

# PRACTITIONERS' NEWSLETTER

August/October 2011

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# EUROPE

## European Commission fails to address ANH-Intl's concerns about herbal directive

Whilst intensive preparations continue for the judicial review [[hyperlink to position paper](#)] of the EU and national laws affecting herbal products, ANH-Intl have been keeping the pressure up on the European Commission, leaving it in no doubt about the serious issues needing to be resolved. Large numbers of practitioners in Europe use herbal products, many of which are now being regarded either as illegal medicines or unauthorised novel foods, effectively becoming victims of an indirect ban.

### ***Whitewash response from EU Commissioner Dalli***

ANH-Intl sent an [open letter](#) to EU Commissioner Dalli in June, detailing their concerns about the herbal directive. A [reply](#) was finally received in August, but this provided no answers to the very serious issues we'd raised over disproportionate impacts on particular sectors, particularly those representing complex herbal products and the longest-standing traditions of medicine, such as Ayurveda and traditional Chinese medicine (TCM). Still not a single THMPD registration has been granted for authentic products associated with these traditional systems.

### ***Next step: Key questions for the European Commission***

ANH-Intl then worked with Marian Harkin MEP on a [list of questions](#) which were subsequently presented by the European Parliament to the European Commission. Evasive and incomplete [replies](#) received in September were once again the order of the day. Our analysis of these answers can be found in two parts: [Part 1](#) , and [Part 2](#).

### ***Unstable regulatory situation for EU herbals***

ANH-Intl is deeply concerned by the problematic legislation facing herbal products in Europe. The THMPD was thought by many to create a regime whereby a very large number of herbal products could be licensed, so forcing large numbers of products sold as herbal food supplements either into this specific drug licensing regime, or off the market altogether. The pretense of those who created the system was that it was needed to protect consumers from dangerous herbal products. The real reason was actually more about locking out many of the smaller players, who would be unable to afford the cost of licensing, handing the market to the large companies. Right up there, leading the charge, have been the German phytopharmaceutical companies like Schwabe Pharma and Bionorica. These companies, and supporters of the THMPD regime, are now very actively campaigning about the risks of botanical food supplements. They have no substantive data to rely on, and keep coming back to St John's wort and the potential risk to women on the contraceptive pill. They forget that nearly all EU governments already view St John's wort as medicinal only. In short, the situation for herbal products continues to be unstable in the EU, and the fact that ANH-Intl and the European Benefyt Foundation's joint efforts in preparing a judicial review is now known by most concerned parties and government authorities. We have heard considerable discussion among governments about their concerns with European case law that is actually strongly in favour of maintaining a diverse market of botanical food supplements. We are strongly of the view that our judicial review will greatly secure the situation for herbal products in the EU.

### ***The need for specific legislation for practitioners of holistic traditions***

Having identified the need, back in 2008, for the development of legislation specifically for practitioners of holistic traditions, the EC Commission has now confirmed to ANH-Intl that this responsibility rests with individual Member States. So far, the UK is the only Member State to have

plans to do this, having announced in February 2011 its intention to bring in Statutory Regulation of herbal medicine practitioners.

Herbalists in the UK have hailed this as the answer to all their concerns about their ability to continue practicing, and the availability of unlicensed herbal medicines. However, the exact form of the regulation has yet to be seen, and will be the result of considerable consultation and, no doubt, ‘horse trading’ between various sectors.

### ***UK herbalists need to remain vigilant on Statutory Regulation***

ANH-Intl believes strongly that UK herbalists [should not be complacent](#) about the UK Government’s plans for Statutory Regulation (SR). The UK Medicines and Healthcare products Regulatory Agency (MHRA) statement implies that the eventual regime could result in increased prices and reduced access to herbal medicines. Their statement may signpost the end of onsite prescribing, possibly ushering in a system of ‘magistral’ prescriptions. There is inconsistency between the statements of the UK Government, and the UK regulatory agency, and much confusion in the press about the issue.

### ***Call to Action***

- If practitioners have any further questions that they would like to put before the EC, please send them to Adam Smith at [adam@anhinternational.org](mailto:adam@anhinternational.org)
- We always appreciate donations from individual practitioners who are concerned about this legislation, and wish to support our campaigns
- Spread the word about the threats to herbal products and medicines in the EU as a result of the THMPD and related laws, and about our campaign – ANH-Intl represents one of the loudest voices for natural health practitioners. To those of you who have already donated, we thank you sincerely for your support.

## **Practitioner websites targeted by UK’s media industry watchdog and skeptics**

UK CAM practitioners continue to receive threatening and intimidating letters from industry regulator, the UK Advertising Standards Authority (ASA), informing them of apparent breaches of the British Code of Advertising, Sales Promotion and Direct Marketing (CAP code). The ASA, in conjunction with an anti-CAM skeptic group are currently targeting the websites and other publicity materials of CAM practitioners, in what can only be described as a ‘witch-hunt’ against CAM practitioners. ANH-Intl and the Complementary Medicine Association (CMA) are concerned about the erosion of the future of CAM practice in the UK, if such a heavy-handed policy is allowed to continue.

### ***Concerns ‘brushed-off’ by unscientific ASA***

Representatives of both organisations met with the senior Advertising Standards Authority (ASA) Head of investigations at the end of July, to express their concerns about the increasing trend and questioned its scientific competence to adjudicate complaints against CAM advertisers. It seems that the ASA have adopted the same highly controversial approach as that favoured by the European Food Safety Authority (EFSA), and yet none of the relevant staff appeared to have scientific qualifications. Their concerns were simply [‘brushed off’](#). It’s imperative that practitioners understand the difference between the ASA’s rules and EU legislation, which constitutes the law. The ASA have no legal remit and use overt bullying tactics to achieve their ends. We urge practitioners to remain steadfast and to take advice before complying with the ASA’s demands.

### ***Rules and regulations affecting clinical practice***

On 21<sup>st</sup> May, ANH-Intl organised a [special seminar](#) for (mainly) UK practitioners, to help equip them with the knowledge and skills to deal with the mass of legislation emanating from Brussels, including covering the ASA remit and CAP Code. Entitled “ Rules and Regulations affecting clinical practice”, this inaugural training event, run in conjunction with the General Naturopathic Council, and was very well received.

### ***Call to Action – UK practitioners***

The seminar is now available to practitioners as a [downloadable pack](#). This is available for £40, with all proceeds going to ANH-Intl’s campaign fund. The pack contains the full delegate volume, the day’s video recording with incorporated slides, the pre-reading pack and extensive supporting documentation. Practitioners are urged to equip themselves with this invaluable information to enable them to communicate with clients, advertise and promote their services while staying within the law.

## **Full implementation of EU Health Claims regime approaches: a black cloud over freedom of speech**

In what we believe to be the greatest [threat to free speech](#) in natural healthcare ever, the [full implementation](#) of EU Nutrition and Health Claims regime could be biting by the beginning of 2012. The natural health sector in Europe is poised with bated breath for the European Commission to release the final proposal list of generic claims on the Community List. The Regulation effectively bans all health claims that have not been specifically approved by EFSA. Given that EFSA’s rejection rate for botanical claims is standing at around 95%, we’re not holding out a great deal of hope for favourable Article 13.1 claims. Many of which are so broad as to be meaningless, even misleading, depriving the consumer of crucial information to make informed health choices on food and food supplements.

### ***Effect of Regulation on Practitioners***

This ban on unapproved health claims does not just apply to labels on supplement bottles and sales literature. It also includes practitioners’ promotional material and websites, as well as verbal communications, which means that practitioners will have to be aware of how they present information about therapeutic commercial products to their patients or clients. European Practitioners will need to familiarise themselves with what is permitted and what is not. Practitioners who are unfamiliar with the NHCR and its impact on practitioners will benefit from purchasing the [download pack](#) of our ‘Rules and Regulations’ seminar.

### ***EU Regulation spreads to USA***

This draconian and restrictive Regulation is likely to end up being exported worldwide through the intergovernmental organisation that is influenced by big business: the [Codex Alimentarius](#) Commission. A [similar](#) regulatory regime is already developing in the USA, and when Europe release the final list of permitted general function claims, this could also spell [trouble](#) in the ‘Land of the Free’.

Industry in Europe is up in arms about this regulation, and it is highly likely that companies may challenge the regulation within the courts.

Read also ANH-Intl's two press releases: '[EFSA says prunes don't loosen the bowel](#)', which is accompanied by a list we compiled of selected nonsensical negative health claim options by EFSA, and '[EFSA says it will clean up its act in Brussels workshop](#)'.

### **Call to Action**

[Write to your Members of the European Parliament](#), expressing your dismay at EFSA's unwillingness to address the issues that bring it into disrepute.

Or [contact EFSA](#) directly - address your letters to:

Ms Catherine Geslain-Laneelle  
European Food Safety Authority  
Largo N. Palli 5/A  
43121 Parma  
ITALY

## **Other Europe news that may be of interest to practitioners**

[Read](#) Dr Rob Verkerk's rebuttal of the Iowa Women's Health Study in the *Archives of Internal Medicine* study suggesting that older women are at risk from supplements

[Read](#) ANH-Europe's feature which questions whether the rise of type 2 diabetes is as unstoppable as governments make out

[Read](#) ANH-Europe's analysis of a flawed study suggesting that herbal products in the UK provide inadequate safety information for consumers: *'Shoddy study casts doubt on herbal products' safety information'*

[Read](#) ANH-Europe's feature on the US Institute of Medicine (IOM's) comprehensive report on the relationship between vaccines and side effects

[Read](#) ANH-Europe's news item: *'No place for prevention in high-profile cancer report'*

[Read](#) ANH-Europe's news item about the worrying new development: Caesarean sections are to be available on demand in the UK. Is medical science trying once again to usurp nature?

[Read](#) ANH-Europe's news item in which we get together with Caduceus magazine and take a closer look at 'attacks' on the traditional food: raw milk

[Read](#) ANH-Europe's report on what appears to be a developing trend in the USA- Increasing State control of its citizens bodies: *'Don't drug my child or I'll shoot'*  
The examiner have also published a worrying [story](#) about this:

[Read](#) ANH-Europe's news item: *'Vaccination by stealth in California'*

# USA

## Overview: The laws threatening integrative doctors and integrative medicine

In the USA, integrative doctors have been approached by the Food Drug Administration (FDA) and threatened with legal action for prescribing things other than FDA-approved drugs or drugs being investigated under FDA procedures. Yet Federal law allows licensed physicians to “*manufacture, prepare, propagate, compound or process drugs solely for use in the course of their professional practice.*” [21 USC 360(g)]. In addition, therapeutic practices cannot be regulated by the Federal Food, Drug, and Cosmetic Act (FD&C).

This and other threats to doctors’ natural right and their patients’ right to choose natural healthcare is a subject dealt with by ANH-USA in their article (Part 1) entitled: “[Can My Doctor Get Into Big Legal Trouble by Offering Natural Health Treatments?](#)”. This subject is further explored in the article: “[Can Physicians Write Prescriptions for Drugs that the FDA Has Not Approved?](#)”.

### ***Why selling natural products is such a dangerous business***

In order to work within the law, these doctors and other practitioners of natural medicine in the USA, like their European counterparts, have to ‘pretend’ that the natural products they use are ineffective when it comes to actually treating disease. This is of course both bizarre and frustrating for doctors, who know full well how effective their protocols actually are. The situation exists in the US because of the Federal Food, Drug and Cosmetic Act (FD&C). This law requires that only drugs can claim to cure, prevent, mitigate, or treat a disease [section 201(g)]. Nothing else, such as a food or food supplement, may make that claim.

This is the subject of Part Two of ANH-USA’s article, entitled: ‘[Why Selling Natural Products is such a Dangerous Business](#)’.

[Recent legislation](#) introduced by Sen. Durbin and the FDA’s disastrous [NDI draft guidance](#) offer even more evidence that the US government is heavily biased in favour of conventional medicine and against integrative or natural medicine

## ANH-USA analysis of disruptive new supplement guidance filed with FDA

ANH-USA has [filed an analysis](#) with the FDA in response to a request for comment on ‘*Premarket Notification for a New Dietary Ingredient (NDI)*’ in the Federal Register. This new NDI guidance is expected to cause major disruption in the dietary supplement industry. It threatens diverse natural ingredients used by practitioners, by targeting new innovative supplements, including ‘new’ products developed after 1994. It threatens to drastically reduce the number of supplements sold, and to drastically increase the cost of those remaining. The analysis was drafted by the renowned constitutional law attorney, Jonathan Emord, with economic analysis by an associate professor of law at Emory University. The FDA’s reply played down the threat to supplements presented by this guidance. The majority of applications for NDI notifications are in fact rejected.

ANH-USA held a [call-in lobbying day](#) on 8<sup>th</sup> September, to ask Congress to direct the FDA to carefully review their draft guidance and hold hearings at the end of the review process unless the FDA amends the guidance to reflect DSHEA (and Congress's) stated values and goals.

Also [read](#) '*NDI Supplement Guidance is Just a Bait-and-Switch—and Time Is Running Out to Stop It!*'

#### **Call to Action**

All US practitioners are urged to [contact](#) the FDA immediately and voice their strong **opposition** [] to the New Dietary Ingredient draft guidance!

## **A bill to support health freedom: The Testimonial Free Speech Act**

At last, thanks to US Congressman Ron Paul, a [bill](#) supporting access to natural health remedies! [The Testimonial Free Speech Act, HR 2908](#), would allow the dissemination of testimonials *"containing a consumer's actual perception of the mitigative, preventive, or curative properties of any food or dietary supplement based on the consumer's experience with that food or dietary supplement."*

Other closely related free speech in healthcare / health freedom bills that Ron Paul has introduced in the current Congress, and which are of course directly or indirectly positive for practitioners also, are:

HR 2044, the Health Freedom Act: Prohibits FDA from preventing a disease claim unless it is "false and misleading in a material respect." Amends the FD&C Act to say, "A food or dietary supplement for which a claim is made...is not a drug solely because of such claim."

HR 2045, the Freedom of Health Speech Act: Increases the burden of proof required by the FTC to prove false advertising cases against dietary supplement manufacturers. Excerpted scientific studies will not be considered advertising.

#### **Call to Action**

US practitioners can [ask](#) their representatives to fully support all three bills.

## **Chicago: Non-participation in 'wellness program' to cost more in premiums**

Chicago city employees will have to pay extra for their insurance premiums (an extra \$50 per family member) if they refuse to participate in a '[wellness program](#)', based on conventional medicine. Its too bad if they want to try natural alternatives instead. Watch out the rest of the US, because the Healthcare Reform Act contains something similar. The idea is the brain child of Chicago Mayor Rahm Emanuel.

## **New roadmap for increased vaccination and immunization in the 21st century**

A new roadmap for increased vaccination and immunization for the 21<sup>st</sup> century has been unveiled by the US Department of Health & Human Services (HHS). [The National Vaccine Plan](#) (NVP) calls

for yet more new vaccines for children, who already receive [far too many](#) vaccines. Worryingly, these are given all at once and at far too young an age.

This will of course include giving three doses of [Human Papilloma Virus \(HPV\) vaccine](#) to girls by the age of 13 to 15, to prevent cervical cancer. Yet the *Journal of the American Medical Association* says that the relationship between infection with HPV at a young age and later development of cancer is unknown. The data provided suggests that the vaccination will have no effect on 87% of the HPV viruses that are associated with cervical cancer, and the causal link between HPV and cervical cancer is far from definitive.

Read also the following ANH-USA vaccination articles:

[‘HPV Continues to Be a Hot Issue in the GOP Debates’](#)

[‘HPV Vaccine Victims Speak Out—Will the Media Finally Get it Right?’](#)

[‘BREAKING NEWS! CDC Has Just Recommended Routine HPV Vaccinations for Boys!’](#)

[‘Readers’ Corner: Are HPV Vaccine-Linked Deaths Being Overstated?’](#)

## The Dietary Supplement Labeling Act must be opposed by Congress

[The Dietary Supplement Labeling Act](#) targets supplements and supplement manufacturers, and will ultimately result in the FDA being given more powers to curtail supplement sales. The bill requires that the Food and Drug Administration (FDA), and the Institute of Medicine (IOM), compile a list of dietary ingredients that could lead to adverse events or are otherwise deemed risky in some way.

Also [read](#) *‘Senator Durbin’s Stealth Move against Supplements’*

### **Call to Action**

US practitioners are urged to [tell Congress](#) to Oppose the Dietary Supplement Labelling Act

## Other USA News that may be of interest to practitioners

Read ANH-USA Action Alert: *Shame on AMA’s Archives of Internal Medicine*—[Part 1](#) and [Part 2](#)

[Read](#) ANH-USA State Action Alert: *California Requires Ridiculous Warning Labels on Bioidentical Hormones DHEA and Pregnenolone*

[Read](#) ANH-USA article: *No More “Pinkwashing”! Support an Integrative Approach to Breast Cancer*

[Read](#) ANH-USA article: *The Threat to Dietary Supplements We Couldn’t Tell You About Last Year*

A supplement to the October edition of the *American Journal of Preventative Medicine* calls for a [greater emphasis](#) on public health and prevention in Medical education. The supplement editors comment that there is an urgent need for doctors with a better appreciation of such issues to address such challenges as *“rising chronic disease burdens, persistent health disparities, and healthcare financing that “encourages treatment over prevention”*.

# AUSTRALASIA

## AIMA hold their 17th International Integrative Medicine Conference

[AIMA's 17<sup>th</sup> International Integrative Medicine Conference](#) took place on the 14<sup>th</sup>, 15<sup>th</sup> and 16<sup>th</sup> of October. The conference featured a distinguished line up of speakers and panelists, including its founder Dr Vicki Kotsirilos, who spoke about ethics and accountability of integrative medicine doctors; and Dr Helen Caldicott, who spoke about the impacts of the Fukushima nuclear event. Other topics included the latest research into A2 milk, and insights into the world's first online Master of Wellness program.

## New Zealand: MPs' briefing notes for Natural Health Products Bill

The New Zealand Parliament has now published MP's briefing notes for the [Natural Health Products Bill](#) (introduced to Parliament on September 7<sup>th</sup>). This follows the publication in June of the Regulatory Impact Statement, which sets out that the aim of the Bill is to "give New Zealanders confidence that the natural health products they use are safe, true to claim and true to label".

\* \* \*

We thank you for your collaboration, contributions and support as we face the mounting challenges and worldwide threats to natural health. Please forward this newsletter to your members, colleagues and other interested parties.

Should your organisation of practitioners be interested in [collaborating](#) with ANH International on any of these issues, we would very much like to hear from you. Please email Yvonne England, our practitioner liaison specialist, at [yvonne@anh-europe.org](mailto:yvonne@anh-europe.org).

In health, naturally.



Yvonne England  
Practitioner Liaison

**For further information:**

ANH International: [www.anhinternational.org](http://www.anhinternational.org)

ANH Europe: [www.anh-europe.org](http://www.anh-europe.org)

ANH USA: [www.anh-usa.org](http://www.anh-usa.org)