alliance for natural health
good science and good law

ANH INNOVATORS CLUB BULLETIN

April/May 2007

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Key EU/US Regulatory Developments:

ANH cautiously optimistic about future of naturally occurring sources of vitamins and minerals within EU Food Supplements Directive

Following the recent submission to the European Commission of 15 dossier applications to the EU Food Supplements Directive (FSD) Positive List, the ANH has been engaged in a positive exchange of correspondence with Basil Mathioudakis (Head of Unit, Food Law, Nutrition and Labelling, Health and Consumer Protection Directorate, European Commission). We are cautiously optimistic that the natural sources argument that the ANH argued in its case in the European Court of Justice (ECJ), which the ECJ, in a seemingly ambiguous way supported in its ruling of 12 July 2005, may well be upheld by the Commission.

The current sticking point for the Commission relates to the 'degree of refinement' of the naturally occurring source of vitamin and mineral. It appears that the Commission is under the misapprehension that edible oils such as wheatgerm, as a source of mixed tocopherols and tocotrienols (Vitamin E)), or even fish oils, as a source of vitamins A and D, are 'unrefined' and therefore could be considered to be outside the scope of the Directive. The ANH has raised the fact that all edible oils are refined to a degree and has suggested that it would not be feasible to determine that a particular level of refinement could be found to be a legally enforceable borderline between a source that is within or outside the scope of the Directive. Depending on the conclusion of these discussions, it is possible that a significant range of naturally occurring source of vitamins and minerals are found to be outside the Directive's scope.

Interestingly, the views of Mr Mathioudakis have already contradicted with those of the Head of Legal Affairs of the Commission, Mr Dimitris Vryonides, as provided to the ANH in a letter in March 2006 where it was indicated that there would be absolutely no exemptions from the Directive.

The European Commission has forwarded the majority of the other dossiers submitted by the ANH in late February/early March to the European Food Safety Authority (EFSA) and has informed the ANH that it has requested that the EFSA provide its opinions within 12 months, which is still within the derogation period which ends on 31 December 2009.

EU Nutrition and Health Claims Regulation

The build-up to full implementation of the Nutrition & Health Claims Regulation is being felt across the EU. The Regulation (1924/2006) was published in the Official Journal of the European Union on 20th December 2006 and will come into force across all 27 EU Member States on **1 July 2007**.

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The Regulation "shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer, including foods which are placed on the market unpacked or supplied in bulk."

There was much debate during the negotiation of this Regulation around the issue of brand names that were considered implied health claims, 'Slim Fast' being a much quoted example. However, the final version of the Regulation has improved the situation allowing implied claims, on the condition that the label is accompanied by an authorised nutrition or health claim which is compliant with the Regulation. This means that it is imperative that as many nutrition or health claims as possible are filed with the purpose of gaining authorisation as possible.

The ANH is working on developing a large number of generic health claims (which do not include references to disease risk reduction) to facilitate this process. These will be filed with the UK competent authority, the Food Standards Agency, by its deadline in September. The Member States are required to file all applications received to the Commission by 31 January 2008. **We urge that all companies ensure that health claims for ingredients within their products are filed with the competent authority in any one of the Member States.** The UK deadline is longer than some others, while the Swedish deadline has already been passed. The Commission is then obliged, by 31 January 2010, to publish a list of permitted claims, following their evaluation by EFSA, along with necessary conditions for their use.

One of the greatest challenges in this Regulation will undoubtedly be scientific substantiation of claims. The Regulation requires that evaluations will be based on "generally accepted scientific data" meaning that new data, particularly if they are not derived from randomised controlled trials (RCTs), might be rejected. This remains a particularly big problem, in our view, for emerging science and innovation. The ANH is working to influence this evaluation process, particularly with a view to elevating the weight given to observational and epidemiological studies, as well as supporting biochemical evidence. We are arguing that allowing the RCT to remain as the sole gold standard is scientifically irrational, particularly given that RCTs may themselves include a wide range of uncontrolled sources of error which lead to confounding of results.

The EFSA has just published draft guidance for technical requirements and data for Article 14, product-specific, disease risk reduction health claims (attached). These follow the weight of evidence approach we fully expected in which randomised controlled trials are considered the gold standard and cohort, case-controlled, cross-sectional and observational studies are likely to be given second billing. We are greatly concerned that the scientific requirements will effectively turn the Article 14 claims environment into one suitable only for the largest, trans-national companies. It is for this reason that we have characterised the Regulation as a "passport system for big business."

Please see *Call for Action* section at the end as we require any comments you have to be received by Monday 11th June 2007 so that we can meet the 17th June deadline set by EFSA for this public/stakeholder consultation.

S. 1082 Food and Drug Administration Revitalization Act

The full text can be downloaded at http://www.govtrack.us/congress/billtext.xpd?bill=s110-1082

ANH take on FDA Revitalization Act

More frenzy has recently emerged, particularly among US health freedom organisations, on the proposed FDA Revitalization Act (Bill S.1082). A division has occurred where some groups are arguing that the Act, proposed originally by arguably one of the most powerful people in healthcare in the US, Senator Edward Kennedy and which seems to

be unstoppable now, will pose a very serious threat to the on-going availability of dietary supplements.

The American Association for Health Freedom (AAHF), the US affiliate of the ANH, has spent a considerable amount of time on the Hill examining this Bill with a wide range of Senators and members of Congress, and have been evaluating its likely consequences and looking for places where it might be used as a covert vehicle to end-run the relatively liberal regime currently experienced under the Dietary Supplement Health & Education Act. The AAHF's position is detailed by their experienced lobbyist, Dr Bill Duncan, at the following link: http://www.healthfreedom.net/index.php?option=com_content&task=view&id=218&Itemid=253.

The essence of the AAHF's position is that the Revitalization Act does not directly present a threat to dietary supplements, as the Act focuses specifically on licensed drugs, and in particular on post-market surveillance of drug side effects. The Act specifically excludes dietary supplements, under Section 605. The AAHF position argues that there may even be some plusses, particularly because better scrutiny will be applied to drugs which we know are harmful to millions. Those of us who are passionate about the place of natural healthcare, who believe it is the exiled and rightful heir to mainstream healthcare, need to look carefully at the provisions the Act is likely to provide, as well as how these might be abused. We need to understand where it might be useful in preventing millions of people being unnecessarily exposed to drugs which offer few benefits and serious side effects. We need to anticipate the climate that will created by Michael Moore's soon-to-be released documentary Sicko (29th June for the US), which has already been raved about since its premiere in Cannes, even by some of Moore's previous critics. See www.michaelmoore.com for the latest information and to receive ongoing e-blasts.

It is clear that the FDA Revitalization Act will go at least some way to making it harder for drug companies to hide adverse effects of their products, such as those caused by Seroxat, Prozac, Paxil and most recently, Avandia. If responsibility for post-market drug surveillance is taken away from the FDA, and is shifted to the soon-to-be-formed Reagan-Udall Foundation, will it occur more independently? How will they scrutinise dietary supplements for which they can find evidence of harmful effects, as misconstrued as such studies might be. The principle of an independent foundation is fine, but only time will tell if surveillance is conducted with the transparency it so badly needs.

There is a potential downside however – a major potential downside. If the FDA decides to use its existing powers, or even additional powers that are mooted in various legislative proposals and frameworks, it will become even easier for dietary supplements to be re-classified as drugs. Under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetics Act, a food is "considered adulterated if, among other things, it is a dietary supplement or contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labelling, or if no conditions of use are suggested or recommended in the labelling, under ordinary conditions of use". The increasing evidence base, be it plausible or implausible (of course a good part of it falls into the latter category in our view), could well be used by a regulator to say that high-dose vitamins present an unreasonable risk and therefore are classified as adulterated foods, which can only find their way back on the market if they are registered as full-blown drugs, which have been subjected to extortionately expensive safety and efficacy trials. Will the Reagan-Udall Foundation be used as an authority to claim lack of safety of dietary supplements? Again, this is something we need to be wary about.

If we couple all of this to the Institute of Medicine's 2002 proposal, as set out in their Proposed Framework for Evaluating the Safety of Dietary Supplements, it's not hard to see how adverse reporting, flagging and priority setting can be used to bring in drug-style data requirements, which could virtually paralyse the natural products industry. And is this not what was anticipated at least in part by the FDA's recently published Draft Guidance on CAM?

So, let's not fail to see the woods for the trees, because the natural products industry, practitioners and health-conscious consumers in the USA, and in other countries that have previously enjoyed liberal approaches to the regulation of natural health products, are currently facing the greatest challenges that have ever been presented. But attempting to block every piece of legislation that comes along, particularly if it has the potential to protect millions of people from the harmful effects of drugs, is surely not a good place to start.

So once again, the health freedom movement finds itself divided over whether this Bill has the capacity to sound the death knell for DSHEA. These are challenging times and in challenging times, the ability to negotiate, shape and see the potential in what faces us is often of greater value than the ability to take a defensive stance and attempt to block whatever the Regulators throw at us. As always, it is our opinion that 'good science and good law' will prevail and natural healthcare will take its rightful place as our healthcare system of choice. But, as the Davids in this Goliath battle, let's fight the fights we know are winnable.

International Developments

United Kingdom

Initial RIA for setting Maximum Permitted Levels

The UK Food Standards Agency (FSA) is collecting data for the development of an Initial Regulatory Impact Assessment (RIA).

The FSA has asked for our feedback on five theoretical options in setting maximum levels of vitamins and minerals, as well as our answers to a number of questions. In order to inform our opinion, we are approaching a very small number of key practitioner suppliers, including you.

The theoretical options, together with the FSA interpretation of impact and an ANH comment on each option, are given below

The Five Options, as given by the FSA:

Option 1: Do nothing, i.e. Failure to implement any amendment directive setting maximum levels.

FSA interpretation of impact: Failure to implement an amendment directive would bring risks and costs to consumers, industry, enforcement authorities and Government. Consumers would not have the benefit of clear safe maximum levels set at the European level. Failure to implement would maintain barriers to intra-community trade. Industry would not have the opportunity to expand trade within Europe. Failure to implement would also be a risk to Government as it would create a serious breach of the UK's obligations under the EC Treaty. This would attract infraction proceedings by the Commission against the UK under Article 226 of the EC Treaty and carry with it the likelihood of heavy fines. Other Member States could also initiate action under Article 227. Ultimately the UK would be forced to implement.

ANH comment: It is in our view unrealistic to imagine that any UK competent authority would ignore an amendment to an EU Directive. Historically, the UK has one of the strongest track records in the EU for implementation of EU Directives and Regulations.

Option 2: Harmonised maximum safe levels for vitamins and minerals in food supplements are not set for trade throughout Europe, by agreement between Member States and the Commission.

FSA interpretation of impact: Failure to set levels would maintain barriers to intra-community trade. Industry would not have the opportunity to expand trade within Europe. Consumers would not have the benefit of clear safe maximum levels set at the European level.

ANH comment: this option would be good for any company that trades almost exclusively within the UK, although it would be bad if significant or expanded trade is likely in other parts of the EU. Realistically, it is also not likely to get support from the UK government. However, if you like this option, and see it as a good option for your business, vote for it.

Option 3: Harmonised maximum safe levels for vitamins and minerals are set at levels below those recommended by the EVM, as reported in 2003: http://www.food.gov.uk/multimedia/webpage/vitandmin/120281. At this stage there is no indication of specific levels to be set – this option is provided to measure the impact of reducing the current UK upper safe and guidance levels.
FSA interpretation of impact: This would allow harmonised trade throughout the European Union, but would reduce the current choice available to consumers of the higher dose products, at or above the EVM levels. Benefits to business would be the potential to increase trade throughout the EU. Benefits to consumers across EC would be maximum levels set at the European level increasing choice in some Member States but a cost to the UK as this would include a reduction in consumer choice. Some manufacturers would need to consider reformulation or removal of products affected as the level agreed may be lower than products currently sold in other Member States and this may lead to loss of a competitive market differential for manufacturers and retailers.
ANH comment: This is a worse case scenario for EU-wide levels, and may be achieved even if the EVM levels are accepted as real Upper Safe Levels and dietary intakes are then
subtracted, which is after all what Article 5 of the Directive states. If you do this you end up with horrendously low levels, such as those devised by the Federal Institute for Risk Assessment in Germany, the BfR. They came up with, for example:

Beta-carotene: 2 mg
Niacin: 17 mg
Vitamin B6: 5.4 mg
Vitamin C: 225 mg
Vitamin D: 5 mcg
Vitamin E: 15 mg
Magnesium : 250 mg
Zinc : 2.25 mg (yes, the decimal point *is* in the right place !)
Selenium: 30 mcg

We advocate that such levels have been derived by using inappropriate risk assessment and risk management techniques and do not properly represent scientifically-derived safety-
based maximum levels for all members of each nutrient group. Simply put, we argue that this is an example of bad science being used for political ends.

Option 4: Harmonised maximum safe levels for vitamins and minerals are set at levels recommended by the EVM, as reported in 2003: http://www.food.gov.uk/multimedia/webpage/vitandmin/120281. This option is provided to measure the impact of setting current UK safe upper and guidance levels across Europe, but not allowing the sale of higher levels with the use of advisory (warning) statements on labels.
FSA interpretation of impact: This would allow harmonised trade throughout the European Union, but would reduce the current choice available to UK consumers of the higher dose products above the EVM levels. Benefits to business would be the potential to increase trade throughout the EU. Benefits to consumers would be clear safe maximum levels set at the European level. Costs would include a reduction in consumer choice of higher dose products. Some manufacturers, who currently sell higher dose products and/or use the agreed advisory statements on product labels, rather than having reformulated products after the EVM report was published, would need to consider reformulation or removal of products affected. This may lead to manufacturers and retailers losing a niche market for these higher dose products.
ANH comment: This is clearly better than Option 3, but still means you would have to live with some of the elements of the EVM report (2003) which is strongly contested by ourselves and other scientists. You will find attached our critique from 2002 on this report.

Option 5: The option discussed and agreed by the FSA Board in September 2005: harmonised maximum safe levels for vitamins and mineral supplement ingredients are set across the EU, based on EVM recommended levels. In addition, a second tier of national guidance levels could be allowed in individual member states. Supplements which exceeded the national guidance level would be permitted for sale at the discretion of national governments provided that they carried warning labels (advisory statements).
FSA interpretation of impact: This option would maintain the current UK market and would allow harmonised trade throughout the European Union. The current choice of higher dose products available to consumers would be maintained. Benefits to business would be the potential to increase trade throughout EU. Benefits to consumers would be clear safe maximum levels set at the European and National level, with advisory statements on products which exceed these levels.
ANH comment: In our view, this is going to be the best of the Options 3 to 5 (as given by the FSA), as it allows higher dose products to remain on the market in the UK. It therefore protects the UK's *status quo*, but would mean lower dose products would need to be manufactured in parallel for export to other EU Member States.

The ANH has gathered information from UK stakeholders and is filing its report to the FSA on Friday 25 May.

USA

Update on FDA Guidance on CAM

The ANH has circulated its views on this Guidance, which came following requests from a range of US interests, on 2 May 2007(see attached). Our key concern was that it provided evidence that the FDA was fully anticipating that products used in a CAM environment might increasingly be considered as drugs or new drugs. In the area of vitamin dosages alone, international guidelines that will be established through Codex, could well set the international borderline between supplements sold under a food regime and those sold under a drugs regime.

The ANH's US affiliate, the American Association for Health Freedom, has successfully been able to ensure that, despite the short deadline given by the FDA, its position will shortly be filed by various members of Congress.

Update to action on Compounding Chemists Bill

Senator Kennedy has proposed a bill to amend the Federal Food, Drug and Cosmetic Act to provide for safe and appropriate compounding of drugs by licensed pharmacists and physicians. It is also referred to as the 'Safe Drug Compounding Act of 2007'.

This so-called Safe Drug Compounding Act will, amongst other things, give the Food and Drug Administration the power to:

- Broadly eliminate the availability of many critical, commonly compounded medications that many patients rely on, such as bioidentical hormones for women, hospice care treatments for the terminally ill and customized medicines for children.
- Determine when compounded medicines are needed - a decision that has always been and should always be made by doctors.
- Restrict the compounded medications your doctor can prescribe even if he or she determines you need them.

Our US affiliate, the American Association for Health Freedom (AAHF), has been active in raising a groundswell of support from the grassroots to challenge this proposed legislative change. They have been reaching out to all those that have large consumer audiences through newsletters, the media, providing a printed alert for practitioners to download and have in their offices and through contacting other associations to encourage their members to take action from through their website. Please visit http://www.healthfreedom.org/ for downloadable information for your customers.

Attached is the letter that has been sent to Senators Kennedy, Burr and Roberts by John Gans, Executive Vice President of the American Pharmacists Association and Bruce Roberts, Executive Vice President and CEO of National Community Pharmacists Association. Also attached is the background information for patients and a proforma letter they can send to their elected representatives in Congress – please distribute to your practitioner customer base.

New Zealand

Why New Zealand's Therapeutic Products and Medicines Bill needs to be rejected

The following has been sent by request from the New Zealand Health Trust and a leading New Zealand sports celebrity as an open letter to the Rt Hon Helen Clarke, Prime Minister, New Zealand from Dr Rob Verkerk of the ANH:

> As an international, European-based, alliance of natural health interests, including consumers, medical doctors, other health practitioners, lawyers, scientists and companies, the Alliance for Natural Health has been deeply engaged in assessing the impact of different regulatory regimes for natural health products in different parts of the world.
>
> In relation to the development of regulatory models affecting natural health, and their relationship to New Zealand's interest in developing its own regime, **four general points** can be made:
>
> 1. Increasingly stringent regulatory regimes are rarely, if ever, developed because of conclusive evidence of risk from use of natural health products which is then shown could be ameliorated through the implementation of the new regulatory model. Presently there is evidence that food constitutes a health risk to the New Zealand population that is intermediate between natural health products, which have by far the lowest risk of any ingested product, and licensed pharmaceutical products.
>
> 2. Pharmaceutical-based regulatory models impose requirements which are *incompatible* with many truly natural products that are comprised either of many different primary or active molecular forms or are complex mixtures of compounds that are naturally-occurring.
>
> 3. Such models therefore act in a disproportionate manner by both excluding some of the fully natural products, as well as providing a relatively greater regulatory burden for smaller companies. They will favour large trans-national corporations over local, New Zealand businesses, and they will lead to a lack of diversity and innovation in the marketplace – for which the New Zealand natural products market is renowned.

4. The European Union has seen fit to develop a regulatory regime for 'food supplements' which continues to view "concentrated sources of nutrients" as foods, rather than as medicines. Given that the EU model is essentially forming the template for international Codex Alimentarius guidelines for food supplements, the development of a pharmaceutical model for natural health products in New Zealand would be out-of-step with Codex, which is already considered by some to be overly restrictive. Additionally, the USA, which is home to one of the richest and largest markets for natural health supplements worldwide, continues to operate a food-based regime for 'dietary supplements'.

In terms of the proposed Therapeutic Products and Medicines Bill, we have the following **five additional comments**:

1. There is no question that regulatory development of the natural products market in New Zealand could be initiated in such a way that it both ensures that public health risks are minimised, while, at the same time, it facilitates the expansion of New Zealand's position as an international supplier of natural products. However, this would require that the existing plans of the Australia New Zealand Therapeutic Products Authority (ANZTPA) are disbanded and that the Therapeutic Products and Medicines Bill is rejected in its present form. The Bill, in our view, should be limited to conventional pharmaceutical products and medical devices.

2. If the New Zealand government is to embrace preventative health strategies, which would in turn greatly benefit its population and reduce the burden on its health service, all effort should be made to ensure that unnecessary, disproportionate regulatory burdens are *not* applied to natural health products so that the cost of finished goods can be minimised, so making them accessible to as wide a sector of the population as possible.

3. By embracing a disproportionate, pharmaceutically-based legislative system for natural health products on the basis of insufficient evidence, the New Zealand government may open itself to potential legal action by New Zealand businesses that are damaged by the new law.

4. The New Zealand government should recognize that there are many differences between the Australian natural products market, and that of New Zealand. The New Zealand market has for many years fostered a much greater diversity of natural product suppliers than the Australian market, and at the same time the New Zealand market would be much more negatively impacted by the development of a pharmaceutically-based regulatory model owing to the broad range of naturally-sourced, locally-produced products in the New Zealand marketplace.

5. New Zealand has the ability to lead the world with a regulatory model that is adapted specifically to the requirements of natural health products. Such a model would then provide an important precedent for other countries that are contemplating development of their own regulatory systems. By ensuring that the model is constrained by food rather than medicinal law, it will also be in keeping with the requirements of Codex Alimentarius, which is in the process of developing risk assessment methods specific to nutrients.

We sincerely hope that the New Zealand government will heed the views of the many experts in the New Zealand natural products industry, as well as others

from outside, who have provided consistent warnings over the danger of harmonizing New Zealand's laws on natural products with those of Australia.

Judging by the level of concern among New Zealand consumers, about which we have been aware for some time, it goes without saying that Trans-Tasman harmonization of natural products laws would be likely to be a deeply unpopular political move.

We would be very happy to help assemble an international expert panel as a means of providing advice to the New Zealand government on a new regulatory approach, which would seek to enhance the development of a competitive, robust, New Zealand natural products industry, both nationally and internationally. Such an approach would also ensure that consumers were properly informed and their health adequately protected, while ensuring that their freedom of choice was not unnecessarily limited.

Australia

The noose of the drug companies continues its stranglehold over natural healthcare in Australia

Two separate developments in Australia during the month of April serve as critical reminders as to who is calling the shots when it comes to healthcare. It would appear that jail time could be on the cards for employees (past or present) of drug companies who decide to whistleblow and the whole Pan Pharmaceuticals debacle written off as, all counts were thrown out of court. Original releases follow:

Jail for leaking drug information http://www.pharmainfocus.com.au
Posted 9 April 2007

In a significant boost to protection of commercial-in-confidence and other sensitive information, Australian employees of the forthcoming ANZTPA face jail if they make unauthorised disclosures.

According to a draft of the Australian bill to implement the ANZ Therapeutic Products Authority (TPA) released last week, unauthorised disclosure of information will be a crime for Australian employees of and other "people performing a service" for the authority, punishable by two years" imprisonment.

New Zealand ANZTPA employees can breathe more easily as the bill covering the scheme in NZ contains no clause making unauthorised disclosure a crime or imposing jail time for any such disclosure. Neither does the *Therapeutic Goods Act* that currently regulates Australian pharma.

Medicines Australia supported the criminalisation of unauthorised disclosure in Australia as protective of commercial-in-confidence information.

"We think it is appropriate for a company's commercial-in-confidence information to be appropriately protected when submitted to the authority for evaluation for obtaining a product licence," a spokesperson said.

"The reference to people performing a service for the Authority would encompass external evaluators employed by the authority, whom we agree should be covered by the same terms as an employee in so far as management of information they receive in the course of performing that service."

However, MA said it could not offer an explanation as to why the measure had been included in the Australian but not the NZ bill.

The whistle blowing sanction is one of a number of differences between the participants in the joint scheme revealed by the exposure draft of the *Therapeutic Products Bill 2007*.

Although they contain similar clauses, in many places the bills are different in structure and language.

The Australian bill will require changes to other Australian legislation to support its stance on parliamentary disallowance of rules and orders made by the Authority.

The scheme proposes that, although rules and orders can be disallowed, they can only be disallowed as a whole. At present, regulations under acts of the Australian Parliament can be disallowed in part as well as whole. ANZTPA will be an exception in this regard and require changes to Australian law as a result.

The two countries will operate different freedom of information regimes pertaining to the scheme. In Australia requests to release information will have to be made under the *Freedom of Information Act* whereas in NZ they will be made under the *Official Information Act*.

This creates the potential for different disclosure regimes in each jurisdiction. For example, the identity of drugs under consideration for licensing may be available through the NZ system but not through the Australian system.

"The Joint Agency Establishment Group has emphasised to us that it is essential that the Australian and NZ bills achieve the same regulatory outcomes in each country. We believe that this remains the objective, which we fully support, and will be considering whether any differences between the two bills might compromise this objective," the MA spokesperson said.

MA said it would definitely be providing detailed comment on the draft legislation by the May for deadline for comment.

The NZ parliamentary select committee currently holding hearings on the "mirror image" legislation presented to the NZ Parliament last December is due to report on June 15.

Pharma in Focus is of course a drug company media outlet so the above article reads in favour of this new legislation.

Pan Pharmaceuticals found innocent

The Supreme Court ruled that Pan Pharmaceuticals were innocent on 18th April 2007, but not before Australia's largest natural health manufacturing company was brought to its knees by the actions of the Therapeutic Goods Association (TGA).

The Australian Democrats have long supported complementary health care and the right of people to access a wide range of remedies. The Australian Democrats continue to campaign on these and other important health issues in the lead up to this year's federal election.

COURT FINDS PAN PHARMACEUTICALS INNOCENT 18 APRIL 2007 SENATOR LYN ALLISON AUSTRALIAN DEMOCRATS LEADER

Democrats demand Howard apologise for Pan Pharmaceuticals witch hunt

http://www.democrats.org.au/news/index.htm?press_id=5806&display=1

The Howard Government must now apologise following the acquittal of Pan

Pharmaceuticals boss Jim Selim in the New South Wales Supreme Court. The pharmaceuticals giant was forced into administration in May 2003 following the largest pharmaceutical recall in Australia's history.

"It was a pointless exercise targeting complementary medicines and it sent hundreds of small businesses broke", Democrats leader and Health spokesperson Senator Allison said today. "The Howard Government turned its back on the mess and just walked away."

1500 products were recalled, not because they caused adverse reactions, but because of speculation about 'inconsistent quality'. Senator Allison raised concerns in the Senate at that time about what was playing out as a destructive over-reaction.

Mr.Selim was accused of a litany of charges, including breaching his manufacturing licence. In the end only two counts made it to court which were thrown out today.

"The unprecedented recall had a devastating effect on small businesses and shook public confidence in complementary health", Senator Allison said. "The very least those who have suffered deserve is an apology."

URGENT: calls for action
Company response required!

1. Please review the attached draft guidance document for Health Claims under Article 14 of the Nutrition and Health Claims Regulation and submit any comments you might have to us by **Monday 11th June 2007.** Please email to mel@anhcampaign.org.

2. We would encourage US companies to contact our affiliate the AAHF (www.healthfreedom.net) to take action on the FDA Revitalisation Act. Please forward the following link to your customers so they can make their voices count: http://ga4.org/campaign/House_PDUFA

3. Companies wishing to apply for generic Article 13 Health Claims should do so immediately. Closing date for submission of Article 13 claims in the UK is September 2009. Please see letter from the UK Food Standards Agency attached. **Please make contact with us to discuss this further and ANH Consultancy Ltd is able to provide support for such applications on a consultancy basis. Alternatively make use of the 2 h free consultancy we offer every month for ANHIC Gold and Silver members (cannot be accumulated or carried forward to next month).**

4. Companies wishing to apply for the Positive List regarding vitamin and mineral supplements should be considering this seriously now – the ANH strongly recommends this course of action, rather than relying on existing derogations. Derogations can be withdrawn at any stage if an unfavourable review is given by EFSA and the derogation phase expires on 31 December 2009. **Please make contact with us to discuss this further and ANH Consultancy Ltd is able to provide support for such applications on a consultancy basis.**

5. **US Innovators:** Charitable tax deductible donations (for US individuals and companies) can be made to the ANH via our US affiliate the American Association for Health Freedom/Health Freedom Foundation. Donations should be sent to The Health Freedom Foundation clearly marked that the gift is in support of European or global work.

The Health Freedom Foundation
4620 Lee Highway, Suite 210
Arlington, VA 22207
Phone: 1800 230 2762 or 703 294 6244 or Fax: 703 624 6380

Note to US companies: We would be extremely grateful if you could publicise this method of making charitable tax deductible donations to the ANH from within the US to your customers in any marketing literature you are about to send out.

Please email our Development Manager, Meleni Aldridge, at mel@anhcampaign.org or telephone +44 (0)1306 646 550.

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

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