



D. Colquhoun FRS
Professor of Pharmacology
Pharmacology, UCL,
Gower Street, London WC1E 6BT

Phone: (+44)-(0)20-7679-3765
Fax: (+44)-(0)20-7679-7298
email: d.colquhoun@ucl.ac.uk
web: <http://www.ucl.ac.uk/Pharmacology/dc.html>

2 October 2009

(This document is submitted by me, not by UCL)

Submission to the Department of Health, for the consultation on the Pittilo report

The gist of my submission is that the sort of things that are taught on courses in Herbal Medicine (HM) and Traditional Chinese Medicine (TCM) endanger the public (and are sometimes illegal). It follows that implementation of the recommendations of the Pittilo recommendations would endanger the public and is therefore undesirable. This case can be made convincingly, simply by looking at what the courses teach (I have provided examples). This is sufficient reason to reject Pittilo's recommendations before we even get to the point of asking whether or not the treatments work

The government has said frequently that it wishes to be guided by the best scientific evidence. It's true that they rejected the advice of David Tredinnick (Conservative, Bosworth) that the 2001 outbreak of foot and mouth disease should be treated with homeopathic borax, Nonetheless, the Department of Health (DH) has a record of consistently avoiding to act on evidence when it comes to alternative medicine, It is critically important that the Department of Health does not, once again, dodge the question of what works and what doesn't. In evading that question, the DH is endangering the public.

There is much talk of "well-trained practitioners" but the question cannot be avoided of what it means to be "well-trained" in a therapy that is ineffective. If the Department of

Health wishes to retain a reputation for relying on the best scientific evidence, it is essential that this question should not, once again, be brushed under the carpet. The decision on the Pittilo report gives an opportunity to demonstrate that the DH really takes evidence seriously.

The main harmful recommendations of the Pittilo report are

- Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine should be subject to statutory regulation by the Health Professions Council (HPC)
- Entry to the register normally be through a Bachelor degree with Honours.

In this submission I shall concentrate on how both of these recommendations would reduce patient safety and compromise medical integrity.

It should be noted that the Pittilo report was written essentially by five acupuncturists, five herbal medical practitioners and five Chinese herbal medicine advocates (plus 11 observers). So every member of the committee would have their income reduced if they came to any conclusion that did not promote the interests of these forms of alternative medicine. The fact that these direct financial interests were not declared in the report is a breach of ethical standards, but it does account for the execrable standards of the assessment of evidence in the report.

Patient safety is paramount, but the Pittilo proposals will endanger it.

I agree with [Ann Keen, Health Minister, who said:](#)

“Patient safety is paramount, whether people are accessing orthodox health service treatments or using alternative treatments”

So first we need to identify what dangers are posed by acupuncture, herbal medicine and traditional Chinese medicine.

- Acupuncture is fairly safe. Its biggest danger lies in the unjustified claims that are routinely made for what can be achieved by being impaled by needles. This poses a danger that people may use acupuncture in place of treatments that work
- Herbal medicines are unstandardised, so even the very few that may work are dangerous to patients because the dose of active principle is unknown and varies from one batch to another. Taking a herbal medicine is a bit like swallowing a

random number of tablets, False health claims pose a danger to patients too, when they cause patients to avoid treatments that work.

- Traditional Chinese Medicine is probably the most dangerous. Like the other two, the medicines are unstandardised so the dose is never known. False health claims abound. And in addition to these dangers, many cases have been found of Chinese medicines being adulterated with poisonous substances or with conventional drugs and they not infrequently use endangered species.

The form of regulation proposed by Pittilo would do little or nothing to protect the public from any of these dangers.

Unstandardised means dangerous

The proposals accept the herbal and Chinese medicine as traditionally practised. Nothing would be done about one of the major dangers, [the lack of standardisation](#). That is a problem that was solved by pharmacologists in the 1930s, when international standards were set for the biological activity of things like tincture of digitalis, and assays were devised so that different batches could be adjusted to the same potency. Now, 80 years later, it is being proposed by Pittilo that we should return to the standards of safety that existed at the beginning of the last century. That is a major threat to patients' safety, but the proposed regulation would do nothing whatsoever to protect the public from this dangerous practice. On the contrary, it would give official government sanction to it.

The other major danger is that patients are deceived by false health claims. This is dangerous (as well as dishonest) because it can cause patients to avoid treatments that work better, The internet abounds with claims that herbs can cure anything from diabetes to cancer. Many are doubtless illegal, but regulators like the HPC have traditionally ignored such claims: they are left to Trading Standards, Advertising Standards and the Medicines and Health Regulatory Authority (MHRA) to deal with. The MHRA already also has responsibility for monitoring side effects. The HPC would not do this.

In fact the HPC has already explicitly ruled out any consideration of whether the treatments it would regulate work or not.

That omission is what endangers patients' safety.

The Health Professions Council breaks its own rules.

If the suggestions were to be accepted, it would put the HPC in breach of its own rules. Their rules state that "[Practise based on evidence of efficacy](#)" is a condition for registration. Since there is practically no "evidence of efficacy" that should rule out the HPC as a regulator. However, bafflingly, the HPC has expressed its willingness to waive its own rules. The HPC published a report on 11 September 2008, [Regulation of Medical Herbalists, Acupuncturists and Traditional Chinese Medicine Practitioners](#). The report says

“ The accepted evidence of efficacy overall for these professions is limited, but regulation should proceed because it is in the public interest.”

In other words, the [HPC simply decided to ignore its own rules](#), Its excuse for doing so is that regulation would protect "public safety".

I provide evidence here that, on the contrary, acceptance of the proposals would endanger patients.

The analogy with chiropractic and the GCC

The foolishness of allowing statutory regulation for unproven treatments has recently been illustrated quite dramatically by the case of chiropractic. Chiropractors have had statutory regulation by the General Chiropractic Council, which was established by the Chiropractors Act of 1994.

The [British Chiropractic Association \(BCA\)](#) recently decided to sue the science writer, Simon Singh, for defamation when he cast doubt on some of the claims made by chiropractors, in particular their claims to be able to cure colic and asthma in children. That led to close examination of the claims. In fact there is no reason to think that spinal manipulation [works for asthma](#), or that it works [for colic](#). In fact there is quite good evidence that the claims are false. The result was that about 600 well-justified complaints have been lodged with the GCC (enough to bankrupt the GCC if the complaints are dealt with properly).

The point of this story is that the statutory regulator had nothing whatsoever to prevent these false health claims being made. Two of the complaints concern submitted to the GCC refer to practices run by the chair of the GCC. Worse, the GCC actually endorsed such claims (and as a consequence, the GCC itself has been referred to the .Advertising Standards Authority).. The statutory regulator saw its duty to defend

chiropractic (apart from a handful of cases of sexual misdemeanours), not to protect the patient from false health claims. The respectability conferred by statutory regulation made false health claims easier and endangered the public. It would be a disaster if the same mistake were made again.

On 11th December 2008 I got a letter from the HPC which said

“ . . . in our opinion a lack of evidence of efficacy would not impede our ability to set standards or deal with complaints we receive. The vast majority of cases we consider are related to conduct.”

No doubt they are right to say that most complaints regard conduct. But the only reason for that is because they haven't tried “regulating” alternative medicine before. Now that the public and the media are far more conscious about health fraud than it used to be, one can predict confidently that the HPC would be similarly overwhelmed by a deluge of complaints about the unjustified health claims made by acupuncturists, herbal medicine and traditional Chinese medicine practitioners. There is no shortage of things to complain about. When this happens, it will not reflect well on the judgement of the DH. It will also cost a great deal in legal fees that must be borne by the Statutory Regulator.

How much should be spent on research?

The [Pittilo report](#) (page 11) says

“In future, it is hoped that more Government funding can be allocated to research into traditional/herbal medicines and acupuncture and that grants will become available to encourage practitioners to undertake postgraduate research work.”

Likewise The [HPC report](#) (page 5) cites these with the words

“ . . . a lack of evidence of efficacy should not prevent regulation but that the professions should be encouraged and funded to strengthen the evidence base.”

These statements, especially the latter, are quite remarkable because they carry the implicit assumption that the outcomes of research will be to *strengthen* the evidence base. If the outcome of the research were to be to show that the treatments are ineffective then the HPC and the Department of Health would look pretty silly.

Thus far, the outcomes of research *have* been largely negative. The Pittilo group has apparently not noticed that the US National Institutes of Health has already spent a billion dollars on research in alternative medicine over ten years and has *failed to come up with a single effective treatment*. See, for example [\\$2.5B Spent, No Alternative Med Cures found](#). (copy attached). An enormous amount of research has already been done and the outcomes have produced no good treatments. Doing yet more is not a good way for the government to spend money.

Bachelor of Science degrees

It is a central recommendation of the Pittilo report that entry to the register normally be through a Bachelor degree with Honours.

There are three major problems with this suggestion.

- (1) Recent revelations about what is actually taught on such courses have shown that their graduates are likely to endanger patients, rather than ensure their safety. This statement is justified by the examples in the accompanying document, *What is taught in degrees in alternative medicine?*
- (2) Partly as a consequence of this, universities are closing down courses in Complementary and Alternative medicine. The University of Salford and the University of Central Lancashire have recently shut down all their courses in this area, and the University of Westminster (previously the biggest provider) has shut down two courses, with more to close soon. Universities have realised that these courses are inappropriate for BSc degrees. To try to make them compulsory at this stage would be absurd, and doomed to failure.
- (3) If more courses were created to satisfy the Pittilo requirement, not only would it reverse the well-founded decision of universities that these subjects are not appropriate for a BSc degree. It would also be a huge drain on the public purse.

It is worth going into some detail about the content of some of the degrees in question, because this has not been known widely until recently. Part of the reason why the content was not known is because the universities concerned are desperate to avoid embarrassment by allowing the public (who largely pay for the courses) to see the material. Despite the [recent ruling by the Office of the Information Commissioner](#) that teaching material cannot be withheld under the Freedom of Information act. Universities continue to deny access to the information. Indeed they often deny possession of the information, because it is taught by an external validated organisation. It seems absurd

that universities have validated external degrees without know what is taught in them. But that is the case, and it endangers patients (as well as academic standards)

It has turned out that these courses teach a mixture of myth, magic and crude 19th century vitalism. They most certainly do *not* equip practitioners to recognise potentially serious conditions. The idea that because someone has such a degree they can be called “properly trained” is absurd in the extreme.

People with this sort of qualification are a danger to patients’ safety.

The evidence for these assertions is included in a separate document entitled ‘*What is taught in degrees in alternative medicine?*’, in order to avoid making this document too long.

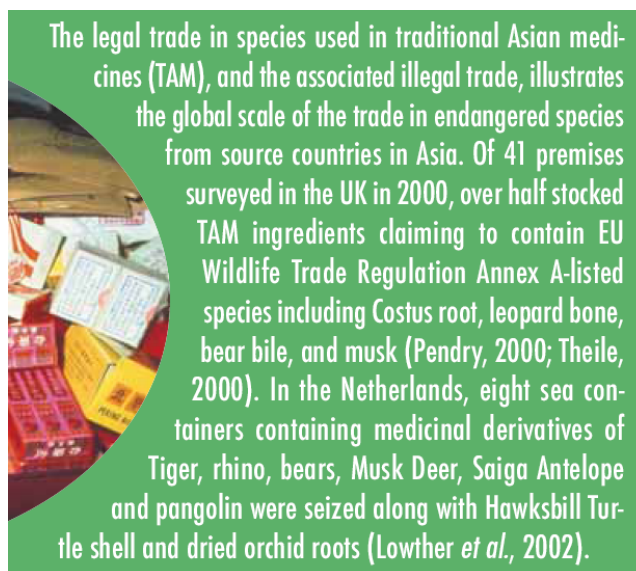
Dangers of Traditional Chinese medicine

The public is endangered by the many cases of adulteration of Chinese herbs that have been [reported by the MHRA](#) on the their web site. A [report on the problem](#) was issued by the MHRA

“Regulation “ by the Health Professions Council would do nothing to help this. It would remain the job of the MHRA.

Another very disturbing aspect of traditional Chinese medicine is its use of endangered species and the cruelty to animals that is involved in some of their products, A [publication of the World Wildlife Fund](#) listed some of them (right). The cruelty to [endangered bears](#) is particularly distressing. It is common to find [endangered species in Chinese medicines](#) sold in the UK

Again “regulation” by the Health Professions Council would do nothing to prevent abuses of this sort..



On the contrary it would make the problem worse by giving an implicit stamp of government approval of these practices.

The sort of ineffective regulation that is being proposed endangers patients.

Other organisations

Although it has been said that the Royal College of Physicians originally gave some support to the Pittilo proposals, my information is that they have reversed that view. And in conversation with the Council for Health Regulatory Excellence I gather that they too now consider that implementation of the Pittilo recommendations would endanger patients, not protect them.

An alternative approach to ensuring patients' safety

I must certainly agree with the minister that protection of the public is an important matter. I believe that I have provided compelling evidence that acceptance of the Pittilo proposals would endanger patients and set back education. It is, therefore, my responsibility to suggest what should be done instead.

Luckily, that is easy, because mechanisms already exist for dealing with the dangers that were listed above.

The monitoring of false claims, and of dangers and [side effects of treatments](#), is already the responsibility of the Medicines and Health Regulatory Authority (MHRA). The HPC could add little or nothing to what they do, and would be an additional cost for no benefit.

The matter of adulteration, which is serious in traditional Chinese medicine, is a matter that is already the responsibility of the Office of Trading Standards. The major problem of false claims being made for treatment is also the responsibility of the Office of Trading Standards, which has a statutory duty to enforce the Unfair Trading Consumer Protection Regulations of May 2008. [These laws state, for example, that](#)

“One of the 31 commercial practices which are in all circumstances considered unfair is “falsely claiming that a product is able to cure illnesses, dysfunction or malformations”

Rather than setting up complicated, expensive and ineffective ‘regulation’ by the HPC, all that need to be done is to ensure that the MHRA and/or Trading Standards have the

funds to enforce existing laws. At the moment, they are not being implemented effectively, so I'd recommend that responsibility for enforcing the law against false health claims be transferred entirely to the MHRA, which has much more expertise in such matters than Trading Standards. This would be both cheaper and more effective than the present system in which the responsibility is divided between the two organisations in an unclear way.

This proposal would protect the public against unsafe and adulterated treatments, and it would protect the public against false and fraudulent claims. That is what matters. It would do so more effectively, more cheaply and more honestly than the Pittilo recommendations.

There would be no reduction in patient choice either, There is no proposal to ban acupuncture, herbal medicine or traditional Chinese medicine. All that is necessary is to ensure that they don't endanger the public.

Since the root of the problem lies in the fact that the evidence for the effectiveness is very weak, the question of efficacy, and cost-benefit ratio, should be referred to NICE. This was recommended by the House of Lords Report (2000). It is recommended again by the Smallwood report (sponsored by the Prince of Wales Foundation). It is baffling that this has not been done already.

It does not seem wise to spend large amounts of money on new research at the moment, in the light of the fact that the US National Institutes of Health has already spent over \$1 billion on such research without finding a single useful treatment. The results of all this research has been to show that hardly any alternative treatments are effective. The DH cannot continue to ignore this fact in the way it has been up to now..

Summary

- (1) The form of 'regulation' recommended by the Pittilo report would endanger the safety of the public (and would also give the impression that the DH is not interested in evidence). The proposals should, therefore, be rejected.
- (2) The HPC would not regard it as part of its job to protect the public from false health claims. This endangers the safety of patients.
- (3) The HPC does not propose to do anything about the fact that herbal medicines are unstandardised, so those that do contain an active ingredient are given in an unknown dose. This endangers the safety of patients.

- (4) The idea that entry to the register should require a BSc (Hons) degree has been overtaken by events (see attached document). Universities have been closing down such degrees all over the country as a result of revelation of the nonsense that was being taught on them. Degrees in crude 18th century vitalism are not acceptable in the 21st century. The people who do these degrees are not competent to detect potentially serious medical problems. They endanger the safety of patients.
- (5) An alternative approach to ensuring the safety of patients is proposed. It would be both cheaper and more effective than the Pittilo recommendations. The most effective way to ensure the safety of patients is to implement existing laws on adulteration, false health claims and monitoring of side effects through the MHRA and Trading Standards officers (I'd suggest that the powers be concentrated in the MHRA which is better qualified for the job than Trading Standards). As long as these laws are enforced, patients are protected..

Attachments

[What is taught in degrees in alternative medicine?](#)

[\\$2.5B Spent, No Alternative Med Cures found.](#)

An example of dangerous (and probably illegal) claims that are routinely made by TCM practitioners ([Chinesemedicine_cancer.pdf](#))