on the nutritional influences on disease...has occurred." (Keith I. Block, MD)[34]

In late 2002, the FDA, announcing the Consumer Health Information for Better Nutrition Initiative[35], made the following concessions:

- Individual dietary choices are important in preventing disease and improving the public's health.
- Enhancing the availability of high-quality health information to help consumers make sound dietary decisions is a top priority of the agency.
- FDA recognizes two subcategories of food: conventional food and dietary supplements. Historically, conventional foods have been consumed for their sensory appeal (smell, taste, and aroma) and nutritional value.
- Increasingly, as a result of better science and innovative food products, foods can be used to achieve health benefits beyond basic nutrition. Dietary supplements, too, are used by consumers with the goal of achieving particular health benefits.
- FDA believes that a market in which food marketers compete based on scientifically substantiated, truthful health claims will yield substantial benefits to the public health.
- Research demonstrates, though, that consumers are more likely to respond to information concerning the health benefits of consuming particular conventional foods and dietary supplements if the information identifies, with specificity, the health benefit associated with the product.
- Provided these messages are presented in a manner that accurately conveys the degree of supporting scientific evidence, evidence on consumer behavior developed by the FTC and other experts indicates that these messages help consumers in selecting foods that are likely to contribute to overall health.
- In the aggregate, even though some scientific evidence will undoubtedly be refined by further studies, decisions by individual consumers that are based on accurate scientific information about the likely benefits of food choices will improve public health.

While these are very positive statements, the FDA has continued to prevent the flow of science information between industry and the public.

This is just a continuation of a long history of impeding the free flow of information about the health benefits of foods and dietary supplements. As noted previously, one of the most egregious examples of this occurred in the early 1990s and likely contributed to thousands of children born with Neural Tube Defects (NTD).

Recognizing the scientific evidence, the Centers for Disease Control and Prevention (CDC) in 1992 published a recommendation that all women of childbearing age consume 0.4 mg of folic acid daily. The CDC noted that by doing so, their chances of having an NTD birth would be reduced by approximately 50%. Ignoring the CDC's findings, the FDA promulgated a rule in early 1993 prohibiting industry from making claims concerning the relationship. In essence the FDA was refusing to allow manufacturers and distributors of foods including dietary supplements from educating the public, in particular young women, about the a simple dietary

intervention that could cut in half the chance of a child being born with a Neural Tube Defect such as spina bifida. The FDA created a firestorm of controversy with this ruling. They would be forced to reverse their stand ten months later, but waited almost three years to authorize the claim. The US Senate Committee on Labor and Human Resources evaluated FDA's actions and concluded ..."Undoubtedly, many children suffered from preventable neural tube defects as a result of FDA's delay in authorizing health claims based on the 1992 CDC recommendation.***"[36]***

In addition to reducing NTD, a recent multicenter study conducted by the University of Texas found that when women took folate (folic acid) for at least a year before conception, their risk of a preterm delivery decreased by up to 70%.[37] According to a recent report of the Institute of Medicine, "in 2005, 12.5 percent of births in the United States were preterm, at less than 37 weeks gestation. This high rate of premature births in the United States constitutes a public health concern that costs society at least $26 billion a year."[38] Children born preterm are at the highest risk for infant mortality and life limiting chronic conditions.

Although the health benefits of fish oil were recognized in the 1930's, in 1993 the FDA rejected a request by industry to inform the public about the beneficial relationship between the consumption of foods and dietary supplements containing omega-3 fatty acids and reduced risk for coronary heart disease (CHD). In 2001, the FDA after extensive litigation agreed to this claim: *"Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive."[39]* An NIH funded clinical trial currently recruiting patients at Ohio State University acknowledges the following: "The beneficial effects of fish oil (or eating fish more frequently) include reductions in triglycerides, blood pressure, and heart rate, as well as increases in HDL cholesterol, the "good" type of cholesterol. In addition, certain aspects of immune function also appear to show favorable responses to fish oil supplementation, and some studies suggest that fish oil helps to improve mood and decrease depression."[40] The Agency for Healthcare Research and Quality (AHRQ) concludes:

- Consumption of omega-3 fatty acids, fish, and fish oil reduces all-cause mortality and various cardiovascular disease (CVD) outcomes such as sudden death, cardiac death, and myocardial infarction. The evidence is strongest for fish and fish oil supplements.
- Animal and isolated organ/cell culture studies demonstrate that omega-3 fatty acids affect cellular functions involved in ensuring a normal heart rate and coronary blood flow.
- Fish oils can lower blood triglyceride levels in a dose-dependent manner. Fish oils have a very small beneficial effect on blood pressure and possible beneficial effects on coronary artery restenosis after angioplasty and exercise capacity in patients with coronary atherosclerosis.

Many within the food and supplement industry as well as the general public have long alleged that the FDA favors the conventional medicine (i.e., pharmaceutical approach) to wellness over complementary and alternative medicine approaches that focus on diet, supplementation and lifestyle. With that in mind, the decade long refusal of the FDA to allow a health claim for fish oils and omega-3 fatty acids is most troubling.

In November 2004, the FDA announced its approval of the drug application of Reliant Pharmaceuticals Inc. for Omacor® as a prescription drug. The product is omega-3-acid ethyl esters[41] and is approved to lower very high triglyceride levels in adult patients. Only 2 clinical trials are noted on the approved label. The 2 studies included a total of 84 patients and lasted 6 and 16 weeks.[42] We should keep in mind that the approval process for new drugs is typically 10 to 15 years, and that between 1993 and 2002 the FDA continually rejected the promotion of information about the health benefits of omega-3 fatty acids to the public by the food and dietary supplement industry. Given the totality of the evidence previously provided to the FDA on omega-3 fatty acids in foods and dietary supplements (and rejected), the threshold for a drug approval seems disproportionately lower.

There is no evidence put forward by the agency that the prescription drug is superior in quality or therapeutic benefit to the dietary supplement. A call to a local pharmacy priced[43] 30 Omacor® capsules at $48.39. The clinical studies utilized 4g or 4 capsules; therefore, a monthly supply would cost $194.56. The same company's website offers three brands of Omega-3 dietary supplements, bottles of 50 to 200 capsules ranging in price from $7 to 13. Taxpayers are footing the bill for a prescription version of Omega-3 which is significantly more expensive than the dietary supplement version of essentially the same product. Medicare Part D pays for Omacor®,[44] not for fish oil supplements. State Medicaid programs are also now providing coverage for Omacor® as well.

A July 2002 hearing by the Committee on Government Reform made the following points:

- Health care costs are skyrocketing. The national health expenditures are projected to reach $2.8 trillion in 2011. If we don't turn things around by 2011, we will be spending 17 percent of the Gross Domestic Product on health care, almost $1 out of every $5. One would think that because we spend more of our GDP on health care than any other country, that we would have the best health status. This, however, is not the case. In June 2000, the World Health Organization announced their first ever analysis of the world's health systems. They compared 191 countries and found that the United States ranked 37th out of 191.
- It may seem like common sense that diet and exercise can improve our health. There is also an increasing body of scientific evidence that supports this. Experts tell us that about 85 percent of diseases and illnesses in this country result from lifestyle decisions. Conversely, the adoption of healthy lifestyle choices, including moderate physical activity, a sensible diet and the appropriate use of dietary supplements, can improve our health.
- Unfortunately, the typical medical school student will spend less time in classes learning about nutrition than we will spend in our hearing today.
- The committee has been active in monitoring the implementation of the Dietary Supplement Health and Education Act of 1994. Previous hearings have focused primarily on the Food and Drug Administration's lack of full implementation. To date the American public has not been well served by the FDA in this respect.
- We already know from traditional use and research that drinking cranberry juice can help prevent certain infections.

- We also know the use of acidophilus, when taking antibiotics, can help prevent the onset of yeast infections.
- Dr. Linus Pauling told me over 30 years ago that taking vitamin C every day would help prevent cancer.
- In a February 1999 hearing, Dr. Dean Ornish testified about his research showing that heart disease could be reversed through a comprehensive lifestyle improvement program that includes a low-fat and plant-based diet, moderate physical activity, stress management, and dietary supplements. This approach has been shown to reverse heart disease, a feat that drug and surgical approaches do not achieve.
- Clinical trials are also under way evaluating the benefit of the Ornish program for preventing a recurrence of prostate cancer. The preliminary findings are promising.
- Last month the *Journal of the American Medical Association* published research that recommended that all Americans take a multivitamin every day.

III. From the Inquisition to the 21st Century – Bureaucracies Blocking Science Speech

> "*Too often scientific knowledge seems to be "sequestered," concealed from those who could benefit from it or who could comment meaningfully on its quality and relevance..."*[45]

Throughout history, scientists have often been met with resistance for publishing ideas and data that create ripples in the fabric of the thoughts of the day on matters of science and medicine. The esteemed mathematician Nicolas Copernicus[46] is now known as the founder of modern astronomy. Copernicus completed his work *De Revolutionibus*, in which he postulated that the earth rotated on its axis daily and traveled around the sun once a year. In the 1500's the Ptolemaic theory then held that the universe was enclosed in a spherical envelope and that nothing existed beyond the universe. Fearing religious persecution, Copernicus suppressed his findings for over thirty years and did not allow his book to be published until he was on his deathbed.[47] In the Middle Ages, the Catholic Church wielded great power and in essence co-governed with the governments of the day across Europe.

Perhaps Goethe best summed up the magnitude of the Copernican Theory on the world: "*Of all discoveries and opinions, none may have exerted a greater effect on the human spirit than the doctrine of Copernicus."*

Copernicus died in 1543 and was never to know what a stir his work would cause. Two other scientists Galileo and Giordano Bruno embraced the Copernican theory and would suffer greatly as a result. Bruno, who expanded upon Copernicus' theory to postulate that there might be other solar systems beyond our universe was tried and convicted of blasphemy before an Inquisition, and burned at the stake in 1600. In 1633, Galileo was brought before an Inquisition, threatened with torture and execution until he renounced all belief in the Copernican theory. He would spend the rest of his life in confinement.[48,49]

The Inquisition[50] as we refer to it in modern times was not an event but rather an ongoing judicial process of the Catholic Church. Special judges, often Dominican or Franciscan priests, 'inquisitors of heretical depravity,' were assigned by the pope to inquire into heresy in specific areas. At the very time that the scientific method was forming, the judges of the Inquisition actively sought to suppress all scientific thought that contradicted the Bible. In 1559, the Church went so far as to produce an Index of Forbidden Books, many of which were scientific publications. It is said that Leonardo Da Vinci out of fear of persecution utilized mirror writing to produce many of his manuscripts to prevent others from reading the results.

The history of the Inquisition is important to keep in mind as one looks at the suppression of science speech in the 21st century. After all, it was this oppressive system that lead to protestant churches and the migration of Europeans to the American continent. It was this very history, so fresh in the minds of our Founding Fathers, that lead to the drafting of founding documents that illuminated our 'inalienable rights' and very specifically detailed freedoms that include speech, the press, and the promotion of science. These freedoms were defended in the 20th century against totalitarian dictators such as Hitler and Stalin, both of whom censored and suppressed scientific information.

No discussion of the intrusion on free speech in the arena of nutritional sciences is complete without a review of the work and FDA assault on Dr. Royal Lee. A brilliant scientist and inventor born in Wisconsin in 1895, Dr. Lee began his gathering of scientific data on nutrition as a young teen.[51] Educated as a dentist, and honored as a Fellow in the American Association for the Advancement of Science, Dr. Lee focused his early work on the connection between dental caries and improper nutrition. A well-respected inventor, he was granted 100 US patents. His inventions include the speed regulator for electric motors, including the dental drill and the Endocardiograph.[52]

Dr. Lee's concentration on the promotion of whole foods rather than highly processed foods would fit in well with the experts of our time. Dr. Lee felt that whole foods and their natural vitamins and minerals were preferred to highly processed foods that had been supplemented with synthetic inert vitamins. He often bought advertisements in newspapers to expose what he considered a food fraud.

In 1929, Dr. Lee's mother was given six months to live due to a heart ailment. A half century ahead of his time in understanding the role of nutrition on heart health, Dr. Lee created a whole-food supplement for his mother that would later become known as Catalyn. The whole food product was derived from defatted wheat germ; carrots; nutritional yeast; bovine adrenal, liver, spleen, and kidney; ovine spleen; dried pea (vine) juice; dried alfalfa juice; mushroom; oat flour; soy bean lecithin; and rice bran extract. His elderly mother would recover to good health and live another dozen years. He shared this product with friends and the demand became so great that he formed the Vitamin Products Company to meet produce the product commercially.

In 1941 Dr. Lee organized the Lee Foundation for Nutritional Research for the purpose of engaging in research and to coordinate and communicate nutritional breakthroughs from laboratories around the world. The Foundation was the world's largest clearinghouse for nutritional information at the time and was widely used by doctors, agriculturists and

homemakers. During its existence the Lee Foundation disseminated research materials and books on health and nutrition. Dr. Lee's activities to educate the public about the importance of nutrition and health would lead to an aggressive assault on free speech by the Federal government.

The International Foundation for Nutrition and Health provides the following account of the government's persecution of Dr. Lee:

> *"Unfortunately in the late fifties Dr. Lee found himself like many other nutritional pioneers under attack for exposing the destruction of whole natural foods by the processed food manufacturers of this country. His lectures and published materials pointed out the difference between synthetic vitamins in devalued foods versus whole natural foods and their nutritional value. This resulted in protracted court battles with the FDA that ultimately resulted in placing a gag order on Dr. Lee.*
>
> *The final decision prohibited him from speaking publicly or writing on health, medicine and nutrition. His research was ordered destroyed as well as many previous published works by the Vitamin Product Company and The Therapeutic Food Company. Dr. Lee was forced to close both The Endocardiograph Company and The Therapeutic Food Company. He found himself branded a racketeer and a quack because of his uncompromising stance promoting whole natural unadulterated foods with their vitamins and minerals intact.*
>
> *John Courtney, a lifelong friend and associate of Dr. Lee, made the following statement to Dr. Leo Roy after Dr. Lee's death. "After Dr. Lee lost his appeals, he found himself forbidden from responding to his critics and barred from participating in his life's passion for research on nutrition and health by his own country. It just broke his heart." In 1961 Dr. Lee's secretary reported from his research facility in Milwaukee that FDA agents were taking wheelbarrow loads of research records and educational materials from the facility, dumping them in burn barrels, pouring diesel fuel over them and setting them on fire. This continued for two weeks. You just had to be there to believe this could happen."*

The Vitamin Products Company became Standard Process Inc. and continues to market high quality whole food supplements grown on organic farms in Wisconsin and manufactured according to technologies developed by Dr. Lee to preserve the nutrient value. The company continues to market its products solely through health care professionals.

While much maligned by the FDA, the following quote from Dr. Lee points to his being a scientist ahead of his time.

"Candy, all white sugar or its products, and white flour including its products such as macaroni, spaghetti, crackers, etc., should be absolutely barred from the diet of the child. All these are energy-producing foods that contain no building materials for the body. The consequences of their toleration are susceptibility to infections, enlarged tonsils, carious teeth, unruly dispositions, stunted growth, rickets, maldevelopment and very often permanent damage to many

organs of the body (especially the endocrine glands) that depend upon the vitamin supply for their normal function and development." – Dr. Royal Lee, October 2, 1933

Dr. Melvin Page, another dentist developed a food plan which focused on the glycemic index and encouraged patients to eat unlimited quantities of green leafy vegetables. In the 1960's the federal government indicted Dr. Page for practicing outside his scope of practice (as a dentist). After a lengthy trial in which Dr. Page introduced over his 35 years of research to substantiate his findings, a federal judge found him not guilty. The judge went on to reprimand the American Medical Association and the FDA for not trying to figure out what he was doing rather than harassing him. His treatment and philosophy was simple and logical:

- The harmful effects of the use of white sugar and refined carbohydrates can't be ignored.
- The harmful effects of using chemical additives and other food preservatives for the sake of "shelf life" upset body chemistry.
- Using whole food vitamins concentrates, minerals and digestive enzymes to supplement daily food intake might be necessary.
- Milk is not the perfect food for everyone.

Dr. Page's observation after this protracted legal battle: "Why does modern medicine find it so hard to look at, and accept, many of these simple truths?"[53] Many within the general public have expressed a similar sentiment.

Beginning in the 1980s, the government assault on the industry and the distribution of health information became more intense – using what some have called 'FDA Gestapo Tactics'. The facilities of dozens of physicians, publishers, and dietary supplement manufacturers were raided by the FDA. These raids were full out police invasions, with armed FDA agents, accompanied by US Marshalls and at times local or state law enforcement. Often the employees on site during these raids reported that the FDA agents used heavy-handed tactics, making verbal threats, and over reaching the scope of warrants in their seizure of materials. These were not raids conducted because of contaminated products or reports of adverse reactions, but rather raids due to the sharing of scientific literature with consumers. The materials seized during these raids, were often destroyed or never returned, even when no charges were filed. Two examples:

In 1987, in Florida, the Life Extension Foundation had its doors knocked down by the FDA and US Marshalls. The government agents spent 12 hours gathering all the files and supplements and even the personal effects of the owners and employees. It is reported that the telephones and computers were 'ripped from the wall.' Fifty-six charges were filed against the company and its owners, including criminal charges. According to a description of the case provided online by the Foundation, "*FDA enforcement officer Martin Katz admitted he had committed perjury in writing up the Search Warrant, and that he had tried to intimidate a radio talk show producer into keeping us off the air. Katz' partner, Roy Rinc, admitted he had threatened to put our printer out of business if he didn't "cooperate" with the agency, and that he believed he could seize anything at all from us, whether it was on the Search Warrant or not. Higher FDA officials testified that the FDA actively encourages its agents to ignore Search Warrants during raids, and that the FDA deliberately avoids defining any of its "rules," "regulations," or "policies," so*

that it can interpret them in any way it wishes, or ignore them completely if it suits their purpose."[54] Nine years later, all 56 charges would be dropped by the government.

In 1990, Highland Laboratories was raided by 9 armed FDA agents, 11 US Marshalls and 8 members of the Oregon state police. They kicked the doors in on the business and for 11 hours systematically confiscated everything in the business. The owner, Ken Scott, and his employees were threatened with violence and his daughter was held in her nearby home under house arrest for 12 hours. The FDA conducted this raid because Mr. Scott mailed scientific literature detailing the research on Coenzyme Q10 (CoQ10) a nutritional supplement known for its cardiovascular benefit to his customers. In order to assuage the FDA, Mr. Scott later hired an outside mailing service owned by his daughter to mail the materials. The FDA went on to raid the mailing service, threatened the owner, including a threat to seize her checkbook and cash. She closed her business entirely rather than risk future government reprisals.[55]

"Progress in science is based on the free publication of study results and on the public release of data, allowing scientists to build on the experiences of others."[56]

Suppression of speech is not limited to nutrition research. There is so much concern about censorship of science within the research community that a National Coalition Against Censorship (NCAC) was formed in 1974. NCAC has on ongoing project, the "Knowledge Project: Censorship and Science" which examines the clash between First Amendment principles of free expression and government suppression or distortion of scientific information. The NCAC states, "By disrupting the free flow of information in the scientific arena, the government has endangered the 'marketplace of ideas,' threatening not only our constitutional rights to freedom of speech, thought and inquiry, but also the decision and policy-making processes that depend on reliable and valid information."[57]

In response to a 2007 Congressional hearing looking at allegations of Administration interference with government scientists' free speech[58], the American Civil Liberties Union (ACLU) issued a joint statement entitled, "Joint Statement on Censorship and Science: A Threat to Science, the Constitution, and Democracy."[59]

"Censorship of science is deeply troubling on many levels. At the most basic, it affronts the fundamental premises of the scientific method....Without the free exchange of ideas, science as we understand it cannot exist and progress....Censorship of science also violates two core constitutional and historical traditions: the respect for knowledge as the basis of democracy, and the commitment to the free exchange of ideas to ensure that knowledge is shared...The freedom of speech and of the press guaranteed by the Constitution embraces at the least the liberty to discuss publicly and truthfully all matters of public concern without previous restraint or fear of subsequent punishment. The exigencies of the colonial period and the efforts to secure freedom from oppressive administration developed a broadened conception of these liberties as adequate to supply the public need for information and education with respect to the significant issues of the times.... Freedom of discussion, if it would fulfill its historic function in this nation, must embrace all issues about which information is needed or appropriate to enable the members of society to cope with the exigencies of their period...."

The ACLU Statement goes on to state, "*...the rights of the general public are deeply implicated by censorship of scientific speech. Just as the Court has recognized the value of speech to the speaker, it has also recognized the concomitant rights of the listener, who has a correlative right to receive information. ..the State may not, consistently with the spirit of the First Amendment, contract the spectrum of available knowledge. The right of freedom of speech and press includes not only the right to utter or to print, but the right to distribute, the right to receive, the right to read … and freedom of inquiry, freedom of thought, and freedom to teach.…"*

The public had the right to receive for instance information in 1993 about the cardiovascular benefits of consuming foods and supplements containing omega-3 fatty acids, but the FDA restricted that right by refusing health claims. The public had a right to receive through the websites of companies that distribute cherry products scientific data about research supporting the therapeutic value of consuming cherries, but was denied that right by the FDA egregious intrusion on free science speech.

IV. The Science Regarding the Therapeutic Value of Specific Foods and Dietary Supplements

A mentioned above, there is already a significant body of science that underscore the therapeutic value of specific foods and dietary supplements. Every year, this body of research grows. The below information provides a snapshot of just a few examples of the therapeutic value.

Omega-3 Fatty Acids have significant cardiovascular benefits. The regular consumption of Omega-3s may decrease the risk of arrhythmias, which can lead to sudden cardiac death; decrease triglyceride levels; decrease growth rate of atherosclerotic plaque; and lower blood pressure slightly. Stroke risks are also lowered.

- ✓ The American Heart Association (AHA)[60] recommends eating fish like mackerel, lake trout, herring, sardines, albacore tuna and salmon twice a week. These fish are known to be high in two kinds of omega-3 fatty acids, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

- ✓ The AHA also recommends the regular consumption of plant such as tofu and other forms of soybeans, canola, walnut and flaxseed, and their oils. These plant products contain alpha-linolenic acid (LNA), which can become omega-3 fatty acid in the body.

Cherries have significant benefit to inflammation.

- ✓ The USDA[61] has published information supporting the health benefits of consuming fresh cherries. Data show that consuming fresh Bing cherries at breakfast or throughout the day may reduce painful arthritic inflammation.

- ✓ The USDA information reports that eating cherries may also help lessen the severity of other inflammatory conditions, such as cardiovascular disease or cancer.

Magnesium is mineral that plays a significant role preventing and managing hypertension, cardiovascular disease, and diabetes.

- ✓ According to the National Institutes of Health[62], magnesium plays a role in 300 biochemical reactions in the body. Magnesium helps maintain
  - o nerve function,
  - o heart rhythm,
  - o muscles,
  - o supports the immune system,
  - o regulates blood sugar levels,
  - o keeps bones strong, and
  - o promotes normal blood pressure.

- ✓ According the NIH:
  - o Magnesium is found in spinach and other green leafy vegetables, beans and peas, nuts and seeds, and whole, unrefined grains.
  - o Magnesium supplementation may be recommended to prevent a deficiency when taking certain diuretics, antibiotics, and medications used to treat cancer.
  - o Individuals with poorly-controlled diabetes may benefit from magnesium supplements because of increased magnesium loss in urine associated with hyperglycemia.
  - o Magnesium supplementation may be indicated for persons with alcoholism. Low blood levels of magnesium occur in 30% to 60% of alcoholics, and in nearly 90% of patients experiencing alcohol withdrawal.
  - o Individuals with Crohn's disease, gluten sensitive enteropathy, regional enteritis, and intestinal surgery may need supplemental magnesium.
  - o Older adults are at increased risk for magnesium deficiency.

Ginkgo has been used for thousands of years in Traditional Chinese Medicine.

- ✓ According the NIH, promising results have been seen for :
  - o Alzheimer's disease/dementia,
  - o Intermittent claudication (leg pain due to narrowed arteries), and
  - o Tinnitus (ringing in the ears).

- ✓ Other potential benefits of ginkgo include for sexual dysfunction and multiple sclerosis.

Folate-Folic Acid: Folate is a water-soluble B vitamin that occurs naturally in food. Folic acid is the synthetic form of folate that is found in supplements and added to fortified foods. Folate helps produce and maintain new cells. Folate is needed to make DNA and RNA, the building blocks of cells. Folate is also essential for the metabolism of homocysteine, and helps maintain normal levels of this amino acid. [63] According to the NIH:

- Anyone taking anti-convulsants and other medications that interfere with the body's ability to use folate should consult with a medical doctor about the need to take a folic acid supplement.

- A deficiency of folate, vitamin B12 or vitamin B6 may increase blood levels of homocysteine, and folate supplementation has been shown to decrease homocysteine levels and to improve endothelial function.
- At least one study has linked low dietary folate intake with an increased risk of coronary events.
- Some evidence associates low blood levels of folate with a greater risk of cancer.
- Folate is involved in the synthesis, repair, and function of DNA, our genetic map, and there is some evidence that a deficiency of folate can cause damage to DNA that may lead to cancer.
- Several studies have associated diets low in folate with increased risk of breast, pancreatic, and colon cancer.

Chromium is a mineral that is known to enhance the action of insulin, a hormone critical to the metabolism and storage of carbohydrate, fat, and protein in the body. Chromium also appears to be directly involved in carbohydrate, fat, and protein metabolism Absorption of chromium is enhanced with vitamin C and the B vitamin niacin. The body's chromium content may be reduced by diets high in simple sugars, after acute exercise, pregnancy, infection, or from stress.

According to the NIH[64], Chromium:

- Is found in Brewers yeast, beef, liver, eggs, chicken, wheat germ, spinach, apples, bananas, and green peppers.
- Stimulates fatty acid and cholesterol synthesis which are important for brain function and other body functions.
- Is important in Insulin metabolism
- Chromium deficiency may be seen as impaired glucose tolerance. It is seen in older people with type 2 diabetes and in infants with protein-calorie malnutrition Supplementation of chromium helps with management of these conditions

The passage of the Dietary Supplement Health and Education Act included a provision to allow the distribution of "Third-Party Literature", something the FDA historically had prevented. A specific benefit of actually providing a full copy of a research article is that information about the specific patient population studied is included as well as certain exclusionary criteria or warnings. For instance, St. Johns Wort, which has a long history for use in emotional disorders has been used successfully as a treatment for depression since the early 20th century. Widely recommended by physicians in Germany, there are more than 15 double-blind clinical studies[65] evaluating its benefit for mild to moderate depression and found that about 55% of the time it was effective. However, sun sensitivity can develop (something also common in prescription drugs for depression). And more importantly, St. Johns Wort may interfere with certain birth control medications and drugs used in the treatment of HIV/AIDS. By allowing manufacturers and distributors of this product to distribute third-party literature which provides these full details, consumers may more wisely use the product.

V. Federal Food Regulators

To develop a plan for the future, it is important to look at our history. Over the past 150 years, the regulatory bureaucracy of the Federal government has expanded dramatically. Excluding defense and the postal service, in 2008, the US government has more than 1.8 million full time employees.[66] The regulation of foods at the federal level has expanded dramatically as well. Today the FDA has more than 9,000 employees and the FTC more than 1,000.

The Federal government began to expand its authority early in the 20th century when the federal authority was limited to imported foods. Like the practice of medicine, regulations regarding foods and drugs were managed principally at the state level. At the dawn of the 20th Century, Federal authorities began seeking an expansion of powers.

Having centralized regulation at the federal level has benefited industry in particular, who prior to Federal expansion of power complained about having to meet 50 different drug standards. The challenge to regulators is to maintain a proper balance between the implementation of regulations to reduce the risks associated with the purchase and consumption of food and drugs while maximizing the health benefits offered through these products and insuring that consumer and industry alike are afforded their freedom in the marketplace. It is a balance that the FDA has been challenged to achieve and maintain.

Our system of government provides opportunities for checks and balances. Legislators, in keeping to their oath to protect and preserve the Constitution, are tasked with the regular review of laws and regulations that have abridged the rights of the states and the people of the United States. Similarly the Judicial branch has the authority to overturn regulations. This system of oversight between the Executive, Judicial, and Legislative branches of government provided in the U.S. Constitution provides consumers an avenue for course correction and has proven valuable in their quest for better access to scientific information about foods and supplements.

Throughout its history, both the Congress and the Courts have reprimanded the FDA repeatedly regarding the approach to foods and supplements. Further, the public has at every instance of rights encroachment by the Federal government actively engaged in campaigns to restore and preserve rights.

A. U.S. Food and Drug Administration

The U.S. Food and Drug Administration (FDA) traces its history to a single chemist in 1862 in a science lab of the newly formed Department of Agriculture. Dr. Charles M. Wetherill's first project was a chemical study of grape juice for winemaking and was focused on determining whether adding sugar to the juice to increase the alcohol content constituted an adulteration. The agency's original conclusion was that it did not, a decision that was overturned with the very first

Notice of Judgment after the creation of formal Food and Drug agency within the Federal government in 1906.

In 2008, the FDA has grown into a massive organization of more than 9,000 full time employees. The FDA regulates items accounting for 25 cents of every dollar spent by consumers. Eighty percent of the foods consumed in the United States are regulated by the FDA. The annual budget of the FDA now exceeds $2 billion.

The FDA mission statement shows how extensive its reach has become:

> *"The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health."*

Throughout its history, Congress has been prompted to expand the powers of the FDA by employees of the agency rather than by the public. Dr. Harvey Wiley was the driving force behind the first such push in the late 19th century, so much so that the Federal Food and Drugs Act of 1906 became known as the Wiley Act. The creation of a law enforcement entity by the Congress was meant to regulate food (and drug) products in interstate commerce to insure they were not falsely labeled or branded and prohibited the sale of adulterated or misbranded foods and drugs.

A drug, according to the 1906 law, was adulterated "when sold having a difference from recognized standards, except where there is an explanatory statement on or in container, and when sold below professed standard." Foods were adulterated, "when concerned with injurious mixtures, use of substitutes, abstraction of valuable constituents, concealment of damage or inferiority, deleterious ingredients, preservatives in shipment conditionally excepted, animal or vegetable substances unfit for food and products of animals diseased or having died otherwise than by slaughter."

A drug was deemed misbranded, "when there is an imitation or use of name of other article, when there is removal and substitution of contents of package or failure to state on label quantity or proportion of narcotics therein, and when there is a false statement of curative or therapeutic effect. Misbranding of foods was defined as " when there is an imitation or use of name of other article, when there is a false label or brand removal and substitution of contents of package, or failure to state or label quantity or proportion of narcotics therein, when the packages are not marked with weight, with certain variations and exemptions permitted, when there are false or misleading statements on package or label as to ingredients or substances; and food, when mixtures or compounds under distinctive names, the articles are labeled, branded as compounds, imitations, or blends; construed the term "blend" and related to disclosure of trade formulas of proprietary foods, and canned food."

In the first half of the 20th century there was no focus on therapeutic claims of foods and dietary supplements as an industry had not yet developed. At the inception of the Franklin Roosevelt Administration, the FDA staff again sought to extend their authority. Their quest languished in Congress for five years until a drug tragedy spurred legislators to swiftly accommodate the FDA's request. The tragedy involved the development and marketing of a new liquid form of Sulfanilamide – a product that in powder and tablet form had long been used safely. The manufacturer dissolved the powder in diethylene glycol but failed to test for toxicity of the elixir before distribution. Diethylene glycol, a chemical used as antifreeze turned out to be a deadly poison and its use led to more than 100 deaths, mostly in children. On the heels of this tragedy, Congress passed the 1938 Food, Drug, and Cosmetic Act (FD&CA).

The FD&CA expanded the authority of the FDA to include cosmetics and medical devices; expanded drug labeling regulations and instituted pre-market approval for drugs in which the manufacturers had to prove the product was safe. The new law also included provisions affecting food packaging, authorized FDA factory inspections and expanded the agency's enforcement arsenal to include injunctions. It is important in looking at food regulations to keep in mind that drugs that were already in the marketplace were not required to go through this safety review and the safety was shown by its time in the marketplace. In the passage of the Dietary Supplement Health and Education Act, legislators utilized the same 'grandfathering in" of allowing dietary supplements already in the marketplace, and products composed of foods already in use.

Over the next 13 years the FDA determined that some drugs could not be labeled as safe unless a physician provided instructions about their use. Thus in 1951, the FDA sought and obtained new legislative authorities creating the prescription category for drugs. A decade later, the world was rocked by the realization that a new drug, thalidomide, had teratogenic effects. Thousands of babies around the world whose mothers had been given thalidomide were born with missing or malformed ears, limbs and internal organs; 40% would die within a year.

While thalidomide was never licensed in the United States, the tragedy led to the passage of another expansion of power for the FDA. The Kefauver-Harris Amendments passed in 1962 and set in place additional pre-market approval requirements for drugs, the requirement that a drug be proven effective before licensing. Additionally, the FDA authorities were extended in regard to their ability to access a manufacturer's facility, process and records.

As a result of these expanded regulations the cost of drug development has soared. According to the Tuft's Center for the Study of Drug Development, the cost of developing a new drug is $802 million and takes between 10 and 15 years to gain FDA approval.[67] The patent protection afforded drug manufacturers is the key reason these industries are able to survive this expensive and lengthy process.[68] Food and supplements, being natural, cannot generally be patented.

The passage of the FD&CA in 1938 expanded the definition of drugs to include "articles (other than foods) intended to affect the structure or function of the body..." A new 'for special dietary use' category of foods was created, to cover dietary products intended for the nutritional needs of 'such persons as infants and invalids.'

During the 1950s a series of laws addressed pesticide residue, food and color additives, and preservatives requiring that manufacturers to establish the safety of the growing number of new chemicals entering the marketplace after World War II.

The dietary supplement industry began to grow and operated under the understanding that their products were either foods or 'foods for special dietary use'. In 1966, the FDA published a proposed regulation in the Federal Register to ban health claims. The proposal included a provision that required dietary supplement manufacturers to put on the label the statement, 'an abundant supply of vitamins and minerals could be found in commonly available foods'; and moved to redesignated all supplements that had potencies of 150% or more of the Recommended Daily Allowance (RDA) as drugs.

The 1960s were a time of increased public interest in preserving the rights of individuals to make personal dietary choices and preserve access to supplements. The public was outraged by the FDA's attempts to discount the benefits of supplements through their proposed labeling requirement and to recategorize vitamins and other dietary supplements as drugs.

A bitter public battle ensued. One example of the actions that so outraged the public occurred in 1972. The agency moved to require Vitamin A dosages exceeding 10,0000 I.U.s and Vitamin D exceeding 400 I.U.s be regulated as prescription drugs because of possible toxicity. A federal Appeals Court ruled against the FDA and preserved American's access to vitamins at these doses.

Driven by the public outrage, Congress worked for a number of years to address a solution to the FDA's regulation. Finally in 1976, William Proxmire of Wisconsin was able to pass an Amendment to Section 411 of the FD&CA which banned the FDA from classifying supplements as drugs based on potency.

It is reported that more than a million letters were received by Congress in the 1970s leading to the passage of the Proxmire Amendment. America spoke loudly about their belief that nutrition through conventional foods and supplementation was an important component of health and the freedom to make personal choices and have products available should not be abridged by a federal bureaucracy.

Health conscious consumers were increasingly frustrated by the FDA's intrusion into their decision making. It is hard to imagine in our free society that in the 1960's the FDA acted to prevent health food stores from displaying scientific literature about nutrition and from selling books, but this is exactly what transpired. When the FDA moved to restrict health claims on foods, the public was outraged even further.

Given that regulators make the determination of whether a product is a food or drug based on the claim that is made on the labeling, one can understand the frustration of the consumer when the FDA moved to define third-party literature such as a research article labeling. If a food product, such as orange juice or oatmeal or Vitamin C, claimed to cure, treat, or prevent a disease such as high cholesterol, cancer, or heart disease on the label or promotional materials, then the food product would immediately fall into the drug category. In addition, because it has not been

through pre-market approval, it would be a 'misbranded' drug and subject to seizure and other enforcement actions.

"Throughout the 1950s and 1960s, the FDA brought hundreds of court actions against nutrition manufacturers for making health-related claims for their products.... The FDA actively prosecuted vitamin retailers that sold vitamins and other supplements in conjunction with books or pamphlets that extolled their use. It was illegal, for example, for a health food store to sell vitamins and books extolling the virtues of vitamins. The FDA justified such practices, which many considered to be a violation of the First Amendment, under the theory that literature that was sold near a product was thereby converted into a product label, and if health claims were made in the literature, then the product had to be regulated as a drug (and thus had to go through FDA clinical trials before being sold)."[69]

In an attempt to moderate the actions of the FDA to ban health claims on foods, the Congress, in 1990, passed the Nutrition Labeling and Education Act (NLEA). Prior to this act, the FDA had prevented food manufacturers from labeling the fat and cholesterol content and other nutritional content on products. Recognizing the health benefits to consumers in having information on labels, the Congress reversed the FDA's policy through new labeling requirements. The NLEA required food manufacturers to disclose the fat (saturated and unsaturated), cholesterol, sodium, sugar, fiber, protein and carbohydrate content in their products; required the Food and Drug Administration to establish standards and definitions for food descriptors such as "low," "lean," "lite," "reduced," etc., and set standards for allowing health claims on foods if the claims are based on sound scientific evidence and are truthful, accurate and not misleading and for allowing third-party references or endorsements.

Even after NLEA was signed into law, the FDA continued to create road blocks for industry and consumer alike where dietary supplements were concerned. Some have defined the FDA's actions as 'willful mis-interpretation of the Congressional intent in regards to health claims.' The public joined with the industry in 1994 and moved Congress to pass the Dietary Supplement Health and Education Act (DSHEA).

DSHEA for the first time defines dietary supplements by law. According to Section 3 of the Act, 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 supplement used by man to supplement the diet by increasing the total dietary intake; or
(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).

According to DSHEA, a dietary supplement is a product that is labeled as a dietary supplement and is not represented for use as a conventional food or as a sole item of a meal or the diet. The definition describes the variety of forms—capsule, powder, softgel, gelcap, tablet, liquid, or other form—in which these products can be ingested. This section of DSHEA specifically excludes dietary supplements from the definition of food additives in Section 409 of FD&CA.[70]

DSHEA also clearly defined the regulatory framework in which they operated (as foods rather than drugs.) In essence all substances that were already in the marketplace as foods could be used in dietary supplements. It is not well understood that DSHEA both clarified and strengthened the FDA's regulatory authority over dietary supplements, while strengthening the public's desire to maintain access. For instance, within DSHEA is a requirement for pre-market approval of new dietary ingredients, while not as onerous as the prescription drug requirements, adequate to afford the FDA the opportunity to assure the safety of new dietary ingredients. More than a dozen years after the passage of DSHEA, the debate over health claims have still not been settled. DSHEA also clarified that third-party literature was not to be construed as labeling.

The 1999 decision of the United States Court of Appeals for the District of Columbia Circuit in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), required the FDA to clarify the meaning of the term significant scientific agreement as used in the NLEA Act. The FDA's interpretation may be impeding the acceptance of health claims and therefore the sharing of science information by industry.

A Snapshot of Petition Outcomes for Health Claims and Qualified Health Claims

Lycopene: The FDA rejected a petition submitted in 2004 health claims and qualified health claims characterizing the relationship between consumption of lycopene, tomatoes, and lycopene-containing tomato-based foods, and reduction in risk of cancer, prostate cancer, lung cancer, gastric cancer, colorectal cancer, breast cancer, cervical cancer, endometrial cancer, ovarian cancer, and pancreatic cancer. "Based on a preliminary review, FDA determined that the scientific evidence supporting the proposed health claims does not meet the "significant scientific agreement" standard"[71] In 2005, the FDA amends this ruling with the following conclusions: *However, FDA concludes that there is very limited credible evidence for qualified health claims for tomatoes and/or tomato sauce, and prostate cancer provided that the qualified claim is appropriately worded so as to not mislead consumers. Thus, FDA intends to consider exercising its enforcement discretion for the following qualified health claim: Prostate Cancer "Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim."* [72]

Walnuts: In 2004, the concluded that there was not significant scientific agreement that the claim "Diets including walnuts can reduce the risk of heart disease." The letter to the California Walnut Commission states[73] that " *the FDA will consider exercising enforcement discretion for a qualified claim: Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts, as part of a low saturated fat and low cholesterol diet and not resulting in increased caloric intake, may reduce the risk of coronary heart disease. See nutrition information for fat [and calorie] content."*

Nuts: In 2003, the FDA rejected two model health claims for these nuts and certain nut-containing products: "Diets containing one ounce of nuts per day can reduce your risk of heart disease." and "Eating a diet that includes one ounce of nuts daily can reduce your risk of heart disease." The FDA determined there was not significant scientific agreement. However, the FDA concluded that there "was a sufficient basis for a qualified health claim about nuts and reduced risk of Chronic Heart Disease (CHD). Therefore, FDA has decided to consider the exercise of its enforcement discretion with regard to the following qualified health claim and disclosure statement, where applicable, on the label or in the labeling of certain nuts cited in your petition and nut-containing products as presented: "Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts [, such as *name of specific nut*,] as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease. [See nutrition information for fat content.]"

Chromium: In 2005, the FDA rejected a petition for qualified health claims for chromium picolinate and reduced risk of: cardiovascular disease when caused by insulin resistance, abnormally elevated blood sugar levels, cardiovascular disease when caused by abnormally elevated blood sugar levels, cardiovascular disease when caused by type 2 diabetes, retinopathy when caused by abnormally high blood sugar levels, or kidney disease when caused by abnormally high blood sugar levels. The FDA concluded that there is very limited credible evidence for qualified health claims for chromium picolinate and a reduced risk of insulin resistance, and therefore a reduced risk of type 2 diabetes, provided that the qualified claim is appropriately worded so as not to mislead consumers. Thus, FDA intends to consider the exercise of its enforcement discretion for the following qualified health claim: "One small study suggests that chromium picolinate may reduce the risk of insulin resistance, and therefore possibly may reduce the risk of type 2 diabetes. FDA concludes, however, that the existence of such a relationship between chromium picolinate and either insulin resistance or type 2 diabetes is highly uncertain."[74]

Vitamin E: In 2001, the FDA concluded that there is no significant scientific agreement for a relationship between vitamin E supplements and cardiovascular disease risk. "A dietary supplement that bears a claim about vitamin E supplements and reduced risk of cardiovascular disease will be subject to regulatory action as a misbranded food under 21 U.S.C. § 343(a)(1) and (r)(1)(B); as a misbranded drug under 21 U.S.C. § 352(a) and (f)(1); and as an unapproved new drug under 21 U.S.C. § 355(a). FDA does not intend to exercise enforcement discretion with respect to the use of a qualified health claim relating dietary supplement vitamin E intake and reduced risk of CVD."

Green Tea: In 2006, the FDA concluded that there is no credible evidence to support qualified health claims for green tea or green tea extract and a reduction of a number of risk factors associated with CVD.[75]

B. Federal Trade Commission

In addition to the FDA, the Federal Trade Commission also has authority to regulate foods and dietary supplements. With a quarter-billion dollar budget, and more than a thousand employees, the FTC's authority has expanded dramatically since its creation in 1914. Originally created to

prevent unfair methods of competition in commerce, Congress has expanded the agencies authority to police anti-competitive practices and unfair and deceptive acts or practices.

While initially an agency focused on business activities, in the last three decades, the FTC's authority has been expanded to include a focus on consumer protection. The agency's Bureau of Consumer Protection's mandate is to protect consumers against unfair, deceptive or fraudulent practices.

In 1938, Congress passed the Wheeler-Lea Amendment, which included a broad prohibition against "unfair and deceptive acts or practices." Congress has broadened this authority by directing the FTC to administer consumer protection laws such as the Telemarketing Sales Rule, the Pay-Per-Call Rule, and the Equal Credit Opportunity Act.

In 1975, Congress passed the Magnuson-Moss Act, which gave the Commission the authority to develop industry specific trade regulations that had the force of law.

The Bureau of Consumer Protection's Division of Advertising Practices is the 'nation's enforcer of federal truth-in-advertising laws.' Its law enforcement activities focus on:

- Claims for foods, drugs, dietary supplements, and other products promising health benefits
- Health fraud on the Internet
- Weight-loss advertising
- Advertising and marketing directed to children
- Performance claims for computers, ISPs and other high-tech products and services
- Tobacco and alcohol advertising, including monitoring for unfair practices or deceptive claims and reporting to Congress on cigarette and smokeless tobacco labeling, advertising and promotion
- Protecting children's privacy online
- Claims about product performance made in national or regional newspapers and magazines; in radio and TV commercials, including infomercials; through direct mail to consumers; or on the Internet [76]

The FTC does not concern itself with whether or not dietary supplements have complied with the labeling regulations of DSHEA (not making disease claims); rather their focus is whether or not the advertised claims are substantiated. In 1997, Jodie Bernstein, Director of the Bureau of Consumer Protection made the following comments in a 1997 speech.

"*A few months ago it became apparent to me from discussions with industry members that many companies were genuinely baffled about how to satisfy the FTC's requirement that claims be adequately substantiated. What did that mean? Did they need clinical studies? What kinds of studies? How many? How big? How long? Would something less than human clinical research suffice?*

I also heard concerns expressed that our standard was inconsistent with the spirit of DSHEA. Let me try to clarify one aspect of the FTC's substantiation standard. Although the standard is a

rigorous one, often requiring competent and reliable scientific evidence, it is also flexible, because it is dependent on the nature of the claim being advertised. It is by virtue of this flexibility that the standard enables us to both protect consumers and facilitate truthful claims. For this reason, I believe the FTC's substantiation standard is fully consistent with the requirement, embodied in DSHEA, that claims for supplements be truthful, not misleading and substantiated.

Having made that basic point, I recognize that many in the industry are still unfamiliar with the FTC's approach and that it would be helpful to provide the industry with more specific and concrete guidance in this area. ...The level of support required depends on many variables, including the nature of the claim asserted and the manner in which it is presented in a specific ad. To create a complete checklist of do's and don'ts and still maintain the necessary and appropriate flexibility may be difficult, if not impossible..."[77]

Several months later the FTC issued a guidance document regarding advertising. In releasing the document, the FTC stated:

"The basic axiom of FTC advertising principles, the Guide points out, is 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."

Staff also noted that the agency's approach to substantiation of supplement claims is a rigorous but also flexible one. The amount and type of support needed will depend greatly on consumers' expectations, based on the specific claim being made, how it is presented in the context of the entire ad and how it is qualified. In evaluating the adequacy of support for a claim, the Commission consults with experts in a wide variety of fields, including those with a background in botanicals and traditional medicines."[78]

The FDA and FTC have at times worked in collaboration on enforcement actions regarding dietary supplements. However, the agencies at times have disagreed about health claims. In January 2004, in response to an Advance Notice of Proposed Rulemaking, the staff of the FTC made a comment to the FDA regarding "qualified health claims" in the labeling of conventional human foods and dietary supplements. The conclusion, "Allowing more truthful health claims for food and dietary supplements is likely to benefit both consumers and competition - better-informed consumers are better able to make healthier choices."[79]

In 2001, the FTC told Congress that "The Federal Trade Commission, Food and Drug Administration, U.S. Postal Service, and state law enforcement and regulatory agencies all play a role in protecting consumers, especially seniors, from health fraud. Over the years, there has been a high degree of cooperation among these agencies, including the sharing of information and technical and scientific expertise as well as the coordination of law enforcement efforts. For example, to combat health fraud on the Internet, the Commission initiated Operation Cure.All, a comprehensive consumer and business education and law enforcement and regulatory initiative targeting deceptive and misleading Internet promotion of products and services as cures or treatments for serious diseases."[80]

While the FTC has attempted through numerous publications to outline their requirements for information to substantiate claims, many within in the industry still feel that the rules are vague and 'a moving target.' Unofficial conversations have suggested an internal requirement that there be two well controlled studies on a product in which the measured outcomes would be generally recognized within the standard medical community's understanding of therapeutic intervention for a specific disease. This is still exceptionally vague.

Minor revisions to the regulations of existing federal regulations can eliminate the existing barriers that continue to impede the free flow of science information about foods including dietary supplements. A draft of the proposed legislation follows in Section VI.

VI. Proposed Legislation

"The Free Speech About Science Act."

110th CONGRESS
2nd Session
H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act concerning the distribution of scientific research in connection with foods and dietary supplements, to amend the Federal Trade Commission Act concerning false advertising, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES
[Date]
A BILL
To amend the Federal Food, Drug, and Cosmetic Act concerning the distribution of scientific research in connection with foods and dietary supplements, to amend the Federal Trade Commission Act concerning false advertising, and for other purposes. Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.
This Act may be cited as the "Free Speech Act."
SEC. 2. FINDINGS.
Congress finds that—
(1) Federal regulators have forbidden:
(a) Cherry growers to cite scientific research on cherries;

(b) A variety of dietary supplement makers to cite independent scientific research on supplements from respected, peer reviewed scientific journals.

(2) Censors of scientific information over the centuries, from the time of Copernicus and Galileo to the present, have always believed that they were protecting the public. But the U.S. Government, guided by our Constitutional protection of free speech, should never censor the dissemination of published scientific research except when such acts would pose a national security risk.

SEC. 3. DEFINITIONS.
(1) Section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)) is amended by adding at the end of subsection (1) the following: "A food or dietary supplement for which a claim appears in legitimate scientific research accompanying the food or dietary supplement in accordance with section 403B(a) is not a drug solely because the legitimate scientific research contains such a claim."
(2) Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

"(rr) The term 'legitimate scientific research' means scientific research, whether performed in vitro, in vivo, in animals, or in humans, conducted in accordance with sound scientific principles
and evaluated and accepted by a scientific or medical panel or published in a chapter of a recognized scholastic textbook or a peer-reviewed scientific publication or database; any publication of the United States Government (including ones published by or at
the request of any department, agency, institute, center, or academy); or an accurate balanced summary or scientific review of any of the above."

SEC. 4. MISBRANDED FOOD.
Section 403(r)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(1)(B)) is amended by adding at the end the following:
"Except that any such claim that appears in legitimate scientific research accompanying the food shall not cause the product to be deemed misbranded."
SEC. 5. FOOD AND DIETARY SUPPLEMENT LABELING
EXEMPTIONS.
Section 403B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-2) is amended to read as follows:
"FOOD AND DIETARY SUPPLEMENT LABELING EXEMPTION
"Sec. 403B. (a) Legitimate scientific research that is used in connection with the sale or distribution of a food or dietary supplement to consumers shall not be defined as labeling and
shall not be deemed evidence of an intent to sell a drug. The Secretary shall not restrict in any way whatsoever the distribution of legitimate scientific research exempt from labeling under this section.
(b) The Secretary shall not prohibit manufacturers or distributors of foods or dietary supplements from including citations to legitimate scientific research on the label or in the labeling of a food or a dietary supplement, even if the citation expressly or implicitly references a disease or a disease condition. Including such a citation on the label or labeling of a food or dietary supplement shall not be deemed evidence of an intent to sell a drug.
(c) In any proceeding before a Court or the Department, the burden of proof shall be on the Secretary to establish that the material being disseminated or cited is not legitimate scientific
research."

SEC. 6. DIAGNOSTIC TESTS
The Federal Food, Drug, and Cosmetic Act is amended by adding after section 331 the following:
"§ 331a. Permitted Acts "The Secretary shall not prohibit or restrict a retailer or wholesaler of any agricultural product, including fresh produce, in any way whatsoever

from "(i) testing any of its agricultural products for any pathogens, including bacteria, viruses, protozoa, fungi, or
parasites, that may
(A) potentially be transmitted to humans; or
(B) potentially cause illness or disease in humans; or "(ii) communicating the results of the tests in subsection (i) to the public."

SEC. 8. FALSE ADVERTISING.
(1) Section 15 of the Federal Trade Commission Act (15 U.S.C. 55) is amended by adding at the end the following:
"(g) Dietary Supplement
"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
(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 21
U.S.C. 411(c)(1)(B)(i); or
(ii) complies with 21 U.S.C. 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 21 U.S.C. 355 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 of Health and Human Services 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
21 U.S.C. 342(f); and
(B) not include—
(i) an article that is approved as a new drug under 21 U.S.C. 355, certified as an antibiotic under 21 U.S.C. 357, 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 has 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 would be lawful under this Act."
"(h) Legitimate scientific research
"The term 'legitimate scientific research' means scientific research, whether performed in vitro, in vivo, in animals, or in humans, conducted in accordance with sound scientific principles and evaluated and accepted by a scientific or medical panel or published in a chapter of a recognized scholastic textbook or a peer-reviewed scientific publication or database; any publication of the United States Government (including ones published by or at the request of any department, agency, institute, center, or academy); or an accurate balanced summary or scientific review of any of the above."
(2) Section 12 of the Federal Trade Commission Act (15 U.S.C. 52) is amended by adding at the end the following:
"(c) Legitimate scientific research
"The dissemination of legitimate scientific research in connection with the sale or distribution of a food or dietary supplement to consumers in accordance with 21 U.S.C. 343-2 shall not be per se false advertising if it does not directly correlate in all respects with the food or dietary supplement
being distributed.
"(d) Burden of proof
"In any proceeding before a Court or the Commission, the burden of proof shall be on the Commission to establish that the literature being disseminated is not legitimate scientific research."

VII. The Effects of the Legislation

Five insertions into the US Code relevant to the FDA and two pertaining to the FTC will assure that free speech about science is restored. These regulations will not create an additional regulatory burden on the agencies. They will however; offer the opportunity for improved health and significant cost savings both to the individual and to the Government.

The seven proposed changes:

1. FD&CA (21 U.S.C. 321(g)) is amended by adding at the end of subsection (1) the following: *"A food or dietary supplement for which a claim appears in legitimate scientific research accompanying the food or dietary supplement in accordance with section 403B(a) is not a drug solely because the legitimate scientific research contains such a claim."*

2. Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following: *"(rr) The term 'legitimate scientific research' means scientific research, whether performed in vitro, in vivo, in animals, or in humans, conducted in accordance with sound scientific principles and evaluated and accepted by a scientific or medical panel or published in a chapter of a recognized scholastic textbook or a peer-reviewed scientific publication or database; any publication of the United States Government (including ones published by or at the request of any department, agency, institute, center, or academy); or an accurate balanced summary or scientific review of any of the above."*

3. Section 403(r)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(1)(B)) is amended by adding at the end the following: "Except that any such claim

that appears in legitimate scientific research accompanying the food shall not cause the product to be deemed misbranded."

4. FOOD AND DIETARY SUPPLEMENT LABELING EXEMPTIONS.
Section 403B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-2) is amended to read as follows:

"FOOD AND DIETARY SUPPLEMENT LABELING EXEMPTION "Sec. 403B.
(a) Legitimate scientific research that is used in connection with the sale or distribution of a food or dietary supplement to consumers shall not be defined as labeling and shall not be deemed evidence of an intent to sell a drug. The Secretary shall not restrict in any way whatsoever the distribution of legitimate scientific research exempt from labeling under this section.
(b) The Secretary shall not prohibit manufacturers or distributors of foods or dietary supplements from including citations to legitimate scientific research on the label or in the labeling of a food or a dietary supplement, even if the citation expressly or implicitly references a disease or a disease condition. Including such a citation on the label or labeling of a food or dietary supplement shall not be deemed evidence of an intent to sell a drug.
(c) In any proceeding before a Court or the Department, the burden of proof shall be on the Secretary to establish that the material being disseminated or cited is not legitimate scientific
research."

5. The Federal Food, Drug, and Cosmetic Act is amended by adding after section 331 the following: *"§ 331a. Permitted Acts "The Secretary shall not prohibit or restrict a retailer or wholesaler of any agricultural product, including fresh produce, in any way whatsoever from "(i) testing any of its agricultural products for any pathogens, including bacteria, viruses, protozoa, fungi, or*
parasites, that may (A) potentially be transmitted to humans; or
(B) potentially cause illness or disease in humans; or "(ii) communicating the results of the tests in subsection (i) to the public."

6. Section 15 of the Federal Trade Commission Act (15 U.S.C. 55) is amended by adding at the end the following: *"(g) Dietary Supplement "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 (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 21 U.S.C. 411(c)(1)(B)(i); or (ii) complies with 21 U.S.C. 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 21 U.S.C. 355 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 of Health and Human Services 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 21 U.S.C. 342(f); and (B) not include— (i) an article that is approved as a new drug under 21 U.S.C. 355, certified as an antibiotic under 21 U.S.C. 357, 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 has 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 would be lawful under this Act." "(h) Legitimate scientific research
"The term 'legitimate scientific research' means scientific research, whether performed in vitro, in vivo, in animals, or in humans, conducted in accordance with sound scientific principles and evaluated and accepted by a scientific or medical panel or published in a chapter of a recognized scholastic textbook or a peer-reviewed scientific publication or database; any publication of the United States Government (including ones published by or at the request of any department, agency, institute, center, or academy); or an accurate balanced summary or scientific review of any of the above."

7. Section 12 of the Federal Trade Commission Act (15 U.S.C. 52) is amended by adding at the end the following: *"(c) Legitimate scientific research "The dissemination of legitimate scientific research in connection with the sale or distribution of a food or dietary supplement to consumers in accordance with 21 U.S.C. 343-2 shall not be per se false advertising if it does not directly correlate in all respects with the food or dietary supplement being distributed. "(d) Burden of proof "In any proceeding before a Court or the Commission, the burden of proof shall be on the Commission to establish that the literature being disseminated is not legitimate scientific research."*

VIII. Conclusions

The United States is built on the principle of free speech. In addition, our society and our economy has led the world in science and technology. It is neither consistent with American values nor with the progress of science to restrict the flow of legitimate scientific research among either specialists or the public.

Much progress has occurred since the onerous actions of the FDA in the 1950s and 1960s when the FDA actively prosecuted vitamin retailers who sold supplements in conjunction with books detailing their benefits. However, the FDA has at times shown a reluctance to fully implement legislation enacted by the Congress and signed into law by the President. This reluctance has at times led to Court actions such as Pearson v. Shalala in which the Courts determined that the FDA impeded the flow of scientific information relative to foods and dietary supplements.

The Congress over time have made certain technical corrections and clarifications to the law in order to better address the will of the People regarding the regulation of foods and dietary supplements and in order to seek a more fair balance between maintaining the freedom of individuals to be informed about scientific findings and to purchase dietary supplements and the responsibility of Federal agencies to protect the public from harm.

Accurate, science based information about nutrition is an essential part of any effort to improve health. As such, the delivery of scientific information from all sources, government, academia,

industry, and individuals should be unfettered. The FTC itself say that, "Allowing more, truthful health claims for food and dietary supplements is likely to benefit both consumers and competition – better-informed consumers are better able to make healthier choices."

Evidence now shows that a majority of grocery shoppers "choose foods and beverages for specific medical purposes at least some of the time…."

Research plays an important role in illuminating the health benefits of foods and supplements. For example, the estimated five year savings in the Medicare population from reduction in the relative risk of coronary artery disease and improved immune functioning and subsequent reduction in infection through providing older adults with a daily multivitamin is approximately $1.6 billion.

The offering of legitimate scientific information to the public through all avenues including manufacturers and distributors of foods including dietary supplements contributes to the health of America. Federal agencies that restrict this free flow of information are impeding the pursuit of health and happiness, impeding the progress of science, and interfering with the general welfare of the People. The restriction of science information related to health (not related to the national security) by Government may even be considered by some to be a human rights violation.

By S. Elizabeth Clay

IX. Appendix A

Congressional Actions to Address the FDA's Interference with the Dissemination of Science Information about Foods

1976 Proxmire Amendment banned the FDA from classifying supplements as drugs based on potency.

1990 Nutritional Labeling and Education Act (NLEA) Became Public Law No: 101-535. Its provisions may be summarized as follows:

Nutrition Labeling and Education Act of 1990 - Amends the Federal Food, Drug, and Cosmetic Act (FDCA) to deem a food misbranded unless its label bears nutrition information that provides: (1) the serving size or other common household unit of measure customarily used; (2) the number of servings or other units per container; (3) the number of calories per serving and derived from total fat and saturated fat; (4) the amount of total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, total protein, and dietary fiber per serving or other unit; and (5) subject to conditions, vitamins, minerals or other nutrients. Authorizes the Secretary of Health and Human Services to: (1) require certain information to be highlighted; (2) require additional nutrients to be included in the labeling; or (3) exempt nutrients from the labeling requirement.

Allows nutrition information on food received in bulk containers at a retail establishment to be displayed at the location in the establishment at which the food is offered for sale.
Directs the Secretary to provide, for raw agricultural commodities and raw fish (defining "fish" to mean aquatic animal life), for furnishing the nutrition information by issuing voluntary nutrition guidelines. Applies the voluntary guidelines only to the 20 varieties most frequently consumed of each of vegetables, fruit, and raw fish. Allows the Secretary to apply the guidelines regionally.
Directs the Secretary, if the Secretary finds after 30 months that there is not substantial compliance with the voluntary guidelines, to issue regulations requiring the nutrition information to be provided for frequently consumed varieties of vegetables, fruit, and raw fish. Regulates the location, content, and manner of presentation of the information. Prohibits prosecution for minor violations if there has been substantial compliance.

Exempts from the labeling requirements food: (1) sold for immediate consumption in restaurants, or sold to restaurants for sale or use in restaurants; (2) processed and prepared primarily in a retail establishment and not for immediate consumption in the establishment; (3) including certain infant formulas; (4) which is a medical food; (5) which is customarily processed, labeled, or repacked in substantial quantities at establishments other than those where it was originally processed or packed; (6) in small packages containing no nutrition information; (7) which contains insignificant amounts of all the nutrients and does not make any claim with respect to the nutritional value of the food; (8) sold by certain small businesses, unless the label provides nutrition information or makes a nutrition claim; and (9) sold by a distributor to restaurants or certain other establishments. Allows the Secretary to require, if a food contains insignificant amounts of more than half the nutrients required to be included in the labeling, that the amounts of such nutrients be stated in a simplified form.

Requires certain vitamins and minerals to include nutrient information in their labeling as appropriate and as specified by the Secretary.
Directs the Secretary to issue regulations which: (1) require the nutrition information on labels to be conveyed in a manner which enables the public to readily observe and comprehend it and to understand its relative significance in the context of a total daily diet; (2) establish standards to define serving size or other unit of measure; (3) permit the inclusion of certain information beyond that which is required; and (4) permit single statements or ranges when there are minor variations in the nutritional value or the food is comprised of an assortment of similar foods which have variations in nutritional value.
Directs the Secretary to carry out consumer education regarding nutrition labeling.
Sets forth the circumstances under which nutrition and health claims may and may not be made for foods. Regulates the presentation of claims, including claims involving cholesterol, saturated fat, or fiber. Authorizes the Secretary to prohibit claims that are misleading in light of another nutrient in the food. Exempts from certain regulations: (1) terms contained in the brand name of a food, if the name was in use on that food before October 25, 1989; (2) the term "diet," when used in the brand name of a soft drink and subject to other requirements; (3) a statement regarding the percentage of vitamins and minerals in the food in relation to recommended daily consumption; and (4) infant formulas subject to specified provisions of the FDCA and medical foods as defined in the Orphan Drug Act.

Allows proceedings for the enforcement, or to restrain violations, of the amendments made by this Act to be brought in the name of a State in which the food that is the subject of the proceedings is located (in addition to the existing authorization to bring such actions to enforce the FDCA in the name of the United States).

Declares that a food which makes a claim which characterizes the relationship of its constituents to a disease or a condition, or makes a claim with respect to a dietary supplement of vitamins, minerals, herbs, or similar nutritional substances, in accordance with the requirements of this Act, is not, solely because of such claim, a drug under specified provisions of FDCA.

Prohibits, subject to exception, a State or its subdivision from establishing or continuing in effect any requirement for a food that is the subject of a standard of identity, or any labeling requirement that is not identical to the requirements of this Act. Provides for exemption petitions by States if a State or local requirement would not cause any food to be in violation of Federal law, would not unduly burden interstate commerce, and is designed to address a particular need for nutrition information which is not met by the requirements of this Act.

Deems any food (currently, any food without a prescribed definition and standard of identity) misbranded unless it bears any common or usual name of the food and lists optional ingredients. Requires a beverage containing vegetable or fruit juice to bear a statement of the percentage of the vegetable or fruit juice in the food. Provides exceptions for spices, flavorings, and colors not required to be certified under specified provisions. Modifies provisions relating to the procedures for the establishment of regulations concerning definitions and standards of identity.

1992 Prescription Drug User Fee Act of 1992

Title II: Dietary Supplements - Dietary Supplement Act of 1992 - Requires the Secretary of Health and Human Services to issue final regulations with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances under the Nutrition Labeling and Education Act of 1990 by December 15, 1993. Prohibits the implementation of such Act prior to the issuance of such regulations. Prohibits the promulgation of regulations that require the use of, or are based upon, recommended daily allowances of vitamins or minerals before November 8, 1993.
Requires the Secretary to report to specified congressional committees on enforcement practices of the FDA with respect to such dietary supplements.
Requires the Comptroller General to report to such committees on a study of the management activities of the FDA related to such dietary supplements.
Requires the Director of the Office of Technology Assessment, in cooperation with the Congressional Research Service and subject to the approval of the Technology Assessment Board to report to such committees on a study of the health outcomes and regulatory systems affecting the development and sale of such dietary supplements.

1994 Dietary Supplement Health and Education Act (DSHEA)

Became Public Law No: 103-417. It may be summarized as follows:

Dietary Supplement Health and Education Act of 1994 - Amends the Federal Food, Drug, and Cosmetic Act to define a "dietary supplement" as a product: (1) other than tobacco, intended to supplement the diet that contains a vitamin, mineral, herb or botanical, dietary substance, or a concentrate, metabolite, constituent, extract, or combination of the above ingredients; (2) that is intended for ingestion, is not represented as food or as a sole item of a meal or diet, and is labeled as a dietary supplement; (3) that includes an article approved as a new drug, certified as an antibiotic, or licensed as a biologic and that was, prior to such approval, certification or licensure, marketed as a dietary supplement or food, unless the conditions of use and dosages are found to be unlawful; and (4) excludes such articles which were not so marketed prior to approval unless found to be lawful. Deems a dietary supplement to be a food. Excludes a dietary supplement from the definition of the term "food additive."
(Sec. 4) Deems food to be adulterated if it is a dietary supplement or contains a dietary ingredient that: (1) presents a significant or unreasonable risk of injury; (2) is a new dietary ingredient for which there is

inadequate information to provide assurance that such ingredient does not present such risk; (3) poses an imminent hazard to public health or safety; or (4) contains an ingredient that renders it adulterated.
(Sec. 5) Provides that a publication shall not be defined as labeling when used in connection with the sale of dietary supplements when it: (1) is not false or misleading; (2) does not promote a particular manufacturer or brand of supplement; (3) is displayed so as to present a balanced view of the available scientific information; (4) is displayed physically separate from such supplements; and (5) does not have appended to it any information by sticker or other method. Places the burden of proof on the United States in establishing that such matter is false or misleading.
(Sec. 6) Sets forth conditions under which nutritional claims may be made with respect to such supplements.
(Sec. 7) Deems a dietary supplement misbranded unless its labeling meets specified guidelines.
(Sec. 8) Deems a dietary supplement which contains a new dietary ingredient adulterated unless: (1) such supplement contains only ingredients which have been present in the food supply as articles used for food in a form in which the food has not been chemically altered; or (2) there is a history of use or other evidence of safety regarding such supplement.
(Sec. 9) Authorizes the Secretary of Health and Human Services to prescribe good manufacturing practices for dietary supplements to be modeled after those for food.
(Sec. 12) Creates the Commission on Dietary Supplement Labels. Authorizes appropriations.
(Sec. 13) Establishes an Office of Dietary Supplements within the National Institutes of Health. Authorizes appropriations.

1997 Food and Drug Administration Modernization Act

Became Public Law No: 105-115. The relevant portion may be summarized as follows:

Title III: Improving Regulation of Food - Amends provisions relating to food nutrition levels and health-related claims to empower the Secretary to make certain regulations effective on publication.

(Sec. 302) Modifies requirements regarding petitions to issue a regulation on health-related claims.

(Sec. 303) Allows a health or nutrient content claim not authorized by the Secretary if: (1) a U.S. governmental scientific body with public health protection or research responsibility directly relating to human nutrition or the National Academy of Sciences has published an authoritative statement, currently in effect, about the relationship to which the health claim refers or that identifies the nutrient level to which the nutrient claim refers; (2) a person has notified the Secretary; (3) the claim and food are in compliance with certain requirements; and (4) the claim is stated in a way that it is an accurate representation of the authoritative statement and in a way that it enables the public to understand the information and its significance.

(Sec. 305) Requires, if a nutrient claim is made and the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet-related, that the label contain, close to the claim, a statement referring to the nutrition information elsewhere on the label.

(Sec. 306) Prohibits construing specified FDCA provisions to require that a food label include a separate radiation disclosure statement more prominent than the declaration of ingredients.

(Sec. 307) Mandates, by a specified deadline: (1) a final determination on any pending petition that would permit red meat irradiation; or (2) a report to specified congressional committees regarding the process followed in reviewing that petition and the reason for the delay.

(Sec. 308) Prohibits implementation of any requirement banning, as an unapproved food additive, lead and cadmium based enamel in the lip and rim area of glass and ceramic ware before one year after the requirement is published. Regulates the circumstances in which such a ban may be imposed.

(Sec. 309) Deems a food contact substance (a substance used as a component of materials used in manufacturing, packing, packaging, transporting, or holding food, but not intended to have any technical effect in the food) unsafe and the food adulterated unless: (1) there is (and the substance is in conformity with) a regulation prescribing the conditions under which the substance may be safely used; or (2) the manufacturer or supplier has notified the Secretary of the identity and intended use of the substance and the manufacturer's or supplier's determination that the substance is safe under a specified standard. Authorizes appropriations for the notification program.

* In 1999 a District Court overturned Section 401 of FDAMA which dealt with the distribution of scientific data from manufacturers to physicians. The court ruled: "Section 401 of the FDAMA violates the First Amendment right to commercial free speech, just as the earlier FDA policies did. It struck down the law and again enjoined the FDA from seeking to limit the following activities:

- *Journal Articles. Manufacturer dissemination or redistribution "to physicians or other medical professionals" of any article previously published in a "bona-fide peer reviewed professional journal," regardless of whether it focuses on off-label uses.*
- *Medical Texts. Disseminating or redistributing "to physicians or other medical professionals" any reference textbook "published by a bona fide independent publisher and otherwise generally available in bookstores or other distribution channels where similar books are normally available" regardless of its discussion of off-label uses.*
- *CME Programs. Suggesting content or speakers to "an independent program provider" in connection with a continuing medical education ("CME") seminar or other symposium regardless of the off-label discussion of the forum.*[81]

There were three important implications of the court ruling:

1. **Burden of proof shifted to the FDA.** The burden of proving that this limited class of scientific information is false and misleading is now on the FDA. Data not submitted for agency review is not inherently false and misleading.
2. **Physician off-label prescribing makes information "legal."** The "lawfulness" of a communication was interpreted narrowly, based not on whether the FDA approval is required, but on whether it refers to a legal activity; in this case off-label prescribing by doctors.
3. **Enhanced dissemination rights.** The ability to disseminate credible peer-reviewed scientific information to physicians is enhanced.[82]

X. Appendix B

A Snapshot of Court Actions Regarding the FDA's Attempts to

Block Access to Health Information Regarding Foods and Dietary Supplements.

1999: Pearson v. Shalala (Durk Pearson and Sandy Shaw were joined by the American Preventive Medical Association[83][now American Association for Health Freedom], and Citizens for Health).

On January 15, 1999, the U.S. Court of Appeals for the D.C. Circuit issued its decision in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999). In Pearson, the plaintiffs had challenged FDA's health claim regulations for dietary supplements and FDA's decision not to authorize health claims for four specific nutrient-disease relationships: Dietary fiber and cancer, antioxidant vitamins and cancer, omega-3 fatty acids and coronary heart disease, and the claim that 0.8 mg of folic acid in dietary supplement form is more effective in reducing the risk of neural tube defects than a lower amount in conventional food form.

The court held in Pearson that, on the administrative record compiled in the challenged rulemakings, the first amendment does not permit FDA to reject health claims that the agency determines to be potentially misleading unless the agency also reasonably determines that no disclaimer would eliminate the potential deception. Accordingly, the court invalidated the regulations prohibiting the four health claims listed above and directed the agency to reconsider whether to authorize the claims. The court further held that the Administrative Procedure Act requires FDA to clarify the ``significant scientific agreement" standard for authorizing health claims, either by issuing a regulatory definition of significant scientific agreement or by defining it on a case-by-case basis.

1999: Pearson v. Shalala en banc The FDA appealed to the Court of Appeals for a reconsideration before the full court. On April 2, 1999, the U.S. Court of Appeals for the D.C. Circuit denied the petition for rehearing. Of note is the reprimand the court gave to the FDA for misinterpreting their ruling: "...The government has misrepresented the panel's opinion in several respects, two of which deserve brief mention. The government claims that the panel "“mistakenly believed that FDA has no concern that the use of dietary supplements may threaten consumer health and safety." Second, the government describes the panel as "concluding that it was arbitrary under the APA for FDA not to specify in advance precisely what evidence will establish 'significant scientific agreement.'" This seems a careless interpretation of the opinion."

2001: Pearson v. Shalala II: Pearson et al (including AAHF) challenged the FDA decision prohibiting from dietary supplement labels a particular folic acid health claim. The Court found that the " FDA's decision to classify Plaintiffs' Folic Acid Claim as "inherently misleading" was arbitrary, capricious, and an abuse of discretion. Plaintiffs' proposed Claim is only potentially misleading, and therefore subject to First Amendment protection. Accordingly, the Court concludes that the FDA acted unconstitutionally, and particularly in violation of the Court of Appeals decision in Pearson v. Shalala, in suppressing Plaintiffs' Claim rather than proposing a clarifying disclaimer to accompany the Claim. Accordingly, the Court grants Plaintiffs' Motion for a Preliminary Injunction insofar as it requests a declaration that the FDA's refusal to authorize the Folic Acid Claim violated the First Amendment. However, because it is the FDA's, rather than the Court's institutional role to draft accurate, adequate, and succinct health claim disclaimers, the Court hereby remands this case to the FDA, instructing the agency to draft one or more appropriately short, succinct, and accurate disclaimers.34 The Court strongly suggests the agency consider the two disclaimers suggested:
("The evidence in support of this claim is inconclusive" and "The FDA does not approve this claim"), as well as the disclaimer put forth by Plaintiffs ("Foods fortified with similar amounts of folic acid may be as effective as dietary supplements in reducing the risk of neural tube defects")."

2001: Pearson v. Thompson The FDA asked the Court to reconsider the Pearson II mandates. In rejecting their motion for reconsideration, the Court wrote, "In moving for reconsideration, Defendants again seem to ignore the thrust of Pearson I. While that decision might leave certain specific issues to be fleshed out in the course of future litigation, the philosophy underlying Pearson I is perfectly clear: that the First Amendment analysis in Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y., 447 U.S. 557, 65 L. Ed. 2d 341, 100 S. Ct. 2343 (1980), applies in this case, and that if a health claim is not inherently misleading, the balance tilts in favor of disclaimers rather than suppression. In its motion for reconsideration, the FDA has again refused to accept the reality and finality of that conclusion by the Court of Appeals."

2003: Whitaker v. Thompson I The FDA rejected a proposed labeling: "Consumption of 320 mg daily of Saw Palmetto extract may improve urine flow, reduce nocturia and reduce voiding urgency associated with mild benign prostatic hyperplasia (BPH)" submitted in 1999. The FDA argued to the courts that dietary supplements could make health claims only when they were based on the nutritive value. The district court granted the FDA's motion to dismiss.

2002: Whitaker V
v Thompson II Whitaker et al Plaintiffs challenged the FDA decision prohibiting dietary supplements' labels from including the health claim that "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers" ("Antioxidant Vitamin Claim"). They sought an injunction enjoining the FDA from taking any action which would prevent the use of the desired antioxidant vitamin health claim as proffered or with reasonable disclaimers. The Court granted Whitakers request for an injunction and remanded, effective immediately, to the Food and Drug Administration, for the purpose of drafting one or more short, succinct, and accurate alternative disclaimers, which may be chosen by the Plaintiffs to accompany their Antioxidant Vitamin Claim, consistent with the accompanying Memorandum Opinion.

XI. Appendix C

In January 2007, the FDA issued a Guidance for Industry through a "Dear Manufacturer Letter Regarding Food Labeling."[84] The letter offers the agency's 'current thinking' and serves as a reminder to manufacturers and distributors of conventional food products about the different types of labeling claims available for use on conventional food products and how these claims are regulated by the Agency. Food labels and labeling generally fall into the following categories: health claims, structure/function claims, nutrient content claims, and dietary guidance...." In this document the FDA states:

- "A health claim is a claim that describes the relationship between a substance (food or food component) and a disease or health-related condition. Health claims are limited to claims about disease risk reduction and cannot be claims about the cure, mitigation, treatment or prevention of disease. There are three ways by which FDA exercises its oversight in determining which health claims may be used on a label or in labeling for a food:

(1) FDA issues a regulation authorizing a health claim that meets the significant scientific agreement standard set forth in the 1990 Nutrition Labeling and Education Act (NLEA);
(2) FDA prohibits or modifies, by regulation, a health claim within 120 days after it has received a health claim notification under the 1997 Food and Drug Administration Modernization Act (FDAMA), which permits health claims based on an authoritative statement from a scientific body of the United States (U.S.) government with official responsibility for public health protection or research directly related to human nutrition or the National Academy of Sciences or any of its subdivisions (in the alternative, a U.S. District Court in an enforcement proceeding may find that the requirements of sections 303 or 304 of FDAMA have not been met); and
(3) FDA issues a letter of enforcement discretion for qualified health claims pursuant to the 2003 FDA Consumer Health Information for Better Nutrition Initiative which provides for qualified health claims where the strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation. These types of health claims must be qualified to ensure accuracy and non-misleading presentation of information to consumers. Although FDA's "enforcement discretion" letters are issued to the petitioner who requested the qualified health claim, the qualified health claims are available for use on other products that meet the enforcement discretion conditions specified in the letter.

- "Structure/function" claims can be made on the labels of conventional foods. These claims describe the role of substances intended to affect the normal structure or function in humans for example, "calcium builds strong bones." In addition, structure/function claims may characterize the means by which substances act to maintain such structure or function, for example, "fiber maintains bowel regularity" or they may describe general well-being from consumption of a nutrient or dietary ingredient. Structure function claims may also describe a benefit related to a nutrient deficiency disease (like Vitamin C and scurvy), as long as the statement also tells how widespread such disease is in the U.S. Such claims may not explicitly or implicitly link the relationship to a disease or health-related condition. We point out that structure/function claims on conventional foods can be made without FDA review or authorization before use, but they must be truthful and not misleading and the claims must derive from the nutritional value of the product.

- Nutrient content claims describe the level of a nutrient in a food using terms such as free, high and low, or they compare the level of a nutrient in a food to that of another food, using terms such as more, reduced and lite. An accurate quantitative statement (e.g., 200 mg of sodium) may be used to describe any amount of a nutrient present. The requirements that govern the use of nutrient content claims help ensure that descriptive terms, such as high or low, are used consistently for all types of food products and are meaningful to consumers. FDA exercises its oversight in determining which nutrient content claims may be used on a label or in labeling for a food by two means:

(1) FDA issues a regulation authorizing a nutrient content claim after FDA's careful review of the scientific evidence submitted in a nutrient content claim petition, and

(2) FDA prohibits or modifies, by regulation, a nutrient content claim within 120 days after it has received a nutrient content claim notification under FDAMA, which provides for nutrient content claims based on an authoritative statement from a scientific body by the U.S. government with official responsibility for public health protection or research directly related to human nutrition or the National Academy of Sciences or any of its subdivisions (in the alternative, a U.S. district court may find that the requirements of sections 303 or 304 of FDAMA have not been met).

- "Dietary" guidance statements can also be made on food labels. While health claims describe the relationship between a substance (specific food or food component) and a disease or health-related condition, dietary guidance statements do not contain both. Dietary Guidance statements tend to focus on general dietary patterns, practices and recommendations that promote health. Typically "dietary guidance" statements make reference to a category of foods and not a specific substance. Dietary guidance statements can be made without FDA review or authorization before use but the statements must be truthful and non-misleading.

- FDA also recognizes that information available through the Internet, including those websites that provide truthful and non-misleading information about conventional food products can serve a valuable and useful function. In certain circumstances, information that is disseminated over the Internet by, or on behalf of, a regulated company meets the definition of labeling.

In 1999, the FDA issued a guidance document for industry outlining the agencies 'current thinking' on the Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements." This review was prompted by both the enactment of the Nutrition Labeling and Education Act of 1990 (NLEA) and the ruling of the Court of Appeals in Pearson v. Shalala.

NLEA was designed to give consumers more scientifically valid information about the foods they eat. The NLEA identified 10 substance/disease relationships for initial consideration. The FDA concurred that evidence supported eight of the proposed claims.

Within NLEA were provisions for any interested person to petition FDA to issue a regulation regarding a health claim. Additional health claims have been authorized in response to such petitions.

FDA Approved Health Claims and Model Statements[85]

Approved Claims	Model Claim, Statements
Calcium and Osteoporosis	Regular exercise and a healthy diet with enough calcium helps teens and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.
Sodium and Hypertension	Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.
Dietary Fat and Cancer	Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.
Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease	While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.
Fiber-Containing Grain Products, Fruits, and Vegetables and Cancer	Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.
Fruits, Vegetables and Grain Products that contain Fiber, particularly Soluble Fiber, and Risk of Coronary Heart Disease	Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.
Fruits and Vegetables and Cancer	Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, Vitamin A, or Vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. Broccoli is high in vitamin A and C, and it is a good source of dietary fiber.
Folate and Neural Tube Defects	Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect.
Dietary Sugar Alcohol and Dental Caries	**Full claim**: Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in [name of food] do not promote tooth decay. **Shortened claim (on small packages only)**: Does not promote tooth decay.
Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease	Soluble fiber from foods such as [*name of soluble fiber source, and, if desired, name of food product*], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [*name of food product*] supplies __ grams of the [necessary daily dietary intake for the benefit] soluble fiber from [*name of soluble fiber source*] necessary per day to have this effect.
Soy Protein and Risk of Coronary Heart Disease	(1) 25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [*name of food*] supplies __ grams of soy protein. (2) Diets low in saturated fat and cholesterol that includes 25 grams of soy protein a day may reduce the risk of heart disease. One serving of [*name of food*] provides __ grams of soy protein.

Approved Claims	**Model Claim, Statements**
Plant Sterol/stanol esters and Risk of Coronary Heart Disease	(1) Foods containing at least 0.65 gram per serving of vegetable oil sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 grams, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [*name of food*] supplies __ grams of vegetable oil sterol esters. (2) Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 3.4 grams of plant stanol esters in two meals may reduce the risk of heart disease. A serving of [*name of food*] supplies __ grams of plant stanol esters.
Whole Grain Foods and Risk of Heart Disease and Certain Cancers	*Required wording of the claim:* "Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol may reduce the risk of heart disease and some cancers."
Potassium and the Risk of High Blood Pressure and Stroke	*Required wording for the claim:* "Diets containing foods that are a good source of potassium and that are low in sodium may reduce the risk of high blood pressure and stroke."

XII. About the Author

S. Elizabeth Clay is an internationally recognized expert in integral[86] health policy. An independent consultant, Ms. Clay served a dozen years in public service. For seven years, Ms. Clay served at the National Institutes of Health in an administrative capacity in the Fogarty International Center, Office of Alternative Medicine and Office of Rare Diseases. In the fall of 1998, she was invited to join the staff the U.S. House of Representatives Committee on Government Reform in a Professional Staff capacity, overseeing the committee's health oversight activities with then Chairman Dan Burton. In January 2003, Ms. Clay transitioned as Senior Professional Staff to the Subcommittee on Human Rights and Wellness. Ms. Clay was responsible for overseeing more than 25 Congressional hearings and conducting an extensive investigation into the FDA's implementation of dietary supplement regulations. While on Capitol Hill, Ms. Clay served as a member of the US Delegation to the CODEX Alimentarious Committee on Nutrition and Foods for Special Dietary Uses (a WTO level regulatory authority). Since returning to the private sector, Ms. Clay has consulted with corporate and non-profit organizations on strategic development, legislative and policy development, and public affairs. She can be reached via email at beth@bethclay.com.

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[34] Keith I. Block, MD, page 490 Essentials of Complementary and Alternative Medicine, Jonas, Levine.....
[35] http://www.fda.gov/oc/nutritioninitiative/whitepaper.html
[36] http://www.emord.com/docs/folicprelim.doc
[37] http://www.medpagetoday.com/Pediatrics/PreventiveCare/tb/8165
[38] http://www.iom.edu/CMS/3740/25471/35813.aspx
[39] http://www.cfsan.fda.gov/~dms/ds-ltr28.html
[40] http://clinicaltrials.gov/show/NCT00385723
[41] http://www.fda.gov/cder/consumerinfo/druginfo/omacor.htm

[42] http://www.fda.gov/cder/foi/label/2004/21654lbl.pdf
[43] The author telephoned her local CVS pharmacy in February 2008 to get a price quote. When asked about whether it was a superior product and worth the extra money, the pharmacist expressed a personal opinion that fish oil supplements were just as good as the prescription product.
[44] http://www.ashp.org/s_ashp/docs/files/MMA_CMSEducationalToolPartB-D.pdf
[45] http://www.defendingscience.org/upload/Jasanoff_Transparency_LCP.pdf Sheila Jasanoff, Transparency in Public Science: Purposes, Reasons, Limits
[46] http://www.blupete.com/Literature/Biographies/Science/Copernicus.htm
[47] Michael White, Isaac Newton: The Last Sorcerer, 1st ed. (Reading, MA: Perseus Books, 1999) 73, Questia, 14 Feb. 2008 <http://www.questia.com/PM.qst?a=o&d=9931542>.
[48] http://galileo.rice.edu/chron/galileo.html
[49] Science and Social Welfare in the Age of Newton. Contributors: G. N. Clark - author. Publisher: The Clarendon Press. Place of Publication: Oxford. Publication Year: 1937
[50] http://www.fordham.edu/halsall/source/inquisition1.html
[51] http://www.ifnh.org/Lee%20Bio%202.htm
52 The endocardiograph a recording stethoscope that can trace the sounds emitting from the chest wall as the heart muscles contract. Dr. Lee and his colleagues discovered that changes in body chemistry almost instantly show up in the heart, and therefore the administration of specific nutrients (in their whole form) could alter its action. They found, for example, that vitamin B2 slows tachycardia (rapid heart rate), and B1 and potassium stabilize arrhythmia (irregular heart rate). Essentially, the endocardiograph, could measure nutritional status, actually using the heart to provide a permanent, detailed recording of the patient's level of health. (http://doctorkeppel.com/home.html)
[53] http://www.ifnh.org/Page%20Bio.htm
[54] http://www.lef.org/fda/victory.htm
[55] http://www.naturalnews.com/z021791.html
[56] http://www.defendingscience.org/upload/Sometimes_Lurie_Zieve_LCP.pdf ; Peter Lurie and Allison Zieve Sometimes the Silence Can Be Like the Thunder: Access to Pharmaceutical Data at the FDA.
[57] http://ncac.org/advocacy_projects/Science_and_Censorship.cfm
[58] While the topic of the hearing was looking into allegations of restrictions of speech of government scientists focused on climate change research, the topic of restriction of speech applies to any area of science.
[59] http://www.aclu.org/freespeech/gen/28270leg20070206.html . This joint statement was co-signed by the American Association of University Professors, American Booksellers Foundation for Free Expression, American Civil Liberties Union, American Library Association, Association of American Publishers, National Center for Science Education National Coalition Against Censorship, PEN American Center, and People For the American Way
[60] http://www.americanheart.org/presenter.jhtml?identifier=4632
[61] http://www.ars.usda.gov/is/AR/archive/may04/cherry0504.pdf
[62] http://dietary-supplements.info.nih.gov/factsheets/magnesium.asp
[63] http://dietary-supplements.info.nih.gov/factsheets/folate.asp
[64] http://www.nlm.nih.gov/medlineplus/ency/article/002418.htm
[65] Steven Bratman, MD, The Natural Pharmacist, 1999 Prima Publishing
[66] http://www.gpoaccess.gov/usbudget/fy08/sheets/24_1.xls
[67] http://www.phrma.org/key_industry_facts_about_phrma/
[68] Typically, foods and dietary supplements do not have the same patent protections.
[69] http://www.fdareview.org/history.shtml
[70] http://web.health.gov/dietsupp/ch1.htm#majorprovisions
[71] http://www.cfsan.fda.gov/~dms/qhclyco.html
[72] http://www.cfsan.fda.gov/~dms/qhclyco2.html
[73] http://www.cfsan.fda.gov/~dms/qhcnuts3.html
[74] http://www.cfsan.fda.gov/~dms/qhccr.html
[75] http://www.cfsan.fda.gov/~dms/qhcgtea2.html
[76] http://www.ftc.gov/bcp/edu/pubs/consumer/general/gen03.shtm
[77] http://www.ftc.gov/speeches/other/jodie2.shtm
[78] http://www.ftc.gov/opa/1998/11/dietary.shtm
[79] http://www.ftc.gov/opa/2004/01/foodlabeling.shtm

[80] http://www.ftc.gov/os/2001/09/healthfraud.htm
[81] http://www.reedsmith.com/library/bulletins.cfm?cit_id=2496&widCall1=customWidgets.content_view_1&usecache=false
[82] http://www.reedsmith.com/library/bulletins.cfm?cit_id=2496&widCall1=customWidgets.content_view_1&usecache=false
[83] The American Preventive Medicine Association changed its name to the American Association for Health Freedom
[84] http://www.cfsan.fda.gov/~dms/flguid.html
[85] http://www.cfsan.fda.gov/~dms/flg-6c.html#upd
[86] An integral approach to health goes beyond the integration of complementary and alternative medicine and incorporates lifestyle, behavior, and social factors that affect personal well being as well as the patient-physician interaction. This arena includes Mind-Body interactions which refer to the relationships among cognitions, emotions, personality, social relationships, and health.