alliance for natural health

"Good Science, Good Law"

ANH INNOVATORS CLUB BULLETIN

April/May 2006

News

European Union

The Precautionary Principle – the invisible enemy

Bert Schwitters, CEO of Netherlands-based International Nutrition Company (INC) and member of ANH's Strategic Advisory Committee, published an article on the ANH website entitled 'The 'Framing' of Food Supplements in the EU". The article drew the attention of a major Oxford University society, the Oxford University European Affairs Society, culminating in an invitation to the ANH to meet with the Society and Bert Schwitters being invited to speak (see below).

ANH has for some time been aware of the massive problems that can be caused by the (mis-)use of this principle in the healthcare area, particularly when applied to foods or food supplements. We raised this issue in our consultation response to the FAO/WHO's nutrient risk assessment project , and then it has been taken up vigorously by the HAN Foundation in the study funded by the INC.

The first peer review publication to emerge from this study has just been published in *Environmental Liability* – the paper can be downloaded at the following link: http://www.alliance-natural-health.org/_docs/ANHwebsiteDoc_240.pdf. Other peer reviewed papers will appear in the near future.

EU Supplement Debate moves to Oxford University

Oxford University's second largest society (5000 members strong), the Oxford University European Affairs Society, hosted a debate on 11th May on the controversial EU Food Supplements Directive. Presenting at the Society's evening meeting was author and former journalist Bert Schwitters, also CEO of the Netherlands-based International Nutrition Company. Lively and stimulating debate followed Mr Schwitters' inspiring speech, which detailed how the precautionary principle has been misapplied to health policy and food supplement law in Europe. Schwitters went on to explain how the precautionary principle, combined with the EU principle of high level of public health protection could wreak havoc with a third key EU principle of law, the principle of free movement of goods.

Schwitters said, "The precautionary principle serves not only as a tool for trade restriction. It also helps European regulators who are faced with the problem of approximating the many different laws of the Member States. When applied in an existing theoretically "common" market as an overriding regulatory tool in the process of ironing out the differences between laws and regulations of Member States, the precautionary principle makes the ironing redundant by first exhausting, without recourse, the fundamental right to market participation. As long as the "information" is embedded in and surrounded by "scientific uncertainty," the precautionary principle can hit and remain in force anywhere in the form of "provisional risk management measures."

Click here for a full copy of the speech.

Note to US companies: The FDA already operates on the basis of the precautionary principle, despite not going as far as accepting it fully in law (see *Nature Biotechnology* paper, 2001). This is the major driver behind the pre-occupation of Senator Durbin and the Institute of Medicine to introduce mandatory Adverse Advent Reporting.

Alliance for Natural Health
The Atrium, Curtis Road, Dorking, Surrey RH4 1XA, United Kingdom
e-mail: info@anhcampaign.org tel: +44 (0)1252 371275
www.anhcampaign.org

Reg. Office: Unit 5, Forge End, St Albans, Hertfordshire AL2 3EQ, United Kingdom. A Company Limited by Guarantee Reg No. 4438769

Nutrition and Health Claims Regulation avoids conciliation

Probably of equal significance to the Food Supplements Directive in the EU, the Nutrition and Health Claims Regulation has been voted through the European Parliament via a compromise package. This deal at least has avoided the fate of the Regulation being decided by the European Commission and Council of Ministers in Conciliation, behind closed doors.

For a detailed briefing on the Regulation, please refer to ANH's public affairs briefing on the Regulation published on the ANH website on 16 May 2006.

Critically important now is for the natural products industry, particularly the innovative sector, to determine the range of generic claims that may be of interest to the industry over the coming years.

> CALL TO COMPANIES: We ask that companies submit by end of June a list of all generic claims for specific nutrients (not just vitamins and minerals, but also essential fatty acids, amino acids, phytonutrients, herbals, probiotics, prebiotics, etc.) about which they are interested. These will be used in ANH submission's to the EU to widen as far as possible SME (small to medium sized enterprise) generic claims. **Please email mel@anhcampaign.org with your proposed generic claims by end of June at the latest.**

Proposed Addition of Nutrients to Foods Regulation

This regulation is extremely important to the functional foods industry, as it will control, throughout the EU, both the types of nutrients that may be added to foods as well as their maximum levels (based at the present time on what ANH regards as flawed risk assessment science).

The Regulation was passed by the European Parliament at first reading plenary on 16 May, again following adoption of a compromise package. It endorses a positive list of vitamins and minerals based on the Food Supplements Directive. The Regulation is likely to enter into force in around 2 years, after maximum levels are agreed.

For more information on the Regulation, please refer to ANH public affairs briefing document.

USA

Natural Health Research Institute Sponsors American Oil Chemists Society Hot Topics Symposium on Vitamin E

The result of consumers having been given mixed messages about vitamin E since the widely publicised release of the meta-analysis on the vitamin at the end of 2004, that linked it with an increased risk of all-cause mortality (Annals of Internal Medicine 2005 Jan 4;142(1):37-46), is being seen in the reduced demand for natural forms of vitamin E. Cognis Nutrition and Health, one of the leading suppliers of vitamin E in the US recently reported a decrease in demand for its natural vitamin E products of 40 per cent, which led to a drop in revenues of 18 per cent in 2005. In an attempt to find a way forward a group of scientists met to discuss the body of evidence that shows vitamin E can contribute to improving health and reducing leading causes of disease at the American Oil Chemists Society's 97th Annual Meeting and Expo (April 30-May 3) at the America 's Centre in St. Louis, Missouri, USA. The Symposium was sponsored by the Natural Health Research Institute (NHRI) and was presented as a "Hot Topics" session. The symposium, presenting the benefits of vitamin E, followed an ABC Evening News broadcast that quoted two studies reporting health risks from use of the vitamin. Professor Ronald Watson, Ph.D., from the University of Arizona, moderator of the symposium, said that the ABC report ignored "the many positive studies showing benefits in lowering heart disease, leaving consumers confused." He then went on to say that consumer confusion was due to "poor journalism, which may have the result of discouraging consumers from taking advantage of this beneficial nutrient."

Consumer Reports introduces new database

Consumer Reports has introduced a new database of information on nearly 14,000 supplements, herbs, and other natural medicines, available for a $19 annual fee. Unfortunately, Consumer Reports is well known for its dislike of dietary supplements. While vocal against the pharmaceutical industry, Consumer Reports has repeatedly called for amending the Dietary Supplement Health and Education Act.

Here is one quote from their press release: “Many users erroneously regard these products as safe because they are “natural” and do not consider them to be drugs, Metcalf noted. In fact, the efficacy of many products is untested, their purity unknown and their safety uncertain because they are largely exempt from the scrutiny of the Food and Drug Administration.”

The database, officially known as the Natural Medicines Comprehensive Database, is the product of the Therapeutic Research Centre in Stockton, Calif., which analyzes prescription and over-the-counter drugs.

Alternative medicine specialist Adriane Fugh-Berman, an associate professor of complementary medicine at Georgetown University School of Medicine, said that while the CU directory is "much more accurate than many other resources," it fails to distinguish between theoretical risks various supplements may pose at a cellular level and actual harm seen in human studies.

"Extreme caution can work against public health outcomes," said Fugh-Berman, who has written about the benefits of some herbal medicines. If consumers are told "everything interacts with everything, people will just stop listening."

TWO OTHER DATABASES
The National Institutes of Health sponsors two databases – through its Office of Dietary Supplements (http://dietary-supplements.info.nih.gov) and its National Centre for Complementary and Alternative Medicine (www.nccam.nih.gov).

Both provide safety and effectiveness information about supplements that is free of commercial influence. But neither site contains as much detailed or easily accessible information as the CU database (www.consumerreportsmedicalguide.org), which allows consumers to check which natural medicines might be effective for specific health problems.

Industry Black Eyes

Utah dietary-supplement maker Basic Research has agreed to pay $3 million in fines to settle complaints by the Federal Trade Commission that it made deceptive claims to sell fat-dissolving gel and weight-loss pills for children. The agreement prohibits the firm from making unsubstantiated claims in the future. "The Federal Trade Commission views it as a very favourable settlement with very strong injunctive relief and monetary relief," Laureen Kapin of the FTC's enforcement division told The Salt Lake Tribune. Basic Research said it did not admit wrongdoing, and agreed to pay the fines to bring the litigation to an end.

In June 2004, the FTC alleged that Basic Research and other affiliated companies made misleading claims about Tummy Flattening Gel, Cutting Gel and Dermalin APg. The company claimed it could be rubbed on to melt away fat. Two pill supplements, Leptoprin and Anorex, were marketed by the company for dieters who wanted to shed more than 20 pounds. And PediaLean, a fibre pill, was billed as causing substantial weight loss for children. The FTC questioned the scientific backing for the claims. Between 2000 and 2004, Basic Research sold nearly $66 million worth of the six products, with Leptoprin bringing in nearly $25 million in 2003 alone. Burbidge said the company has stopped marketing all of the products.

Black Cohosh under the cosh

Millions of women buy the herb black cohosh and use this dietary supplement to treat hot flashes and other menopausal symptoms. Clinical trials are still relatively few in number. Some report that black cohosh helps relieve menopausal symptoms such as hot flashes, while others do not. A new study, scheduled for May 17 publication in the Journal of Agricultural & Food Chemistry, reports for the first time that a significant number of black cohosh supplements sold in the United States did not contain black cohosh. Instead, these products contained a related Asian species of the plant that does not have the same chemical compounds or clinical uses as the native North American plant.

Using a new and simplified technique, the researchers analyzed 11 products marketed as black cohosh. Three contained the Asian adulterant, and one contained both genuine black cohosh and the Asian imitator. Products containing only black cohosh varied significantly in the amounts of the compounds believed to relieve menopausal symptoms.

FDA rejects green tea claim

There is no credible scientific evidence that drinking green tea reduces the risk of heart disease, federal regulators said in rejecting a petition that sought to allow tea labels to make that claim. The Food and Drug Administration said it reviewed 105 articles and other publications submitted as part of the petition but could find no evidence to support claims of the beverage's health benefits.

"FDA concludes 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," or cardiovascular disease, Barbara O. Schneeman, director of the agency's Office of Nutritional Products, Labelling and Dietary Supplements, wrote in a letter denying the petition.

FDA asks Court to restore Ephedra ban

A federal judge who lifted the ban on dietary supplements containing low doses of the weight-loss aid ephedra misunderstood the law, the Food and Drug Administration argued Monday in trying to restore the ban. An attorney for a Utah company that successfully challenged the ban told a three-judge panel of the 10th U.S. Circuit Court of Appeals that if the judge's decision is overturned, the FDA could ban virtually any substance on the market it determines is harmful in large doses, such as vitamin C tablets or peanut butter. Nutraceutical Corp. challenged the ban, and U.S. District Judge Tena Campbell in Salt Lake City ruled last year the ban could not be enforced against supplements containing doses of ephedra up to 10 milligrams.

The FDA based its ban in part on work by a doctor who studied the intake of various substances similar to ephedra rather than on use of ephedra itself. Kohl said because the substance is defined under the law as a dietary supplement rather than a drug, there was little or no scientific data available on its effectiveness or safety because manufacturers aren't required to conduct such studies.

NNFA Changing Name? Probably

National Nutritional Foods Association (NNFA) has announced board approval of a new mission, a first time vision statement, and the recommendation of a name change for the association to the Natural Products Association.

Regulatory Developments

European Union

Nutrition and Health Claims Regulations – 2nd Reading

See News section above.

Proposed Addition of Nutrients to Foods Regulation

See News section above.

USA

Current Good Manufacturing Practices (cGMPs) publication date set for December 2006

FDA has finally announced that publication of current good manufacturing practice for dietary supplements has been set for the end of 2006, but past disappointments have led an industry organization to consider self regulation as an alternative. The Department of Health and Human Services (HHS) and the FDA announced last October that the rule had been forwarded to the Office of Management and Budget for review which generally means the rule would be published within 90 days (OMB is the last step in the rule-making process). This projection was included in that department's semi-annual regulatory agenda of "potential rule-making" published in the *Federal Register* on April 24.

FDA published proposed cGMP in March 2003 and a final rule has languished at the Office of Management and Budget since October 2005.

The cGMPs form part of the Dietary Supplements Health and Education Act (DSHEA), which was signed into law more than decade ago in 1994. The news that they are imminent will be welcomed by many in the

industry who believe that DHSEA is a good law that will effectively ensure the safety and quality of dietary supplements when properly enforced.

The hold-up over the guidelines has laid DSHEA open to criticism from those, particularly in the medical community, who would have dietary supplements subjected to the same rigorous approvals process as pharmaceutical drugs.

The new projection was included in the April 24 semi-annual agenda of "potential rule-making" published in the *Federal Register*, which also included four other initiatives with direct implications for the dietary supplements industry, including a review of the existing rules for use of the terms "high potency" or "antioxidant" on labels of conventional food and supplements, finalizing guidance for rules on qualified health claims for food and supplements, prohibiting the use of specific cattle materials in food and supplements to limit the risk of mad-cow disease (BSE), and prohibiting the sale of food, including supplements, that contain elk or deer-derived products exposed to chronic wasting disease.

For further information about the ANH, the ANH Innovators Club or ANH Consultancy Ltd, please contact:

Meleni Aldridge
Development Manager
Alliance for Natural Health
Tel: +44 (0)1306 646 550
Email: mel@anhcampaign.org