

Statutory Regulation of Practitioners of Herbal and Traditional Medicine, Traditional Chinese Medicine and Acupuncture: Breaking News...

Shortly after the Department of Health's public consultation on our statutory regulation closed on November 16th, we were told that the DH had received an unprecedented 4000 replies. A fortnight or so later, this number was reassessed at 5000 and just before Christmas the DH told us that they had actually received over 6000 replies. We understand that the usual haul for a DH consultation like this is between ten and 80 responses. The DH spokesperson said "they would have to hire extra staff to deal with the huge response." Given the extraordinary complexity of the consultation document, the number of replies is truly extraordinary! Well done to everyone who responded and got their patients to reply. That's terrific and clearly demonstrates the level of public interest in the delivery of herbal medicine.

The campaign continues!

Statutory regulation has been under consideration for a decade since the call in 2000 from the House of Lords' Select Committee on Science and Technology for the statutory regulation of practitioners of herbal medicine and acupuncture. The Government itself backed statutory regulation of this sector in 2001: as recently as 2006 the DH website recorded that "*The Government is committed to the statutory regulation of herbal medicine, acupuncture and traditional Chinese medicine practitioners.*"

Over the past eight years the Department of Health (DH) has initiated three working groups to look at implementing this policy. All three working parties strongly supported the aim of statutory regulation of this sector. In 2005, the DH ran a public consultation on the statutory regulation of herbal medicine and acupuncture. This registered a 98% response in favour of statutory regulation. As a consequence the DH published a timetable for the statutory regulation of this sector with a section 60 order (the legal process to bring this about) to be published later that year. This timetable has not been adhered to. The Government says it will make a decision on this matter but continues to dilly-dally. If statutory regulation does not go ahead with immediate effect, there will be a significant loss of consumer choice and huge damage to many small and medium sized businesses across the herbal supply and manufacturing sector as well as to many herbal practices throughout the UK. **It is clear that in not making a decision to go ahead with statutory regulation, the Government is effectively undermining herbal medicine practice in this country.**

Action now!

For this reason we urge you to write (yet again if you have already done so!) and to get your patients to write to MPs to say that the delay in conferring statutory regulation will seriously reduce patient choice and will undermine many small and medium businesses in the herbal practitioner and supply sector. To help you do this see the model letter on page 11 which explains the issue in detail and which you can copy and give to your patients to send their MPs. We suggest that each person adds a sentence or two to say why he/she is a fan of herbal medicine. See also the copy of the letter sent by the EHTPA to Peter Mandelson on page 3.

Mass Lobby of Parliament

Following on from the very successful mass lobby of Parliament on 2nd Nov organised by Afifah Hamilton, Hayley Jones and other colleagues, we have now organised another:

Mass Lobby calling for the Statutory Regulation of herbalists

Wednesday 3 February 2010

12 - 4pm

Venue

Old Palace Yard Westminster.

The Paved Area (not the grass) of Old Palace Yard (opposite the long side of Parliament).

Please do your best to come, but the police have to be informed as to numbers so 'RSVP' to gail.breeze@ehpa.eu.

It is important that you lobby your MP on the day. We have chosen a Wednesday as this is when Prime Minister's Question Time (held from 12 – 12.30pm) occurs and most MPs are in the House. We begin the MP lobby at 2,30pm. **Arrange to meet your MP on the day** from 2,30pm onwards.



The best way to contact your MP is to write to him or her at the House of Commons, Westminster, London, SW1A 0AA. Most MPs also use email, and should treat emails in the same manner as a letter. You can find out your MP's email address at the following website:

<http://www.parliament.uk/directories/hciolists/alm.s.cfm>. Remember to give your home address even

in an email, as MPs have a strict rule about dealing only with their own constituents. For further information about the day, look at the EHTPA website <http://www.ehpa.eu/>.

Politics

Meeting with Baroness Thornton

In late December Emma Farrant (RCHM) and Michael McIntyre (Chair EHTPA) met with the junior Labour Minister in the House of Lords, Baroness Thornton. Also present were Lord Colwyn (Cons), Lord Pearson (UKIP), senior civil servants from the DH and Medicines and Healthcare products Regulatory Agency (MHRA). The Shadow Health Spokesman, Earl Howe, apologised for not being able to attend but spoke to Baroness Thornton before the meeting, declaring his party's interest in getting the matter of our statutory regulation sorted out. We particularly focused on the very significant numbers of people using herbal medicines (referring to a recent MHRA survey), the loss of consumer choice if statutory regulation does not go ahead and the likely danger to the public that would result if people were forced to buy from the internet and bogus back-street suppliers. We also handed the Minister a copy of the survey that we had carried out that clearly showed the disastrous financial impact on suppliers and practitioners because of the loss of business resulting from the ending of third-party supply after April 2011. Emma said that she would no longer be able to practise after 2011 as she had no dispensary of her own and was totally reliant on a third-part prescription service.

The Minister was clearly alarmed by what we had to say. She said to DH civil servant "this is very serious" and asked when we could expect the result of the public consultation. The civil servant said that given the 6000 replies, the assessment was going to take several weeks and that the DH would have to take on more staff to undertake this massive job. She said that, having done this, the results would have to be published and Ministers come up with a recommendation based on its outcome. All this would take time and as there was a possibility that an election might be called as early as March, the process might be overtaken by events. Baroness Thornton was said that she would write about our difficulties to the three health ministers, Gillian Merron, Ann Keen, and Mike O'Brien. She said that she thought this

would lead to another meeting early in 2010. This might speed the process up.

The meeting finished in good spirits with Lord Pearson offering to show the Minister his leg which had an outbreak of *lichen planus* that had not responded to the best of western medicine and had only healed by visiting a member of the RCHM. The Minister demurred but was clearly amused. The civil servants' faces were a picture!

Meetings with Earl Howe and Lord Walton

Also before Christmas, Michael McIntyre met with Earl Howe, the Conservative Health Spokesman, to discuss the move to statutory regulation.

Earl Howe is supportive and it seems likely that the Conservatives will back our move to statutory regulation. McIntyre also met with Lord Walton, who headed the House of Lords' Select Committee on Science and Technology that had called for us to be statutorily regulated in 2000. Lord Walton also declared his continuing support for the statutory regulation of herbal medicine and acupuncture.

Upcoming meeting with Lib Dem Health Spokesman

A meeting is scheduled at the end of January between Norman Lamb (Lib Dem Health Spokesman) and Michael McIntyre and Andrew Chevallier.

Letter to the Business Secretary Lord Mandelson

The EHTPA chair wrote the following letter to the Business Secretary Lord Mandelson:

The Rt Hon Lord Mandelson
Secretary of State for Business, Innovation & Skills
& President of the Board of Trade
Ministerial Correspondence Unit
Department for Business, Innovation & Skills
1 Victoria Street
London SW1H 0ET
04/01/2010

Dear Lord Mandelson,

The Statutory Regulation of herbal practitioners in the UK and its regulatory impact implications

I write to you in my capacity as chair of the European Herbal and Traditional Medicine Practitioners Association (EHTPA) which represents some 2,500 practitioners of herbal medicine working in the UK. These are generally

small enterprises which themselves rely on the support of around 60 -80 other small to medium enterprises in the form of herbal manufacturers and suppliers. The future of many of these businesses is now in doubt because of the Government's tardy move towards the statutory regulation of herbal practitioners - something which the Department of Health has been publically committed to for many years. As you no doubt know, The Department of Health Recently consulted on the proposed statutory regulation (closing date Nov 16 09) of herbal/traditional medicine, TCM and acupuncture practitioners.

This matter has been under consideration for a decade since the call in 2000 from the House of Lords' Select Committee on Science and Technology for the statutory regulation of practitioners of herbal medicine and acupuncture. The Government itself backed statutory regulation of this sector in 2001 and more recently key regulatory bodies, the Health Professions Council (HPC) and the Medicines and Healthcare products Regulatory Agency (MHRA) have both concluded that, like the osteopaths and chiropractors, acupuncture and herbal medicine practitioners should be subject to statutory regulation. As recently as 2006 the DH website recorded that "*The Government is committed to the statutory regulation of herbal medicine, acupuncture and traditional Chinese medicine practitioners.*"¹

Over the past eight years the DH has initiated three working groups to look at implementing this policy. All three working parties strongly supported the aim of statutory regulation of this sector. In 2005, the DH ran a public consultation on the statutory regulation of herbal medicine and acupuncture. This registered a 98% response in favour of statutory regulation. As a consequence the DH published a timetable for the statutory regulation of this sector with a section 60 order (the legal process to bring this about) to be published later that year. This timetable has not been adhered to. The Government says it will make a decision on this matter but continues to delay. As explained below, if statutory regulation does not go ahead with immediate effect, there will be a significant loss of consumer choice and huge damage to many small and medium sized businesses across the herbal supply and manufacturing sector as well as to many herbal practices throughout the UK. It is clear that in not making a decision, the Government is effectively undermining herbal medicine practice in this country.

If statutory regulation fails to go ahead there will be a loss of a wide range of herbal medicines currently supplied by manufacturers and suppliers to practitioners. Full implementation of the new European Traditional Herbal Medicine Directive in April 2011 will see the end of Section 12(2) of the Medicines Act of 1968 and with it the right of practitioners to access finished medicines from manufacturers and herbal suppliers for prescription to individual patients. This includes all finished products such as medicinal herbal pills, tablets, capsules, dried herb mixtures and medicinal herbal ointments made up for individual patients by third-party suppliers. Also under threat are third-party herbal prescription services that supply

¹ DH Workforce Update
<file:///c:/Users/Mic/Documents/EHPA/Workforce%20update%20The%20Department%20of%20Health%20-%20P&G%20Human%20resources%20and%20training.htm>

individualised herbal prescriptions (including those comprising tinctures and dried herbs) to named patients at the practitioner's request. Over the past 40 years this mode of supply has become an essential part of herbal practice in the UK and many practitioners are totally reliant on such services. All that will remain will be herbal medicines prepared by practitioners from their own premises. Herbal medicine is extraordinarily popular. According to an Ipsos MORI report commissioned by the MHRA (January 2009), 35% of adults in the UK have used a herbal medicine whilst 26% of adults in the UK have used a herbal medicine in the past two years. This report also found that 77% of adults agree it is important that herbal medicines are regulated, with this figure rising to 87% among regular users of herbal medicines (defined as those who have used a herbal medicine within the last 2 years).²

From April 2011 the ability to order medicinal products from suppliers for individual patients is only available to statutory regulated health professionals. Without statutory regulation, from this time onwards, many patients will be unable to obtain their usual medicines. The loss of this facility will put many practitioners and several of their suppliers out of business. This will further damage the UK economy and swell unemployment during the current economic downturn. To illustrate what will happen, I enclose the results of a survey we have carried out on regulatory impact on the herbal sector if statutory regulation does not go ahead. Frankly, the results make alarming reading.

The MHRA has proposed that third-party medicines supplied on request of statutorily regulated practitioners for individual patients can continue under MHRA licence via Section 5.1 of the main European Medicines Act 2001/83/EC³. The key point here is that this facility is only available to statutory regulated health professionals. In short, if herbal practitioners were to secure 'authorized health care professional' status through statutory regulation, they could legally commission herbal medicines from manufacturers for supply to their patients. These would have to be made to assured medicinal quality. The statutorily registered herbal practitioner would ensure high standards in the supply of the many useful traditional medicines for the benefit of patients. Their businesses would be secured and the public will have a professional group able to deliver expert herbal treatment tailored to the individual. Herbalists will be a source of information and education about the use of herbal and traditional remedies. I write to you now, to ask if you will intercede with the DH to impress on its Ministers the need to determine that herbal practitioners in the UK should be statutorily regulated as soon as possible otherwise the financial viability of many SMEs throughout the country will be put at significant risk. As I am writing to you in your capacity as Business Secretary, this letter has emphasised the negative impact on SME's of Government's failure to statutorily regulate herbal

medicine practitioners. However, that is not to lose sight of the vitally important fact that in the interests of patient safety, it is essential that statutory regulation is achieved. This matter has been debated enough; we need to get on with it!

I look forward to hearing from you.
Michael McIntyre
Chair EHTPA

Media Coverage

There has been plenty of press coverage about our statutory regulation.

On 19 November Dee Atkinson ably engaged Edzard Ernst in debate about our regulation on the BBC 4 programme, *You and Yours*.

The *Daily Telegraph* noted (4th December) that the Royal College of Physicians had done a U-turn and withdrawn support for our statutory regulation. The article read as follows:

**"Doctors abandoning patients over herbal medicine, claims charity boss
Doctors have been accused of "abandoning patients to quackery" by failing to push for tighter regulation on herbal and Chinese medicine.**

"The head of one of the Prince of Wales's charities launched an attack on doctors saying they were "washing their hands" over tightening the law alternative medicine.

"Dr Michael Dixon, medical director of the Prince's Foundation for Integrated Health, said the Royal College of Physicians (RCP) had "missed the point" on introducing statutory regulation.

The Government is consulting on the issue after some people suffered liver failure and kidney problems as a result of taking herbal medicines.

"While the College is in favour of regulating acupuncture, it believes doing so for herbal and traditional Chinese medicine risks giving them credibility.

"In its submission to the Government, it said acupuncture should be considered for statutory regulation because evidence had shown it could be beneficial. But it said herbal and traditional medicine was "largely or completely of unproven benefit". It added: "The vast majority of herbal and traditional Chinese medication is not based on scientific evidence of efficacy.

"Regulation (except for acupuncture) by regimes similar to those applied to medicine nursing midwifery etc runs the risk of leading the public to believe that these complementary approaches have a similar efficacy." The RCP thinks these practices should actually be regulated under consumer protection laws.

² MHRA website - Ipsos Mori report
<http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON036071>, Jan 2009.

³ This proposal can be read in detail on the MHRA website at <http://www.mhra.gov.uk/home/groups/es-herbal/documents/websiteresources/con2024908.pdf>

“However, the Prince's Foundation believes patients risk being "abandoned to quackery" if the Government fails to introduce statutory regulation of herbalists and acupuncturists. Dr Dixon said the College had missed the point of regulation, which was to protect the public, not to act as a badge of honour. He said the College had performed a U-turn after saying in 2008 that herbalists should be regulated.

"The question we should be answering is not 'how can we best protect our trade monopoly as doctors?'," he said. "It is 'how can we best protect the public from ill trained or bogus practitioners?'"

'It's not just individual herbalists we need to worry about. Unregulated internet sites are a significant source of 'herbal' medicines but give no guarantees of quality or safety.

"There have already been deaths caused by toxic and dangerous products masquerading as 'natural' or 'herbal' remedies. "We fear there will be more if statutory regulation is refused.

"Millions of people use herbal medicine – and will continue to do so even if the Government refuses statutory regulation – while people from Asian and African-Caribbean backgrounds are twice as likely to consult a herbal practitioner "We are sure the RCP does not wish to suggest that people using Western or traditional Chinese herbal medicines don't deserve proper protection. This late volte-face is mistaken and wrong."

“Dr Dixon said regulation would arm patients with knowledge about whether their practitioner is qualified and can practise safely.



House of Lords

On January 7th the Chair of Sense about Science Lord Taverne, actively campaigning against our regulation), put down an oral question in the House of Lords asking “To ask Her Majesty's Government whether, following their proposals to regulate practitioners of alternative medicine, they plan to regulate astrologers.” His rather puerile attempt at irony made no impact and Baroness Thornton, rather gracefully put Taverne in his place. Before asking the question Taverne gave an interview to the political website *ePolitix*. This was responded to by Michael McIntyre. The interview and the EHTPA response follow.

Taverne: “My parliamentary question about regulating astrologers is inspired by the government's proposed statutory regulation of alternative medicine. The government proposes to regulate practitioners of

acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems.

This is clearly a response to intense lobbying by Prince Charles' Foundation for Integrated Medicine.

The proposal is strongly opposed by Sense About Science (of which I am chairman), the Medical Research Council, the Academy of Medical Royal Colleges, the Institute of Biomedical science, the Medical Schools Council, the Physiological Society and the Royal College of Pathologists.

It would give practitioners of alternative medicine a spurious respectability, as being sanctioned by official regulation, which implies that their practices are evidence-based when there is little if any scientific evidence in their support.

They offer accounts of basic physiology and pharmacology that are highly implausible. In fact, they have about as much scientific basis as astrology. So why not add parapsychologists or astrologers to the list?

In defence of alternative medicine systems, it is argued that they are popular. But astrology is even more popular. In fact, pseudo-science generally is fashionable.

Several universities actually give 'science' degrees in homeopathy, ayurveda and reflexology and other forms of alternative medicine.

It is also argued that many of the practices must be effective because they have been around for centuries. So has witchcraft, or the belief that prayer can cure disease. But medicine is not like a piece of antique furniture, which becomes more valuable with age.

If the government is worried about patient safety it should require practitioners of alternative medicine to undergo conventional medical training. It should take a firm stand in favour of science-based policy, not appear to legitimise quackery.

McIntyre: As chairman of 'Sense about Science', the least we should expect from Lord Taverne is to write accurately and impartially. But his piece on the regulation of practitioners of acupuncture and herbal medicine is ill-informed, highly opinionated and surprisingly inaccurate. Worst of all, by arguing against regulation, Taverne actually puts the public at serious risk, since regulation will ensure the proper training of these practitioners and the quality and safety of herbal products they use. It is clearly in the public interest for statutory regulation to go ahead.

Taverne says that the government's move to statutorily regulate herbal medicine and acupuncture is a response to lobbying from Prince Charles' Foundation for Integrated Medicine (sic), but this is not true. As a Member of the House of Lords, Taverne should know that the impetus for statutory regulation actually came from the House of Lords' select committee on science and technology (on which sat several eminent scientists and doctors), which

recommended in 2000 that acupuncture and herbal medicine should be statutorily regulated as soon as possible. In the light of this recommendation, the government agreed in 2001 that statutory regulation should go ahead.

Over the past eight years the Department of Health has initiated three working groups to look at implementing this policy. All three working parties strongly supported the aim of statutory regulation of this sector. In 2005, the DoH ran a public consultation on it. This registered a 98 per cent response in favour of statutory regulation. Given the thoroughness with which the DoH has examined this issue over the years, it is questionable whether the recent second public consultation was a good use of public money.

Taverne also says: "If the government is worried about patient safety it should require practitioners of alternative medicine to undergo conventional medical training", but here too he displays ignorance. The agreed training in herbal medicine in the UK requires practitioners to be well versed in a wide range of conventional medical instruction including differential diagnosis and pharmacology. Taverne opines that official regulation would give practitioners "a spurious respectability, as being sanctioned by official regulation, which implies that their practices are evidence-based, when there is little if any scientific evidence in their support". Here Taverne clearly misunderstands the role of regulation. Regulation is not a badge of rank but is all about public protection.

Herbal medicine is enormously popular. Recent research by Ipsos MORI for the Medicines and Healthcare products Regulatory Agency (MHRA) has found that millions of people in the UK use herbal medicines, and that more than a quarter of the population had bought herbal medicines over the counter in the previous two years, with 1 in 12 consulting a practitioner of Western herbal medicine, and about 1 in 20 consulting a practitioner of traditional Chinese medicine. It also noted that 77 per cent of adults agree it is important that herbal medicines are regulated, with this figure rising to 87 per cent among regular users of herbal medicines (defined as those who have used a herbal medicine within the last two years). Is Taverne really saying that the public is foolish in its use of herbal medicine and in its clearly expressed wish to have its practitioners properly regulated?

As to evidence; those in glass houses should not throw stones. Taverne clearly assumes that mainstream medical practice is mostly based on evidence-based medicine. Recent findings published in the BMJ's online Journal Clinical Evidence shows that far from having a complete evidence base, only about 13 per cent of 2,500 medical treatments surveyed are rated as beneficial, with 46 per cent "of unknown effectiveness". But there is plenty of evidence on the efficacy of herbal medicine; there are scores of scientific papers on the efficacy of commonly used herbal medicines such as ginger, garlic, hawthorn etc. Indeed, who could doubt the medical efficacy of botanic medicines, since many modern drugs are derived from plant medicines?

Interestingly, it is not just plant medicines themselves that modern medicine has exploited: more recently, it has come

to adopt a strategy central to traditional herbal treatment which harnesses the healing potential of several medicaments together for their synergistic effect, rather than using one herb at a time. These days it is common for doctors to prescribe a number of drugs together, as seen in the treatment of a wide range of serious diseases like HIV, Aids, TB, malaria, diabetes, hypertension, cancer, MRSA etc.

Pharmacologists now acknowledge that the individual actions of one drug are subject to modification by a second drug and that multi-drug regimens ('combination therapy') may confer unique and beneficial new actions that do not occur when using each drug on its own. Moreover, it has become evident that combination therapy can frequently attain the same therapeutic effect as when using a single drug, but with fewer deleterious side effects. Last week scientists announced that they had found that a combination of pomegranate rind, vitamin C and a metal salt gave good results in combating the MRSA superbug.

Perhaps modern medicine has still much to learn from herbal medicine. The frank protectionism Taverne and his colleagues now display is yet another way that he and 'Sense about Science' ill-serve the public interest.

Taverne's question and the Government response are recorded in *Hansard* and read a bit like the text of a Monty Python sketch with everyone revealing their astrological sign. This is how it went...

House of Lords Debate

Alternative Medicine: Astrologers

Question

11.21 am

Asked By *Lord Taverne*

To ask Her Majesty's Government whether, following their proposals to regulate practitioners of alternative medicine, they plan to regulate astrologers.

Baroness Thornton: No, my Lords, the Government have no plans to regulate astrologers.

Lord Taverne: My Lords, I declare an interest as chairman of the charity Sense About Science. The forms of alternative medicine which the Government propose to regulate have as much scientific basis as astrology. As official regulation is likely to give such practices a spurious scientific reliability and respectability, is it not unfair to leave out astrologers? More seriously, will the Government note that august bodies of proper scientists—the Medical Research Council, the Royal College of Pathologists, the Academy of Royal Medical Colleges and other eminent professional bodies—

strongly oppose the proposed regulation? Will the Government ignore the assiduous lobbying for pseudoscience from Clarence House?

Baroness Thornton: My Lords, I am aware that the noble Lord is making a wider and serious point about alternative therapies. At present there is no statutory regulatory system in the United Kingdom to govern the practice of complementary and alternative medicine, with the exception of chiropractitioners (sic) and osteopaths who are regulated by statute. We are undertaking a consultation exercise to determine whether and, if so, how to regulate the practitioners of acupuncture, herbal medicine and traditional Chinese medicine. The Science and Technology Committee of this House suggested that we should address that issue. No other complementary therapies, including medical astrology, are within the scope of this consultation and we have no proposals to regulate in any of these other groups.

Baroness Pitkeathley: My Lords, I declare an interest as chair of the Council for Healthcare Regulatory Excellence. I remind the House and the noble Lord who asked the Question that the purpose of regulation is to protect the public, and that is what we try to do. However, in order to help me do my job better, can my noble friend give me a definition of medical astrology?

Baroness Thornton: My Lords, medical astrology is traditionally known as iatromathematics and is an ancient medical system associated with various parts of the body, diseases and drugs and the influence of the sun, moon, planets and the 12 astrological signs. For example-I did the research on this issue myself-the noble Lord, Lord Taverne, and I share the same birth sign, Libra, which apparently rules excretory functions through the kidneys and skin. I could go on about lumbar regions but noble Lords will get the picture. I am happy to say that the underlying basis for medical

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astrology is considered to be a pseudoscience and superstition as there is no scientific basis for its core beliefs. The Government remain neutral on this issue.

Earl Howe: My Lords, does the Minister share my view that this is an uncharacteristically flippant Question from the noble Lord, Lord Taverne? Does she accept that statutory regulation is not a badge of rank but exists, as the noble Baroness, Lady Pitkeathley, has just said, to safeguard the public? The key regulatory bodies-the Health Professions Council and the Medicines and Healthcare products Regulatory Agency-have both concluded that acupuncture and herbal medicine practitioners should be subject to statutory regulation.

Baroness Thornton: The noble Earl is quite correct and I concur with him that this is a very serious matter. Although we do not specifically promote or endorse the use of complementary or alternative medicine, we have to appreciate that a high proportion of the population actually uses these medicines, and our concern, as my noble friend said, is to protect patients. Responsible complementary

practitioners adhere to codes of ethics, know the limits of their competence and make appropriate referral of patients to orthodox practitioners where there is potential risk to their health and well-being. However, the noble Earl is completely correct-we have to look to how best to safeguard patients in respect of those complementary medicines such as acupuncture and Chinese herbal medicines that have the potential to cause harm. Therefore we need to take serious action to make sure they are regulated in the correct fashion.

Baroness Tonge: My Lords, I confess to being an Aquarian, and share my birth date with Copernicus and my Auntie Ivy, although I have to say that my Auntie Ivy had much more influence on me than my birth sign. However, on a more serious note, does the Minister agree that the popularity of mumbo-jumbo such as astrology and many forms of alternative medicine is due to the fact that people have very little scientific education at school? Will she say what this Government, in their 10 years in power, have done to further education in science and mathematics?

Baroness Thornton: We have done a great deal for further education in science and mathematics, although that is not exactly what this Question was about. I agree with the noble Baroness that of course people often turn to things like medical astrology because they do not understand the basis of whatever ailment it is they are looking at, and that can be a risky thing to do. However, I simply do not accept this Government have not put a significant amount of investment into mathematics and science in our schools.

Baroness McIntosh of Hudnall: My Lords-

Lord Rees of Ludlow: My Lords-

The Minister of State, Department of Energy and Climate Change (Lord Hunt of Kings Heath): My Lords, we have not heard from the Cross Benches yet.

Lord Rees of Ludlow: My Lords, I declare an interest as Astronomer Royal, and therefore as someone who could enhance his income hugely by becoming an astrologer and offering horoscopes. Does the Minister agree that, even though were we in India it might be appropriate to regulate astrology because government ministers there, one is told, are heavily guided by it, in this country to do so might imply that the problem has rather more seriousness that it really deserves?

Baroness Thornton: The noble Lord is completely correct.

Baroness McIntosh of Hudnall: My Lords, does my noble friend agree that we should indeed have no truck with pseudoscience? As it happens, I have some sympathy with the point that the noble Baroness, Lady Tonge, raised about the teaching of science and mathematics. None the less, there are, as Hamlet observed,

"more things in heaven and earth ... than are dreamt of in your philosophy",

and some very respectable branches of medicine were once alternative in their day. Therefore, it is important that we keep an eye on the things in which people invest confidence, and make sure, as my noble friend Lady Pitkeathley observed, that they do not cause harm.

Baroness Thornton: My noble friend is right. Complementary and alternative medicine therapies have proven to be effective, cost-effective and safe. Decisions about which treatments to commission and fund, for example, are the responsibility of the NHS locally, and indeed primary care trusts often have their own policies about funding complementary medicine such as osteopathy or chiropractic. Indeed, we are funding research into complementary therapies, for example in the care of cancer patients.

Lord Harris of Haringey: My Lords, I speak to the Minister as a fellow Libran. Is she satisfied with the quality of regulation of therapies such as psychotherapy? Is it still the case that anyone can set themselves up as a college of psychotherapy or any other therapy, and offer diplomas and apparent validation to practitioners whose skills may be negligible?

Baroness Thornton: My noble friend raises an important point, which the House has discussed in the past year. I had a huge postbag about that; I was inundated by suggestions from psychotherapists of all different kinds on this issue. My noble friend is quite right that there is an issue, and the department is looking at it. **[this debate ends]**



BMJ articles and responses

An editorial in the *BMJ* (19 -26th) Dec. Gave arch-anti -Cam ranter David Colquhoun a further opportunity to climb aboard his soapbox to launch another attack on the notion of our regulation.

“The Pittilo report recommended official recognition by statutory regulation and entry by honours degree. But you cannot start to think about a sensible form of regulation unless you first decide whether or not the thing you are trying to regulate is nonsense. This idea, however, is apparently lost on the Department of Health and the authors of the Pittilo report. Fortunately, consultation on statutory regulation has attracted many submissions that point out the danger to patients of appearing to give official endorsement to treatments that have no proper evidence base. The Royal College of Physicians seems to have experienced a major change of heart: its submission points out with admirable clarity that the statutory regulation of things that don't work endangers patients (though they still have a blind spot about the evidence for acupuncture, partly as a result of the recent uncharacteristically bad assessment of the evidence by NICE). Such enlightenment doesn't extend to the Prince of

Wales, who made a well publicised intervention on behalf of herbalists after the public consultation closed.”

There were some good rapid responses to this. Here are those from George Lewith, Mike Pittilo and Adrian White.

Prof. Lewith: No-one would agree that we should legitimise quack medicine and snake oil salesmen as Colquhoun seems to imply in his recent editorial(1). However, acupuncture has been rigorously investigated for a number of painful conditions in large, rigorous, randomised controlled trials and it appears to work almost twice as well as standard conventional care for chronic benign conditions such as back pain, osteoarthritis of the knee, migraine and headache (2) . Furthermore, there is some evidence that it is cost-effective (3) as well as being safe. The science therefore supports its more widespread use.

The main thrust of the House of Lords' Report (4) with respect to regulating herbal medicines and acupuncture was too ensure public safety with appropriate and safe standards for clinical practice and herbal medicine provision. The process of regulation and consequent improved standards of practice has been part of the development of clinical medicine for the last 100 years and in this instance has been actively supported by the Royal College of Physicians, the MHRA and the Health Professions' Council (HPC). There was no suggestion in the original House of Lords' Report or from Professor Michael Pittilo that these therapies would be automatically provided by the NHS without a proper assessment by NICE. It is interesting, however, that NICE now recommended the provision of acupuncture for back pain prior to the regulation of acupuncturists. Ernst suggests that there is no evidence for Chinese herbal medicine (5), but the systematic review that he co authored failed to search or review the available and substantial volume of Chinese literature when coming to this conclusion. This happened in spite of the fact that there is an excellent Cochrane Centre for Traditional Chinese Medicine in Beijing that is more than willing to cooperate in such endeavours and is actively promoting evidence based practice.

If we fail to adequately regulate the provision and practice of herbal medicine and acupuncture we place vulnerable patients at greater risk from quacks and charlatans. This is particularly important for those who practice traditional medicine among ethnic minorities in the Asian and Chinese communities. The MHRA is also very concerned about the illegal import of unregulated and potentially unsafe herbal product and the HPC is happy to regulate these professions. It was never intended this issue should be a debate about evidence from randomised controlled trials or indeed a turf war about legitimising practice. The proposed legislation for both product and practitioners could do much to safeguard public safety, both in the UK and throughout the EU; indeed that is the whole point of this process.

Prof. Pittilo: In the editorial 'Secret Remedies 100 years on', Colquhoun makes assertions about the Department of

Health (DH) Steering Group and its recommendations (1) that are unfounded. Given that a public consultation has only recently closed, Colquhoun's views should not be seen as representative.

He states, as he has done before (2), that decisions must be taken on whether or not disciplines being considered for statutory regulation represent "nonsense" or are sufficiently grounded in science and evidence-based practice to justify regulation. If acupuncture and herbal medicine are "nonsense", his view is that statutory regulation may give official endorsement to treatments that have no proper evidence base. Colquhoun wrongly asserts that the steering group and the DH lost this important point. On the contrary the report states clearly that NHS funding should only be available to CAM where there is evidence of efficacy, safety and quality assurance (3) and considerable attention was directed to a review of how best to implement meaningful research. My own view is that both statutory regulation and the quest for evidence should proceed together, and in the interests of patient safety, the latter should not be an absolute prerequisite for the former (4). After all, in conventional medicine, many treatments prove ineffective as research proceeds, but for the protection of patients, practitioners are regulated while they practise according to current evidence. Lastly, public demand for CAM indicates that as many as 10.6% of adults in England have accessed the more established therapies. Regardless of the views of orthodox practitioners, there is high demand and regulation to protect the public is a priority.

Over the past ten years there have been several reports and consultations on CAM initiated by the Department of Health, and a timeframe for implementing statutory regulation was published in 2005 (5). Some have questioned whether the recent consultation was a good use of public money given the thoroughness with which the DH has examined this issue over many years.

Adrian White: Colquhoun's commentary exposes an important dilemma for science publishing: does healthcare benefit more from passionate polemic unrestrained by peer review, or from carefully constructed argument and balanced, well informed writing?

Science begins with definitions. Colquhoun defines acupuncture as: 'A rather theatrical placebo, with no real therapeutic benefit in most, if not all, cases.' This definition comprises vague, ambiguous terms and is internally inconsistent. Either it is intended as a joke, or it is opinionated bombast. It is not a serious contribution to a debate on health care, and would never have passed peer review. It may be appropriate for the Boy's Own Journal, but it is alien to the kind of scientific debate we expect in the BMJ.

In fact, this definition fits Colquhoun's own criticism of the homeopathic literature, a few lines higher in the commentary. I quote: '... a parody of scientific writing, in a style that Ben Goldacre calls 'sciencey'. It reads quite plausibly [well, that bit doesn't fit!] until you check the references.' So check the references, and Colquhoun cites – his own blog! That source of balanced debate well known to

be based on reasoned argument and critical analysis. When I contributed some data to the blog, in the form of standardised mean difference and confidence intervals from a systematic review of acupuncture, it met the predictable two responses: Doh (as in 'I haven't actually read the studies or meta- analyses on acupuncture') ; and, And Anyway (as in 'And anyway, acupuncture can't work because qi and meridians don't exist').

Colquhoun's view on the role of blogs is summarised succinctly in his book review, Trust me, I'm a scientist [1]. Again I quote: '... individual scientists have found they can write their own blog. It costs next to nothing, and you can say what you think.' Great, no need for those tricky peer reviews, then, to restrain these vital contributions to the scientific debate.

So this blogger now spreads his bombast onto the hallowed turf of a respected scientific journal. Is generating interest and a response – in whatever way is necessary – so crucial that the BMJ can sustain its policy of publishing commentaries without peer review?

Also worth reading is the rapid response to another article about regulation in the BMJ (2nd Jan 10) by Nigel Hawkes, "a spanner in the herbal works". The response from Jon L Wardle, Research Scholar, University of Queensland, reads:

Nigel Hawke's overly simplistic synopsis of the issue of regulation of complementary therapists misses the point entirely.

The issue of credibility of complementary medicines is now moot. More than half the populations of most developed nations now utilise the services of complementary therapists and a sizeable proportion rely on these therapists as their primary care providers[. In the eyes of the public these therapists already enjoy the legitimacy and credibility the Royal College of Physicians fears will be conferred by the legislation. However, without an appropriate regulatory regime in place these therapists also enjoy freedom from any responsibility or accountability that would normally come with such a role.

Regulation would ensure minimum standards of training – not just in 'crystal therapy', 'rebalancing Qi' or 'miasms' as many detractors fear but in basic health sciences as well. This not only informs therapists in dispensing their own therapies but also allows practitioners to identify the limitations of their therapies and refer appropriately. Moreover, a regulated environment means they would be required to do so. This is particularly important considering that acts of omission (such as the opportunity costs borne by not referring serious cases), often form a greater risk than acts of commission when discussing complementary therapists. Statutory regulation also provides very clear guidelines, processes and pathways for punitive action in cases of negligence, incompetence or financial exploitation. The current situation means that unless an aggrieved party is

prepared to undergo a long, protracted and often expensive civil case, the perpetrators of many of these nefarious behaviours are often left free to unleash these behaviours on new and unsuspecting patients. Lack of appropriate legislation or regulation has meant that in extreme cases some practitioners have even been able to continue practising whilst charged with multiple sexual crimes against patients. The current situation is of course untenable.

This is a public health issue, not professional politics, and deserves to be treated as one without emotive and often misinformed arguments about legitimisation or aspirant professions coming into play. Suggestions such as those made by the Royal College of Physicians serve only to run the risk of driving complementary therapies even further underground and the therapists even further from accountability. Not only does this deny the choice of the patient of what is in many instances an entirely valid option but it also exposes the public the unnecessary and unwarranted risk.

Throwing the baby out with the bath water helps no-one – least of all the patient. There are thousands of clinical trials and over 500 systematic reviews suggesting that many complementary therapies - many of them herbal - are doing more good than harm, though it is usually the more 'exotic' and untested therapies that detractors point to as being 'representative'. Tarring all complementary therapists or therapies with the same brush is akin to quashing all surgical interventions because of the actions of a few rogue surgeons or slamming all pharmaceutical interventions when the findings of 'the next Vioxx' become known. The public will continue to see complementary therapists. Making these therapists legally accountable for their actions will ensure that the public are afforded protection when doing so.

Article from the Independent Herbalism: Kill or cure? 5/1/2010

Line after line of colourful cardboard boxes hug the edges of a stack of shelves. Sitting inside a herbal remedy store in west London, the containers' evocative images of plants, bark and berries are emblematic of the natural world's healing properties.

But soon, such remedies, sold by the likes of herbal medicine retailers such as Cornucopia, run by 91-year-old Margaret Weesz just off the capital's King's Road, could be in trouble. From 2011 European law will dictate that sales of all herbal remedies will need to be licensed by the Government. Licenses are likely to only be granted to a small number of products for minor ailments, which include St John's Wort (used to treat low mood) and echinacea (which can cut the chances of catching a cold). This will hugely restrict the practices of the country's 750 herbalists – as well with the UK's Chinese herbalists – who use a blend of many herbs to treat major ailments that can include everything from epilepsy to hysteria.

"It's just silly," says Weesz, who sells a wide variety of herbs at her shop, many of which are likely to be banned. "I have a number of different herbs which I import from all over the world. In Italy, I can buy them in the chemist so I don't see why I can't do the same thing here. I want to go to the House of Commons and tell them about the clinical evidence for the herbs that I sell. The Government could save a lot of money through using herbs instead of expensive medicines."

For some, though, the legislation could not come soon enough. Many in the medical world say there is scant clinical evidence that herbal remedies are of any use at all – and those that are can have harmful side effects. In 1993 Professor Edzard Ernst left his chair in physical medicine and rehabilitation at the University of Vienna to set up the department of complementary medicine at the University of Exeter. Since then he has written more than 700 papers in an attempt to scientifically test herbalists' claims regarding complementary medicine.

"I am keen not to write off herbal medicine because scientifically, around half of modern drugs were derived from herbs," he says. "But it is important to realise that herbs are pharmacologically active compounds and can cause harm and sometimes even kill." He says there is evidence to suggest some herbs work: like devil's claw, used to treat back pain, or St John's Wort, which can effectively treat depression.

He does, however, have less approving words to say about Britain's herbalists. "They assess you according to a series of criteria that are obsolete in modern medicine," he says. "They then treat you according to a further list of rules before giving you their individually tailored treatment." He says there is little scientific evidence to suggest this approach works. "We have reviewed the work published and conclude there is no evidence that this type of herbalism does more good than harm," he continues. "That is to say, the potential for harm is greater than the potential for good."

So what do the herbalists think? The European Herbal and Traditional Medicine Practitioners Association chair Michael McIntyre says a herbalist is someone who uses plant medicines to "restore and strengthen the body's systems". "Oats can strengthen the nervous system," he explains. "If you are very stressed we might give you skullcap [a type of mint] or valerian [a flowering plant which has sedative properties]." He says far from being quacks, herbalists are following a tradition that has been practised for thousands of years, and have often studied for several years to become experts in their craft. What's more, when confronted with a serious medical complaint, they will often refer the patient to a traditional doctor. But when they can, herbalists rely on taking long medical histories, analysing people's constitution, diet and lifestyle, before treating the patient with a complex, individually tailored combination of natural substances.

"What I would say is that clinical trials work in a reductionist way whereas herbalists don't," says Kent-based herbalist Hayley Jones. "In orthodoxy there is no room for synergy or interactions between different things, which is

what herbalists talk about. We might prescribe between three to 12 herbs for a patient that are tailored specifically to their make-up; there is no one-size-fits-all prescription, which is something doctors rely upon."

The herbalist community also takes issue with the way the Government has consulted them over their future. "The herbalist community was due to receive its own form of regulation after we were consulted earlier in the year, but out of the blue the Government appeared to change its mind and asked us again," says National Institute of Medical Herbalists spokesperson Andrew Hoyle. "But the way they organised this process was so clouded with obfuscation that even experienced medical professionals are unable to make sense of it."



Letter to MPs

As explained above, everyone should be getting their patients to write to their MPs and to help this we have written a standard for letter that could be used. We suggest that each correspondent adds a sentence or two to the letter to say why he/she is a supporter of herbal medicine. This will personalise the letter and give it more impact.

Letter

Dear

The statutory regulation of practitioners of herbal medicine and acupuncture

I am a user of herbal medicine and am writing to you to urge the Government to move to statutory regulation of herbal practitioners without delay.

As you may be aware, The Department of Health (DH) recently consulted on the proposed statutory regulation (closing date 16/11/09) of herbal/traditional medicine, TCM and acupuncture practitioners.

Statutory regulation of herbal practitioners is a matter of considerable public interest. Recent research by Ipsos MORI for the Medicines and Healthcare products Regulatory Agency (MHRA) has found that millions of people in the UK use herbal medicines. In particular:

- more than a quarter of the population had bought herbal medicines over-the-counter in the previous two years;
- one in twenty had consulted a practitioner of traditional Chinese Medicine;
- around one in twelve had consulted a practitioner of Western herbal medicine.

- 77% of adults agree it is important that herbal medicines are regulated, with this figure rising to 87% among regular users of herbal medicines (defined as those who have used a herbal medicine within the last 2 years).

Statutory regulation has been under consideration for a decade since the call in 2000 from the House of Lords' Select Committee on Science and Technology for the statutory regulation of practitioners of herbal medicine and acupuncture. The Government itself backed statutory regulation of this sector in 2001 and more recently key regulatory bodies, the Health Professions Council (HPC) and the Medicines and Healthcare products Regulatory Agency (MHRA) have both concluded that, like the osteopaths and chiropractors, acupuncture and herbal medicine practitioners should be subject to statutory regulation. As recently as 2006 the DH website recorded that "*The Government is committed to the statutory regulation of herbal medicine, acupuncture and traditional Chinese medicine practitioners.*"

Over the past eight years the Department of Health (DH) has initiated three working groups to look at implementing this policy. All three working parties strongly supported the aim of statutory regulation of this sector. In 2005, the DH ran a public consultation on the statutory regulation of herbal medicine and acupuncture. This registered a 98% response in favour of statutory regulation. As a consequence the DH published a timetable for the statutory regulation of this sector with a section 60 order (the legal process to bring this about) to be published later that year. This timetable has not been adhered to. The Government says it will make a decision on this matter but continues to dilly-dally. As explained below, if statutory regulation does not go ahead with immediate effect, there will be a significant loss of consumer choice and huge damage to many small and medium sized businesses across the herbal supply and manufacturing sector as well as to many herbal practices throughout the UK. **It is clear that in not making a decision to go ahead with statutory regulation, the Government is effectively undermining herbal medicine practice in this country.**

Why is statutory regulation vital?

Firstly it is important to ensure that those practising herbal medicine are properly qualified. Today, most practitioners are educated to degree level with a curriculum which includes a significant amount of orthodox training such as pharmacology and differential diagnosis. However, there is currently no regulation whatsoever: anyone, whether trained or not, can call themselves a herbalist or traditional practitioner and gain access to powerful herbal medicines. This is clearly not in the public interest.

A second important reason for statutory regulation is that if it fails to go ahead there will be a loss of a wide range of herbal medicines currently supplied by practitioners to their patients. Full implementation of the new European Traditional Herbal Medicine Directive in April 2011 will see the end the right of practitioners to access finished medicines from manufacturers and herbal suppliers for prescription to individual patients. This includes all finished products such as medicinal herbal pills, tablets, capsules, dried herb mixtures and medicinal herbal ointments made up for individual patients by third-party suppliers. Also

under threat are third-party herbal prescription services that supply individualised herbal prescriptions (including those comprising tinctures and dried herbs) to named patients at the practitioner's request. Over the past 40 years this mode of supply has become an essential part of herbal practice in the UK and many practitioners are totally reliant on such services. All that will remain will be herbal medicines prepared by practitioners from their own premises. Thus without statutory regulation, from April 2010, many patients will be unable to obtain their usual medicines. The loss of this facility will put many practitioners and several of their suppliers out of business. This will further damage the UK economy and swell unemployment during the current economic downturn.

The loss of planned arrangements to enable continuing supply, under the supervision of the MHRA, will undoubtedly mean an unacceptable increase in the purchase of unregulated medicines via the internet and from bogus back-street traders. Such products lack any reliable quality assurance and some have been found to be illegally mixed with conventional drugs.

Lack of statutory regulation puts the public at significant risk!

How will statutory regulation assure the range and quality of herbal supply?

The MHRA has proposed that third-party medicines supplied on request of statutorily regulated practitioners for individual patients can continue under MHRA licence via Section 5.1 of the main European Medicines Act 2001/83/EC⁴. The key point here is that this facility is only available to statutory regulated health professionals.

In short, if herbal practitioners were to secure 'authorized health care professional' status through statutory regulation, they could legally commission herbal medicines from manufacturers for supply to their patients. These would have to be made to assured medicinal quality. The statutorily registered herbal practitioner would ensure high standards in the supply of the many useful traditional medicines for the benefit of patients. The public will have a professional group able to deliver expert herbal treatment tailored to the individual. Herbalists will be a source of information and education about the use of herbal and traditional remedies.

I hope you will agree that these are all compelling reasons why the Government should, honour its previous commitment and adopt statutory regulation for herbal medicine and acupuncture without further delay. I would be most grateful if you were to press this case home with the Minister of Health.

Yours sincerely,

Remember to add a few personal words as to why you support herbal medicine at the beginning or end of the letter.

⁴~~This proposal can be read in detail~~ on the MHRA website at <http://www.mhra.gov.uk/home/groups/es-herbal/documents/websiteresources/con2024908.pdf>

WHO

In December 2008, the World Health Organisation (WHO) published a statement on Traditional Medicine. This says:

WHO and its Member States cooperate to promote the use of traditional medicine for health care. The collaboration aims to:

- *support and integrate traditional medicine into national health systems in combination with national policy and regulation for products, practices and providers to ensure safety and quality;*
- *ensure the use of safe, effective and quality products and practices, based on available evidence;*
- *acknowledge traditional medicine as part of primary health care, to increase access to care and preserve knowledge and resources; and*
- *ensure patient safety by upgrading the skills and knowledge of traditional medicine providers.*

Gaining statutory regulation will ensure these aims are met in the UK.....



2010 Diary Date

“Save Herbal Medicine” Mass Lobby **3rd February 2010** Time: 1200 – 1600 hrs

EHTPA Council meeting dates for 2010:

8th February; 17th May; 13th September; 13th December