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DIETARY SUPPLEMENTS – SECOND CLASS SAFETY?

By Jim Griffiths, Ph.D.

Part one of a two-part article



When Congress passed the Dietary Supplement Health & Education Act (DSHEA) in 1994, the intent was to give consumers the 'option' to evaluate for themselves and make an informed 'choice' to purchase and consume 'dietary supplements' (or not). The legislation was meant to remove or at least lower the 'hurdle' that is required to be in place for *bona fide* food ingredients for which the consumer may have no knowledge and thus, no control over consuming. With DSHEA, Congress intended to link 'freedom of choice' with 'personal responsibility.' A dietary supplement manufacturer would be held to lesser standards in demonstrating safety at the recommended label intake, *i.e.* 'reasonable expectation of safety;' in that, the consumer would assume some risk.

The safety of an added food ingredient cannot rely on this level of uncertainty, as the general public does not make the decision to use or consume a novel texturizer, humectant, flavor modifier, or processing aid. Because of the need for certainty that no harm will result from the unknowing consumption of a novel food additive, the FDA requires a 'reasonable certainty of safety' be demonstrated *via* a food additive petition or a Generally Recognized As Safe (GRAS) determination.

In principle and in law (and from a common sense perspective – 'accepting risk with choice'), there should be two tiers for safety. That is what the dietary supplement aficionados and purveyors wanted; that is what the FDA wanted (out from under the 'no-win' safety decisions and gray area bordering pharmaceutical efficacy decisions); and that is what Congress delivered. So after October 15, 1994, one would expect this to be non-contentious and smoothly running from all viewpoints.

Alas, this has not been the case. The FDA has not wanted to completely relinquish control. Fully 69% of submitted 'New Dietary Ingredient Notifications' - the process whereby a manufacturer submits intent to market and documentation to the aforementioned 'reasonable expectation of safety' standard - have been rejected by the Agency.

(Continued on page 3)

FRONT-PAGE NEWS FLASHES ON FIBER

By Berna Magnuson, Ph.D.

Dietary fiber made front-page news flashes again during the past couple of months, raising the question: "Is it really worth the effort it takes to chomp down that oatmeal, celery, or Fiber-One?" In December, the FDA confirmed its conviction that soluble fiber is beneficial in preventing cardiovascular disease (CVD), issuing a final ruling authorizing barley products to carry a health claim on the relationship between soluble fiber and reduced risk of coronary heart disease (CHD). Evidence from five clinical trials demonstrated that consuming whole grain barley and dry milled barley products — such as barley bran, flakes, flour, and pearled barley, providing at least 3 g beta-glucan fiber per day — effectively lowered serum total and LDL-cholesterol levels, which in turn may reduce the risk of CHD. Therefore, in addition to certain oat products, whole grain barley and certain dry milled barley grain products are appropriate sources of beta-glucan soluble fiber for the health claim. In the December issue of the *American Journal of Clinical Nutrition*, D. Lairon and coworkers reported that the insoluble fiber from cereals also reduces risk factors of CVD, including being overweight and having a high body mass index. These findings suggest that it is time to "fiber-up" if your concern is CHD.

However, if it is colon cancer, the news was not so convincing. A meta-analysis of 13 prospective colon cancer studies by Y. Park and colleagues — involving over 725,000 participants and reported in the *Journal of the American Medical Association* — found that although dietary fiber intake was inversely associated with risk of colorectal cancer in age-adjusted analyses, the association between dietary fiber and risk of colon cancer was no longer significant, after accounting for other dietary risk factors. So if you need a $p < 0.05$ to make you eat fiber to prevent colon cancer, you are off the hook for now. But overall, adding both soluble and insoluble fiber to your diet still would be a smart resolution for good health in 2006.

¹<http://www.cfsan.fda.gov/~lrd/fr051223.html>

²Lairon *et al.*, *Am. J. Clin. Nutr.* 2005. 82:1185-94.

³Park *et al.*, *JAMA* 2005. 294:2849-57.



REGULATORY STRATEGIES

Inside this issue:

- ◆ Dietary Supplements—Second Class Safety?
- ◆ Front-page News Flashes on Fiber
- ◆ The Common Cold - Fact Sheet
- ◆ In the News...
- ◆ Past and Upcoming Events

TWO NEW MEMBERS JOIN BURDOCK GROUP



Sabine Teske
Staff Toxicologist

Sabine Teske has joined Burdock Group as a Staff Toxicologist in the Group's Vero Beach, Florida office. Sabine comes to us from the Ph.D. program in Toxicology/Pharmacology at Washington State University, Pullman, WA. Her area of expertise is both Toxicology and Immunology. Her background in these fields broadens the scope of professional services and adds to the synergism of the collaborative environment at Burdock Group. Sabine's contributions to the field of Toxicology may be researched further by visiting the Group's website, www.burdockgroup.com. Feel free to contact Sabine by email at steske@burdockgroup.com.



David Luedeke
Research Associate

Mr. Luedeke has joined Burdock Group as a Research Associate in the Group's Vero Beach office. Mr. Luedeke has a diverse background, having conducted original research in biology and toxicology and, most recently in microbiology at a large contract laboratory. David brings hands on, practical, scientific and managerial experience and will serve as another valuable resource to the collaboration of scientists at Burdock Group. Feel free to contact David by email at dluedeke@burdockgroup.com.

Burdock Group to present annual Student Travel Awards at both SOT and IFT 2006 events

Burdock Group showcased their expertise and services at the Annual Society of Toxicology (SOT) Conference, which was held at the San Diego Convention Center in San Diego, CA from March 5-9th. During this event, Burdock Group presented travel awards to five outstanding students in the sections of Food and Safety, Regulatory and Safety and Risk Assessment. The five awardees were acknowledged for their hard work and diligence.

In June 2006, Burdock Group will present four more student travel awards at the Annual Institute of Food Technologies (IFT) meeting. These awards will be given in the divisions of Food Law and Regulations and Toxicology and Safety Evaluation. This meeting will be held at the Orange County Convention Center in Orlando, FL. For more information, contact info@burdockgroup.com.

Burdock Group Toxicologist Cited in recent issue of the *Tan Sheet*

Dr. Berna Magnuson, staff toxicologist at Burdock Group recently spoke at the FDA-sponsored Public Meeting (November 17, 2005) on "Assessing Consumer Perceptions of Health Claims." The November 21, 2005 issue of the "Tan Sheet" quoted Dr. Magnuson in her proposal for a new system for claims evaluation. Dr. Magnuson stated, "FDA should implement use of an 'expert panel' that would work with the petitioner to analyze research supporting the claim. The panel would compile the data into a dossier that would include background information on the disease, shifting burden of proof into the petitioner and panel rather than a resources-strapped FDA." For additional details on Dr. Magnuson's comments please review the transcript located at <http://www.cfsan.fda.gov/~dms/qhctran.html>.

Burdock Group travels 8,000 miles to Food Ingredients Asia-China

In mid-February, Dr. Jim Griffiths, Burdock Group's Director of Toxicology and Dr. Ioana Carabin, Medical Consultant for Burdock Group, hopped on a plane and traveled approximately 8,000 miles to Shanghai, China where they attended the Food Ingredients Asia-China trade show held at the Shanghai New International Expo Centre. Burdock Group was one of several comprising the U.S. Pavilion at this tradeshow.

Dr. Jim Griffiths was invited to present on the topic of "Generally Recognized As Safe (GRAS), functional foods and the relationship to dietary supplements" that sparked great interest among the attendees.



H O T T O P I C S

- **March 7, 2006**—*Society of Toxicology Annual Conference*: Dr. George Burdock will be participating in a workshop on the "Potential Human Health Risk From Estrogenic Food and Consumer Product Additives," which will be moderated by Dr. Madhu Soni.
- **March 7, 2006**—*Society of Toxicology Annual Conference*: Drs. Jim Griffiths will be moderating a workshop on "New Food Ingredients Do Not Need New Food Regulations," and speakers will include Drs. Ray Matulka and Ioana Carabin.
- **April 7, 2006**—*Food and Drug Law Institute (FDLI)*: Drs. George Burdock and Ioana Carabin will be speaking (title TBA).
- **May 10, 2006**—*Joint Institute For Food Safety And Nutrition (JIFSAN)*: Dr. Berna Magnuson will be speaking on "Safety Assessment of Dietary Supplements: Challenges and Opportunities."
- **May 17, 2006**—*Consumer Healthcare Products Association (CHPA)*: Drs. George Burdock, Ioana Carabin and Berna Magnuson will be conducting a symposium on Qualified Health Claims.
- **June 13, 2006**—*Council for Responsible Nutrition (CRN) Science Day*: Dr. George Burdock will be speaking on "New Dietary Ingredient Notifications."
- **June 25-27, 2006**—*Institute of Food Technologies (IFT)*: Drs. Ioana Carabin and Berna Magnuson will be conducting a symposium on "Functional Foods and Women's Health" (date TBA).
- **June 25-27, 2006**—*Institute of Food Technologies (IFT)*: Dr. George Burdock will be speaking on "Nutragenomics." (date TBA).

THE COMMON COLD

- FACT SHEET -

Women's Health Sciences Institute



If you were lucky enough to avoid an episode of the *common cold* this winter, the odds are that you will 'catch one' soon. In the course of a year, people in the United States suffer one billion colds. Adults average 2 to 4 colds; however, the frequency drops to less than

one per year for people over 60. Women, especially those between the ages of 20 and 30, have more colds than men, probably because of their closer contact with children. (NIH/NIAID, December 2004).ⁱ Children have 6 to 12 colds a year, with absence from school associated with higher frequency. According to the Centers for Disease Control and Prevention, 22 million school days are lost annually in the United States due to the *common cold*.

The *common cold* — in reality, a mild viral infection of the upper respiratory tract — is the most common acute infectious illness in humans. Symptoms include sneezing, sniffing, runny nose, scratchy-sore throat, coughing, headache, and tiredness. Fever is usually slight, but can climb to 102°F in infants and young children. Ninety-five percent of people exposed to one of the responsible viruses will become infected.

More than 200 different viruses can cause symptoms we associate with the *common cold*. Rhinoviruses (from the Greek rhin, meaning "nose"), the most common viral infective agents in humans, cause an estimated 30 to 35 percent of all colds and are most active from spring through early fall. Rhinoviruses can live up to three hours on the skin, as well as inanimate objects such as telephones and stair railings.

Following an episode of the *common cold*, an individual develops immunity to the particular offending virus. However, because of the large number of different cold-causing viruses, this immunity is of limited protection. An individual can easily be infected by another cold virus, which will start the process all over again.

Currently, there is no cure for the *common cold*. The great diversity of the causative viruses and their ability to mutate to survive make the development of a vaccine or any antiviral medications all but impossible. Antibiotics are not useful for managing a cold and should be taken only if bacterial complications occur.

Treatment is mainly focused on the relief of symptoms and includes a wide range of options, from over-the-counter (OTC) drugs (e.g., decongestants and cough suppressants) to herbal therapies (e.g., Echinacea and garlic). In the recently published *Diagnosis and Management of Cough: ACCP Guidelines* (Chest, January, 2006), the American College of Chest Physicians concludes that OTC cough suppressants show limited efficacy in patients with a cough from an upper respiratory tract infection. This controversial statement precipitated an immediate press release from the Consumer Healthcare Products Association (CHPA) on January 11, 2006, stating: "The U.S. Food and Drug Administration and other regulatory agencies worldwide support the use of over-the-counter (OTC) cough/cold products for providing relief of coughs and other symptoms associated with the *common cold*, and studies demonstrate symptom relief among consumers using these products."ⁱⁱⁱ

Herbal therapies are always of interest to consumers in the United States, but do they work? The National Institutes of Health (NIH) is in the process of conducting two Phase III clinical trials. One clinical study is assessing the effects of *Echinacea, Propolis and Vitamin C on Upper Respiratory Tract Infections in Preschoolers*. The study design is a prospective, randomized, double-blind, placebo control with 104 children between the ages of 3 and 6, to be concluded in March 2006. The second clinical trial is evaluating the effects of *Echinacea vs. Placebo Effect in Common Cold*. The study design is a randomized, double-blind, placebo control with 800 participants; it will be completed in December 2006.

Rx

So until the results of the studies are available, the doctor recommends plenty of sleep and extra helpings of chicken soup!

Ioana Carabin, M.D.

Medical Consultant to Burdock Group

ⁱNIAID – National Institute of Allergy and Infectious Diseases at <http://www.niaid.nih.gov/factsheets/cold.htm>

ⁱⁱⁱCHPA Statement on ACCP's Cough Guidelines: http://www.chpa-info.org/Web/press_room/news_releases/2006/01_11_06_CoughCold.htm

WWW.WOMENSCI.ORG

(Continued from page 1, Dietary Supplement article)

On the other hand, some dietary supplement manufacturers have equated a lesser standard of safety with virtually no safety stand at all (lack of standardization, quality issues, disinterest in current Good Manufacturing Practices, toxic contaminants, etc.). And the general public, the linchpin to DSHEA...has, fallen into the philosophical trap, "that if one is good, two must be better." The unhappy result is the fact that the Agency, Congress and tort lawyers have become involved in the micromanagement of dietary supplement access (e.g., demise of kava kava and ephedra).

Although counter-intuitive and surely counter-DSHEA, one attractive and successful opportunity does exist for the reputable dietary supplement manufacturer (or their ingredient supplier) to avoid this seeming morass of Agency rejections, medical community 'tarnish,' civic watchdog scrutiny, FTC enforcement, public hysteria, Congressional meddling and legal class-actions. Simply, opt out of the lesser safety standard.

The FDA has shown it has only one definition of safety, so the distinction between 'reasonable expectation' and 'reasonable certainty' is without a difference, i.e., the Agency expects the manufacturer to be certain. The GRAS process is available for dietary supplement ingredients and although this process may require additional time and cost (to develop the required safety data to meet 'reasonable certainty'), it may in the long run be just the right ticket to...avoid Agency gate-keeper decisions, demonstrate high-road corporate ethics to consumers, pacify public interest groups, respond to media critics and deter tort lawyers, and be poised for the leap into functional food ingredients.

Part Two to be continued next issue...





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Burdock Group offers focused expertise to three principal industries:

- * **Food and Beverage**
- * **Dietary Supplements**
- * **Cosmetic and Personal Care Products**

We have the *breadth* to cover entire product lines and the *depth* to manage the most complex assessments. Our consultants have expertise in a range of scientific and regulatory areas, which gives Burdock Group uncommon diversity and your product a competitive edge.

Burdock Group offers a unique mix of capabilities to bring your product to market: access to proprietary databases of the most up-to-date research, vast experience in regulatory compliance, and critical project management skills.

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Select Pending and Recent Publications

G. A. Burdock, I. G. Carabin and J. C. Griffiths (2006). **The Importance of GRAS to the Functional Food and Nutraceutical Industries** in press *Toxicology*.

P.L. Casterton (2005). **Benefits from the scientific side of cosmetics. Update—Food and Drug Law, Regulation, and Education.**

Soni, M.G., Carabin, I.G. and Burdock, G.A. (2005). **Safety Assessment of Esters of p-Hydroxybenzoic Acid (Parabens).** *Food and Chemical Toxicology* 43:985-1015.

J.C. Griffiths and J.F. Borzelleca (2005). **Food Additives.** *The Encyclopedia of Toxicology.* 351-357.

J.C. Griffiths (2005). **The value of playing it safe.** *Functional Foods and Nutraceuticals.*

L. Stösser, W. Tietze, R. Heinrich-Weltzien, C. Kruger, J.C. Griffiths and M.H. Auerbach (2005). **Polydextrose –ein "zahnfreundlicher" Kohlenhydrat-Füllstoff (Polydextrose – A "Tooth Friendly" Carbohydrate).** *Oralprophylaxe und Kinderzahnheilkunde.* 27:144-149.

R.M. Matulka (2005). **Food Ingredient Consumption and Target Population Surveys.** *Natural Products Industry Insider.*

J.C. Griffiths (2005). **Coloring Foods and Beverages.** *Food Technology.*

UPCOMING MEETINGS & SYMPOSIA

March

Society of Toxicology (SOT) Conference
Booth 841
San Diego, CA

Natural Products Expo West
Booth 717
Anaheim, CA

April

Food Drug Law Institute (FDLI)
Washington, DC

May

Consumer Healthcare Products Association (CHPA)
Washington, DC

June

Council for Responsible Nutrition (CRN)
Washington, DC

Institute of Food Technologies (IFT)
Booth 1664
Orlando, FL

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