alliance for natural health

"Good Science, Good Law"

ANH INNOVATORS CLUB BULLETIN

March/April 2006

News

European Union

ANH rebuttal to Omega 3 meta-analysis

Hooper *et al*'s meta-analysis published in the *British Medical Journal* on 27 March provided fuel for the media to unleash a rash of negative headlines which have already impacted the bottom line on some EFA product lines. UK nutritionist, author and ANH Expert Committee member, Patrick Holford, published a short rebuttal the day after the release which went some way to limit damage caused by the negative press.

ANH's Medical Director, Dr Damien Downing, has since published a short Rapid Response entitled "Find the Pony" in the *BMJ*, the full text of which is published below:

> The BMJ must have known that this paper would lead to headlines such as "Debunked!" (Independent) and "The benefits of fish and linseed oils as elixir of life are another health myth" (Times) – statements that are unjustified, but useful to the pharmaceutical industry – even though the paper does not claim to show this (the abstract says " ...omega 3 fats do not have a clear effect..."), and the accompanying editorial hardly condemns omega 3 supplementation.
>
> Richard Smith has written on this (1), as has Richard Horton (2). Mind you, the BMJ did publish the manual on how to do it (3) – and yes, I do know it was humorous, but I think most of this paper comes under "FPSU (Find the Pony Statistical Unit); Execute sub-n-group analysis where n=keep going until you find a statistically significant effect in your favour."
>
> Meta-analysis (which the media always describes as "new research" – does nobody in biomedical publication worry about that?) is being debased as a tool to discredit non-pharmaceutical treatments. In the last 3 years there has been a series of such studies, each declared as new research, and each arguably a variation on Find the Pony. The problem of course is that to adequately peer-review a meta-analysis it is necessary to peer-review all the papers it uses, AND those it excludes, in order to judge the selection criteria. The selection process in Hooper et al has already been extensively criticised here by others.
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> Any analysis of the effects of increasing omega 3 intake alone contributes to the medicalisation of nutrition; while the drug model of intervention requires a single intervention to yield an effect, nutrition is an integrative approach involving all aspects of diet and lifestyle. Nobody who understands this would expect taking omega 3s to over-ride the effects of smoking, eating high- calorie junk food and trans-fats, being overweight and taking insufficient exercise etc.
>
> On the basis of cui bono? it is noteworthy that the only stated competing interest in the Hooper paper is the receipt of fees from Solvay Heathcare, who market Omacor – the first ever prescription-only fish oil. In September 2005, Solvay and Pronova Biocare signed a licensing agreement for exclusive distribution rights on Omacor. Whether intentionally or not, this paper will help to persuade patients to shun OTC fish-oil supplements, ignore nutritional and lifestyle recommendations, and elect for the prescription-only version.
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> 1. Smith R, Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies. PLOS Medicine 2 (5): e138 2. Horton R (2004) The dawn of McScience. New York Rev Books 51(4): 7-9 3. Sackett DL, Oxman AD (2003) HARLOT plc: An amalgamation of the world's two oldest professions. BMJ 327: 1442-1445

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The link to this rebuttal can be found at: http://bmj.bmjjournals.com/cgi/eletters/332/7544/752.

Following from this, Dr Robert Verkerk, ANH Executive & Scientific Director, has written a detailed rebuttal entitled "Meta-analysis: a new tool to discredit natural health products?", which is released internationally simultaneously with this Bulletin. The aim is to see very wide publication of the rebuttal on websites, via email lists and, where the press are not conflicted, in the media.

This rebuttal can be found as an attachment to this email and at the following link: http://www.alliance-natural-health.org/index.cfm?action=news&ID=233

We encourage companies to publicise, but not modify, this article as far as possible.

ANH submits extensive report to WHO on natural products for bird flu

Having been approached by the WHO in March with a view to providing information on potential natural product use, the ANH completed a report entitled "*The pivotal role of natural products in countering an avian influenza pandemic*" by its Avian Influenza Expert Committee on 27 March, forwarding it the same day to the WHO. The WHO has requested that the ANH hold back for a limited period on the general release of the report, although it is interested in finding out how widely the protocols contained within are endorsed by the medical community. ANH is thus seeking as broad a possible endorsement from qualified medical doctors as possible and is approaching the major nutritional and functional medical societies and associations in this regard.

ANH is prepared to release the report to medical doctors for the purpose of seeking endorsement, and any assistance from companies in helping us reach doctors would be greatly appreciated as a matter of urgency.

ANH is preparing to release its report publicly via a press conference in late April.

British Nutrition Foundation welcomes folic acid proposals

The British Nutrition Foundation gave its backing on 5 April to plans to make food manufacturers add folic acid to all white flour and bread sold in the UK. The Food Standards Agency were considering a proposal on 6 April to make fortification compulsory, in order to cut the incidence of spina bifida and other neural defects. Anna Denny, a BNF nutrition scientist, told DeHavilland Information Service that neural tube defects were 'an awful thing to happen' to parents. They were present in up to 900 pregnancies a year, of which 750 had to be terminated. Fatality rates were 'quite high' among children born with defects and even those that survived found it had a 'huge impact' on their lives, she added. Neural tube defects led to some of the 'most profound' disabilities.

Ms Denny said: 'If we can do anything to prevent it, for example fortification, we should do that really.' She said fortification would be useful to the majority of women whose pregnancies were not planned -- particularly 'at risk' groups including young mothers and women from low income backgrounds. However, she acknowledged that fortifying products with folic acid could end up masking vitamin B12 deficiencies in the elderly. Around five to 10% of the over-65 population would be affected, and it was for that reason that previous attempts to introduce fortification had been defeated, she said.

However, evidence subsequently obtained from the US and Canada -- where fortification has been compulsory for some years -- showed it made a significant impact in cutting neural defects. Ms Denny said the elderly would be at risk but the problems could be picked up through better screening at GP clinics. Asked whether the public would object to being forced to consume folic acid, she pointed out that manufacturers were already required by law to fortify white bread with calcium and iron. She added: 'It's really important that there are products [without folic acid] out there that consumers can choose, but fortification is a good way to target those most at risk.'

Important note: Folic acid fortification of white bread will encourage people into thinking white bread is a healthy food when it is one of the least healthy foods around. Obesity affects 22% of the adult population and high GI white bread should be restricted in diets, not encouraged. White bread is a bad delivery system for nutrients as it doesn't allow accurate control of dosage because people eat such varying amounts.

What do you do if you are already taking a multivitamin containing 400 mcg of folic acid? Do you stop taking it and then risk not getting enough vitamin A, C, D or E, or zinc, selenium or iron?

Also the form used for fortification with folic acid will be the pharmaceutical (synthetic) monoglutamate form, not the 5-methyl-tetrahydrofolate form that exists in green vegetables like spinach. We should be encouraging healthy eating of whole foods (eg whole grain breads, green vegetables) that are rich in B vitamins including folates and vitamin B12, together with providing information about optional supplementation. Mass medication of highly processed foods is not compatible with healthy living.

USA

As usual, mainstream media showed its bias with uninformed articles or commentary:

Wall Street article against vitamins gains widespread attention

In particular The Wall Street Journal's recent article "The Case Against Vitamins" originally ran on March 20, 2006 is being widely reprinted. The "several studies" cited in this report have been seriously criticized by experts without their rebuttals resulting in any real effort to set the record straight. This WSJ article singled out beta-carotene as promoting cancer, mentioning a study on Finnish smokers. Yet that study's data was recently reanalyzed, with researchers looking instead at total antioxidant intake. They discovered that low antioxidant intake was the real culprit in that original cancer study, not beta-carotene supplementation.

Red Yeast Rice is the only supplement that works.....

From the National Public Radio on March 13, 2006. "New research casts doubts on the effectiveness of popular dietary supplements used to treat arthritis pain and prostate enlargement. Madeleine Brand discusses the findings with Slate contributor and Yale Medical School professor Dr Sydney Spiesel."

According to Dr Spiesel the only supplement he can think of that works is Red Yeast Rice, and that only worked because it contains a prescription drug. He then went on to remark that "manufacturers don't want their products tested because they are afraid that the ones that work do so because they also contain prescription drugs."

Erroneous, ignorant, misinformed, and prejudiced "news" items continue to make a dent in public opinion of dietary supplements. Industry, scientists, and associations need to work together to change the tide.

US Dept of Agriculture begins massive study on the efficacy of calcium

Armed with an $840,000 grant from the U.S. Department of Agriculture and the latest in world-class body scanning technology, a Florida State University researcher in the College of Human Sciences soon will begin the largest, longest study to-date on the efficacy of calcium – through dairy products, supplements or both – for weight reduction and bone preservation in overweight or obese postmenopausal women.

Red Bull® Becomes First Company to Receive Certification under the NSF Athletic Banned Substances Program

NSF International have announced that Red Bull® Energy Drink is the first company to successfully complete all requirements of the NSF Athletic Banned Substances Certification Program - NSF Certified for Sport™ -- establishing a new benchmark in quality for dietary supplements and nutritional products. The Athletic Banned Substances Certification Program has ostensibly been instituted to meet the growing demands of athletes, coaches and all those concerned about banned substances in sports supplements. Recommended by the Major League Baseball (MLB) and the MLB Player's Association, the new program is designed to minimize the risk that a dietary supplement or sports nutrition product contains banned substances.

To obtain certification, products must be evaluated by NSF to show that what is on the label matches the content of the product, and that there are no banned substances present. Requirements of the program include: Formulation and label review, Toxicology review, Facility Good Manufacturing Practices (GMP) inspection, and Laboratory analysis for label contents and banned substances.

Regulatory Developments

European Union

The UK Food Standards Agency advises dossiers submitted after 12/7/05 invalid

After advising authorities last year that the 12th July 2005 deadline had been extended for the submission of derogation dossiers, the European Commission has just advised that there is now no discretion for late submission. Hence, substances for which dossiers were accepted after this date are now on the market illegally. Please see excerpted letter from Dr Clair Baynton of the UK FSA below:

"DOSSIERS SUBMITTED TO THE FOOD STANDARDS AGENCY AFTER 12 JULY 2005

Further to my telephone call on 6 April I am writing to confirm the situation with respect to the dossiers submitted after 12 July.

The deadline for submitted dossiers in the Food Supplements Directive was 12 July 2005 and over 400 dossiers were submitted. These dossiers have been forwarded to the European Food Safety Authority (EFSA) by the European Commission and EFSA will assess the information in the dossiers.

The Agency wrote to trade associations for the supplements industry on 26 July 2005 informing them that the deadline for submitting dossiers under the Food Supplements Directive had been extended. This information was forwarded to the trade associations following advice from the European Commission that there was some flexibility with the 12 July deadline. Your company submitted X dossiers to the Food Standards Agency after receiving this letter and I wrote to you informing you that the dossiers had been forwarded to the European Commission and that the substances in question could remain on the UK market.

The Food Standards Agency has subsequently been informed by the European Commission that there is no discretion under the Directive for dossiers to be accepted after the 12 July deadline. The consequence of this is that the substances for which dossiers were accepted after 12 July shouldn't be available on the UK market as their sale is prohibited by the Food Supplements Directive and the implementing regulations in the UK. The dossiers submitted before 12 July comply with the requirements of the Directive, and the substances to which they relate can remain on the market pending an opinion from EFSA and agreement by member states when a decision is taken at an EC Standing Committee.

Any substances for which dossiers were accepted after 12 July that are being used in products are therefore on the market illegally. I would be grateful if you could clarify whether any of those substances are in fact currently being used in products.

Following this advice from the European Commission, we have been exploring with the Commission who this situation can be resolved, and how the substances can lawfully be on the UK market.

The Commission has said that if you are able to provide additional safety data in addition to the information you have provided to date they will liaise with EFSA and ask them to consider the dossiers accepted after 12 July as a matter of priority. This may speed up the process for adding substances to the positive lists in the Directive but this process could take several months to complete."

Important note: This is typical of the mixed and conflicting agenda that has typified European regulatory authorities approach to food supplements, both before and after the passage of the Food Supplements Directive. **The ANH would be keen to hear from any companies that have been reliant on dossiers approved after 12 July 2005.** This data could be very useful in building the final phase of our case against the Food Supplements Directive, to be brought in due course in the High Court, London. We are awaiting notice from the Administrative Court of a date for this phase of the legal action.

USA

Trend to exclude dietary supplements from food category?

Is there a trend to build a history of legislation that excludes dietary supplements from the food category? In addition to bills to amend Dietary Supplement Health and Education Act of 1994 (DSHEA), we have to remain

vigilant in reviewing all related bills. For instance, there are two food bills that could affect dietary supplements – by EXCLUDING them. American Association for Health Freedom was the first organization to recognize that the Safe Food Act (first introduced by Sen. Durbin in the 108th Congress) could be a back door to DSHEA. Bill text reads:

"EXCLUSION- The term `food' does not include dietary supplements, as defined in section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff))." Now the amended National Uniformity for Food Act (H.R. 4167) goes down the same road. An amendment to the HR 4167 excludes dietary supplement from its scope.

The Bill, passed by the US House of Representatives by a vote of 238 to 139 on March 8, 2006, would generally prohibit individual states from requiring food products in interstate trade to conform to state regulations or labelling rules that are not identical to federal provisions. It would also allow states to petition for an exemption or for the establishment of a national standard regarding any requirement under federal laws relating to food regulation. The original draft of the Bill would have extended to all foods, including dietary supplements, but an amendment offered by Congressman Joe Barton (R-TX) revised the exclusion section of the original version so that the proposed law would have no effect on dietary supplements.

There has not been a Congressional hearing to explore this bill's potential impact. As of April 15, 2006 there has not been a Senate companion bill. The text of the Bill and other information can be found at http://thomas.loc.gov/cgi-bin/bdquery/z?d109:h.r.04167:

Congressional Hearing on the Regulation of Dietary Supplements

House Government Reform Committee held a Congressional Hearing on March 9, 2006 entitled: "The Regulation of Dietary Supplements: A Review of Consumer Safeguards."

While there were no industry advocates testifying, it wasn't a slam dunk against dietary supplements. In response to questioning from Rep. Chris Cannon, R-Utah, Robert Brackett, director of the FDA's Center for Food Safety and Applied Nutrition, testified that current law gives regulators sufficient authority to enforce laws on dangerous supplements and said that the supplement industry "is regulated." But the Consumers Union of the U.S. Inc., which publishes Consumer Reports magazine, said the law has "serious regulatory loopholes that have opened the floodgates to thousands of untested dietary supplement products."

According to testimony from Janell Mayo Duncan, the CU's senior counsel, the group would like to see Congress create an expert panel to review supplement safety, create "pre-market" test requirements and require risks to be written on labels.

For more information, please visit:
http://reform.house.gov/GovReform/News/DocumentSingle.aspx?DocumentID=40458

New Commissioner for FDA also Director of National Cancer Institute

On March 15, 2006 President George W. Bush announced his intention to nominate Andrew C. von Eschenbach, MD, to be Commissioner of the Food and Drug Administration (FDA). Dr. von Eschenbach has served as that agency's acting commissioner since September 2005, concurrently with his position as director of the National Cancer Institute.

Some lawmakers and consumer groups have criticized von Eschenbach for continuing his duty at the NCI while acting as temporary FDA commissioner, stating that both agencies needed full-time leaders. On April 11, 2006, von Eschenbach finally announced that he will resign from his position as director of NCI.

The Senate must vote to confirm von Eschenbach before he can take the position permanently. Sens. Hillary Rodham Clinton (D- N.Y.) and Patty Murray (D-Wash.) have said they will block the confirmation vote until FDA makes a decision on whether to allow over-the-counter sales of the emergency contraceptive Plan B.

Liquid dietary supplements at risk in the US

A recent letter from the FDA in response to a new dietary ingredient notification is worth following. The FDA takes the position that the product in question may not qualify for sale as a dietary supplement as it is "a liquid form with a serving size comparable to an ordinary beverage."

Formal adoption of such a position by FDA may jeopardize the ability of many dietary supplements in water base to remain on the market

The company, Shannon Mineral, Inc., intends to market SuperCitriMaxt as a new dietary ingredient in liquid form with a serving size comparable to that of an "ordinary beverage." The FDA feels that this is an issue that requires further examination and stated that "it is not clear that such a product meets the requirements for a dietary supplement in 21 U.S .C. 321(ff)(2) and 350(c)."

To review the premarket notification materials and FDA responses, please visit: http://www.fda.gov/ohrms/dockets/dockets/95s0316/95s-0316-rpt0313-toc.htm

Dietary supplements omitted from FDA's 2005 list of accomplishments

FDA recently released their 2005 accomplishments. One glaring omission: the phrase "dietary supplement" does not appear anywhere in their release or in the accompanying documents.

They highlighted their "continued strengthening the performance of its core functions: ensuring the safety and effectiveness of drugs, biologics, and medical products; protecting the safety and security of 80 percent of the food supply; making certain that cosmetics and equipment that emits radiation do no harm; and ensuring the safety of animal drugs and feed."

Visit http://www.fda.gov/bbs/topics/news/2006/NEW01342.html for more information.

NSF International launches Athletic Banned Substances Certification Program

Dietary supplement manufacturers will be forced to get their products approved by NSF International if they want to sell to major league baseball players. In an effort to improve their image and prevent positive drug tests, management and players' association agreed to the certification process. NSF has been certifying supplements for the National Football League and its players association for two years and recently formed a relationship with Canada's anti-doping agency. Additionally, the U.S. Olympic Committee has contacted NSF, and others might not be far behind.

Twelve major league players tested positive for banned substances last year and Tampa Bay outfielder Alex Sanchez blamed an over-the-counter supplement that included a previously approved substance. Some players speculated substances they bought legally outside the United States might have caused the positive tests. With this new program, that explanation won't cut it.

Once a supplement is certified, teams will buy the products and make them available for resale to players in the 30 major league clubhouses. Companies that want athletes to use their products pay NSF to participate in the program, which allows them to test their products and audit their manufacturing process,"

If a player wants to take a supplement, eat a nutritional bar or drink something to aid performance, he will have to look for the NSF Certified for Sport mark on the package or find the product listed on NSF's Web site. If a player's favourite brand is not part of the program, that company might be compelled to go through NSF's certification process to keep its high-profile customers – and everyday consumers.

Other Developments

UK Trade Shows

- The ANH had a booth at the Natural Products Europe Trade Show in Olympia, London on 9-10th April and Drs Robert Verkerk and Damien Downing gave a lecture entitled ***Winter colds, influenza or bird flu: The use of natural products in immune system modulation.*** Both the show and the ANH booth were well attended and Rob and Damien's lecture drew, according to the show's organisers, the largest auditorium crowd of the day. Please find a copy of their power point presentation on the ANH website.

US Trade Shows

- At the recent Expo West, several organizations representing trade association and consumer groups met to discuss how (and if) they can work together on issues. Some of the groups represented included NNFA, AHPA, AAHF, Citizens for Health, The Campaign. More information about this effort will follow.

- Dr Robert Verkerk and Meleni Aldridge will be attending the 13th International Symposium on Functional Medicine in Tampa, Florida, 19-23 April - ***Managing Biotransformation: The Metabolic, Genomic and Detoxification Balance Points***. We look forward to meeting with any of you who intend to be present.

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

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