

## Regulation of Alternative Medicine- why it doesn't work

### BALANCING MEDICAL MATTERS - OPINION

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Readers may like ---> [Colquhoun D \(2007\). What to do about CAM? BMJ. 2007;335:736.](#)

NB: All blue text in this article are hyperlinks

### Abstract

There are strong advocates and opponents to alternative medicine being widely available to the general population, whether this is over the counter or through the NHS. Indeed, if anything this area is increasingly becoming a major discussion point both medically and socially, especially with new constraints on budgets. In this balancing medical matters opinion piece, Professor David Colquhoun outlines his concerns regarding the regulation of this industry and the potential dangers and problems this may cause patients and consumers.

### Introduction

We are witnessing an increasing commercialisation of medicine. It's really taken off since the passage of the Health and Social Security Bill into law. Not only does that mean having NHS hospitals run by private companies, but it means that "any qualified provider" can bid for just about any service. The problem lies, of course, in what you consider "qualified" to mean. Any qualified homeopath or herbalist will, no doubt, be eligible. University College London Hospital advertised for a spiritual healer (Fig 1). The "person specification" specified a "qualification", but only HR people think that a paper qualification means that spiritual healing is anything but a delusion.

Figure 1 - University College London Hospital advertisement

PERSON SPECIFICATION				
POST: <u>Complementary Therapist</u> : Healer	CANDIDATE			
REQUIREMENTS	E/D <sup>1</sup>	Tested A/I/T <sup>2</sup>	MET	NOT MET
<u>Qualifications:</u> Relevant professional quals for specialism 1. Full National Federation of Spiritual Healer certificate with two years post certificate experience	E			

### The vocabulary of bait and switch

First, a bit of vocabulary. Alternative medicine is a term that is used for medical treatments that don't work (or at least haven't been shown to work). If they worked, they'd be called "medicine". The anti-malarial, artemisinin, came originally from a Chinese herb, but once it had been purified and properly tested, it was no longer alternative. But the word alternative

is not favoured by quacks. They prefer their nostrums to be described as “complementary” –it sounds more respectable. So CAM (complementary and alternative medicine became the politically-correct euphemism. Now it has gone a stage further, and the euphemism in vogue with quacks at the moment is “integrated” or “integrative” medicine. That means, very often, integrating things that don’t work with things that do. But it sounds fashionable. In reality it is designed to confuse politicians who ask for, say, integrated services for old people. Put another way, the salespeople of quackery have become rather good at bait and switch. The Wikipedia definition is as good as any:

**Bait-and-switch** is a form of [fraud](#)<sup>1</sup>, most commonly used in [retail sales](#)<sup>2</sup> but also applicable to other contexts. First, customers are "baited" by [advertising](#)<sup>3</sup> for a product or service at a low price. Second, the customers discover that the advertised good is not available and are "switched" to a costlier product.

As applied to the alternative medicine industry, the bait is usually in the form of some nice touchy-feely stuff that barely mentions the mystical nonsense. But when you've bought into it you get the whole panoply of nonsense. Steven Novella has [written eloquently](#)<sup>4</sup> about the use of bait and switch in the USA to sell chiropractic, acupuncture, homeopathy and herbal medicine: The key point is that the bait is that CAM offers legitimate alternatives, the switch is that it primarily promotes treatments (sometimes costly for individuals) that don’t work or are at best untested and highly implausible.

**The "College of Medicine"** provides a near-perfect example of bait and switch. It is the direct successor of the Prince of Wales' Foundation for Integrated Health. The Prince's Foundation was a consistent purveyor of dangerous medical myths. When it collapsed in 2010 because of a financial scandal, a company was formed called "The College for Integrated Health". [A slide show](#)<sup>5</sup>, not meant for public consumption, said "The College represents a new strategy to take forward the vision of HRH Prince Charles". However, it seems that too many people have now tumbled to the idea that "integrated", in this context, means barmpottery. Within less than a month, the new institution was renamed "The College of Medicine". That might be a deceptive name, but it's much better bait. That's why I described the College as a [fraud and delusion](#)<sup>6</sup>.

Not only did the directors, all of them quacks, devise a respectable sounding name, but they also succeeded in recruiting some respectable-sounding people to act as figureheads for the new organisation. The president of the College is Professor Sir Graham Catto, emeritus professor of medicine at the University of Aberdeen and former head of the General Medical Council. Names like his make the bait sound even more plausible. He claims not to believe that homeopathy works, but seems quite happy to have a homeopathic pharmacist, Christine Glover, on the [governing council of his college](#)<sup>7</sup>. At least half of the governing Council can safely be classified as quacks.

So the bait is clear. What about the switch? The first thing to notice is that the whole outfit is [skewed towards private medicine](#)<sup>8</sup>. The founder, and presumably the main provider of funds (they won't say how much) is the huge outsourcing company, Capita. This is company known in Private Eye as Crapita. Their inefficiency is legendary. They are the folks who messed up the NHS computer system and the courts computer system. After swallowing large amounts of taxpayers' money, they failed to deliver anything that worked. Their latest failure is the [court translation service](#)<sup>9</sup>. The College of Medicine President (Prof. Graeme Catto), the vice president (Harry Brunjes) and the CEO (Mark Ratnarajah) are all employees of Capita.

The second thing to notice is that their conferences and courses are a bizarre mixture of real medicine and pure quackery. Their 2012 conference had some very good speakers, but then it had a ["herbal workshop" with Simon Mills](#)<sup>10</sup> (see a [video](#)<sup>11</sup>) and David Peters (the man who tolerates [dowsing as a way to diagnose](#)<sup>12</sup> which herb to give you). The other speaker was Dick Middleton, who represents the huge herbal company, Schwabe (I debated with him [on BBC Breakfast](#)<sup>13</sup>). In fact the College's Faculty of Self-care appears to resemble a marketing device for Schwabe.

### Why regulation isn't working and can't work

There are various levels of regulation. The "highest" level is the statutory regulation of osteopathy and chiropractic. **The General Chiropractic Council (GCC)** has exactly the same legal status as the General Medical Council (GMC). This ludicrous state of affairs arose because nobody in John Major's government had enough scientific knowledge to realise that chiropractic, and some parts of osteopathy, are pure quackery.

The problem is that organisations like the GCC function more to promote their discipline rather than regulate them. This became very obvious when the British Chiropractic Association (BCA) decided to sue Simon Singh for defamation, after he described some of their treatments as ["bogus", "without a jot of evidence"](#)<sup>14</sup>. In order to support Singh, several bloggers assessed the "plethora of evidence" which the BCA said could be used to justify their claims. After judicial review the claim of defamation was rejected with the court decision summarised by lawyer, David Allen Green, in [The BCA's Worst Day](#)<sup>15</sup>.

In the wake of this, over 600 complaints were made to the GCC about unjustified claims made by chiropractors, thanks in large part to the work of two people, [Simon Perry](#)<sup>16</sup> and [Allan Hennessy](#)<sup>17</sup>. Simon Perry's [Fishbarrel](#)<sup>18</sup> allows complaints to be made quickly and easily. The majority of these complaints were rejected by the GCC, apparently on the grounds that chiropractors could not be blamed because the false claims had been endorsed by the GCC itself. My own complaint was based on phone calls to two chiropractors, [I was told](#)<sup>19</sup> such nonsense as "colic is down to, faulty movement patterns in the spine". However, my complaint never reached the Conduct and Competence committee because it had been judged by a preliminary investigating committee that there was no case to answer. The impression one got from this (very costly) exercise was that the GCC was there to protect chiropractors, not to protect the public.

The outcome was a disaster for chiropractors, who emerged totally discredited. It was also a disaster for the GCC that was forced to admit that it hadn't properly advised chiropractors about what they could and couldn't claim. The recantation culminated in the [GCC declaring, in August 2010](#)<sup>20</sup>, that the mythical "subluxation" is a "historical concept" and it is not supported by any clinical research evidence that would allow claims to be made that it is the cause of disease." Subluxation was a product of the fevered imagination of the founder of the chiropractic cult, D.D. Palmer. It referred to an imaginary spinal lesion that he claimed to be the cause of most diseases. Since 'subluxation' is the only thing that's distinguished chiropractic from any other sort of orthopaedic manipulation, the admission by the GCC that it does not exist, after a century of pretending that it does, is quite an admission.

The President of the BCA himself [admitted in November 2011](#)<sup>21</sup>

"The BCA sued Simon Singh personally for libel. In doing so, the BCA began one of the darkest periods in its history; one that was ultimately to cost it financially."

As a result of all this, the deficiencies of chiropractic, and the deficiencies of its regulator were revealed, and advertisements for chiropractic are somewhat less misleading. But this change for the better was brought about entirely by the unpaid efforts of bloggers and a few journalists, and not at all by the official regulator, the GCC. This was part of the problem, not the solution. And it was certainly not helped by the organisation that is meant to regulate the GCC, the **Council for Health Regulatory Excellence (CHRE)** that did nothing whatsoever to stop the farce.

At the other end of the regulatory spectrum, **voluntary self-regulation** is an even worse farce than the GCC. They all have grand sounding "Codes of Practice" which, in practice, they ignore totally. The **Society of Homeopaths** has recently been shown to be ineffective at protecting patients. When homeopaths were caught out recommending [sugar pills for prevention of malaria](#)<sup>22</sup>, they did nothing (arguably such homicidal advice deserves a [significant punishment](#)<sup>23</sup>). The **Complementary and Natural Healthcare Council (CNHC)** is widely known in the medical circles as "Ofquack". I know about them from the inside, having [been a member of](#)<sup>24</sup> their Conduct and Competence Committee. It was set up with the help of a £900,000 grant from the Department of Health to the Prince of Wales, to oversee voluntary self-regulation. It fails utterly to do anything useful. The CNHC code of practice, paragraph 15, states:

"Any advertising you undertake in relation to your professional activities must be accurate. Advertisements must not be misleading, false, unfair or exaggerated".

When [Simon Perry made a complaint](#)<sup>25</sup> to the CNHC about claims being made by a CNHC-registered reflexologist, the Investigating Committee upheld all 15 complaints. But it then went on to say that there was no case to answer because the unjustified claims were what the person had been taught, and were made in good faith. This is precisely the ludicrous situation that will occur again and again. The CNHC said, correctly, that the reflexologist had been taught things that were not true, but then did nothing whatsoever about it apart from toning down the advertisements a bit. They still register reflexologists who make outrageously false claims. Once again we see that no sensible regulation is possible for subjects that are pure make-believe. The first two examples deal (or rather, fail to deal) with regulation of outright quackery. More concerningly, there are dozens of other organisations that sound a lot more respectable.

### **European Food Standards Agency (EFSA)**

One of the common scams is to have your favourite quack treatment classified as a food not as a medicine. The reasons for this is that the current European laws about what you can claim have been a lot laxer for foods. However, more recently the EFSA has done a pretty good job in stopping unjustified claims for health benefits from foods. Dozens of claims made by makers of probiotics have been banned. The food industry, needless to say, objects very strongly to be being forced to tell the truth. In my view, the EFSA has not gone far enough. They recently [issued a directive](#)<sup>26</sup> about claims that could legally be made. Some of these betray the previously high standards of the EFSA. For example you are allowed to say that "Vitamin C contributes to the reduction of tiredness and fatigue" (as long as the product contains above a specified amount of Vitamin C). However, I'm not aware of any trials that show vitamin C has the slightest effect on tiredness or fatigue. Although these laws do not come into effect until December 2012, they have already been [invoked by the ASA](#)<sup>27</sup> to uphold a complaint about a multivitamin pill that claimed that it "includes 8 nutrients that can contribute to the reduction in tiredness and fatigue".

## The Advertising Standards Authority (ASA)

This is almost the only organisation that has done a good job on false health claims. Their [Guidance on Health Therapies & Evidence](#)<sup>28</sup> says, "Whether you use the words 'treatment', 'treat' or 'cure', all are likely to be seen by members of the public as claims to alleviate effectively a condition or symptom. We would advise that they are not used. Before and after' studies with little or no control, studies without human subjects, self-assessment studies and anecdotal evidence are unlikely to be considered acceptable". They are spot on. The ASA's [Guidance for Advertisers of Homeopathic Services](#)<sup>29</sup> is wonderful. "In the simplest terms, you should avoid using efficacy claims, whether implied or direct." To date, the ASA has have not seen persuasive evidence to support claims that homeopathy can treat, cure or relieve specific conditions or symptoms.<sup>29</sup>

That seems to condemn the (mis)labelling allowed by the MHRA<sup>30</sup> as breaking the rules. Sadly, though, the ASA has no powers to enforce its decisions and [only too often they are ignored](#)<sup>31</sup>. The [Nightingale collaboration](#)<sup>32</sup> has produced an [excellent letter](#)<sup>33</sup> that you can hand to any pharmacist who breaks the rules. The ASA has also [judged against claims](#)<sup>34</sup> made by "Craniosacral therapists" (that's a fringe of osteopathy). They will presumably uphold complaints about [similar claims](#)<sup>35</sup> made by UCLH Hospitals.

**OfQual and Edexcel** set [exams in antiscientific subjects](#)<sup>36</sup>, so mis-educating children. **The Department of Education** has failed to do anything about the mis-education of children in CAM. In fact it has encouraged it by, for the first time, giving taxpayers' money to a Steiner (Waldorf) school (at Frome, in Somerset). Steiner schools are run by a secretive body of people ([read about it](#))<sup>37</sup>. They teach about reincarnation, karma, gnomes, and all manner of nonsense, sometimes with unpleasant racial overtones. The [teachers are trained](#)<sup>38</sup> Steiner's **Anthroposophy**, so if your child gets ill at school they are often managed with homeopathic sugar pills. They might well get measles, mumps or rubells too, since Steiner people don't believe in vaccination.

Incredibly, the **University of Aberdeen** came perilously close to appointing a [chair in anthroposophical medicine](#)<sup>39</sup>. This disaster was aborted [by bloggers](#)<sup>40</sup> and a last minute intervention [from journalists](#).<sup>41</sup> Neither the university's regulatory mechanisms, nor any others, seemed to realise that a chair in [mystical barmpottery](#)<sup>42</sup> was a bad idea.

## Trading Standards offices and the Office of Fair Trading

It is the statutory duty of Trading Standards to enforce the Consumer Protection Regulations (2008). This European legislation is pretty good. It caused a lawyer to write "[Has the UK Quietly Outlawed 'Alternative' Medicine?](#)".<sup>43</sup> Unfortunately Trading Standards people have consistently refused to enforce these laws. The whole organisation is a mess and its local office arrangement fails totally to deal with the age of the internet. The situation is so bad that a group of us decided to put them to the test. The results were published in the *Medico-Legal Journal*, Rose *et al.*, 2012. "[Spurious Claims for Health-care Products](#)".<sup>44</sup> They concluded that the EU directive 2005/29/EC is largely ineffective in preventing misleading health claims for consumer products in the UK.

**The Quality Assurance Agency (QAA)** is supposed to ensure the quality of university courses. In fact it endorses courses in nonsense alternative medicine and so does more harm than good. The worst recent failure of the QAA was in the case of the University of Wales: see [Scandal of the University of Wales and the Quality Assurance Agency](#)<sup>45</sup>. The university was making money by validating thousands of external degrees in everything from fundamentalist theology to Chinese Medicine. These validations were revealed as [utterly](#)

[incompetent](#)<sup>46</sup> by bloggers, and later by BBC Wales journalist Ciaran Jenkins (now working for Channel 4). The mainstream media eventually caught up with bloggers. In 2010, BBC1 TV (Wales) produced an excellent TV programme that [exposed the enormous degree validation scam](#)<sup>45</sup> run by the University of Wales. The programme can be seen on YouTube ([Part 1](#)<sup>47</sup> and [Part 2](#)<sup>48</sup>). The outcome was that the University of Wales stopped endorsing external courses, with the QAA providing very little help.

### **Council for Health Regulatory Excellence (CHRE)**

Back now to the CHRE, the people who failed so signally to sort out the GCC. They are being reorganised. Their [consultation document](#)<sup>49</sup> says

"The Health and Social Care Act 2012 confers a new function on the Professional Standards Authority for Health and Social Care (the renamed Council for Healthcare Regulatory Excellence). From November 2012 we will set standards for organisations that hold voluntary registers for people working in health and social care occupations and we will accredit the register if they meet those standards. It will then be known as an 'Accredited Register'."

They are trying to decide what the criteria should be for "accreditation" of a regulatory body. The [list of those interested](#)<sup>50</sup> has some perfectly respectable organisations, like the [British Psychological Society](#)<sup>51</sup> It also contains a large number of crackpot organisations, like [Crystal and Healing International](#).<sup>52</sup>

They already oversee the Health Professions Council that is [due to take over Herbal medicine](#)<sup>53</sup> and Traditional Chinese Medicine, with predictably disastrous consequences. Two of the proposed criteria for "accreditation" appear to be directly contradictory.

Paragraph 2.5 makes the whole accreditation pointless from the point of view of patients. It will not be an endorsement of the therapeutic validity or effectiveness of any particular discipline or treatment. Since the only thing that matters to the patient is whether the therapy works (and is safe), accrediting of organisations that ignore this will merely give the appearance of official approval of crystal healing for example. This appears to contradict directly with another section (A7). This section notes that the organisation can demonstrate that there either is a sound knowledge base underpinning the profession or it is developing one and makes that explicit to the public. A "sound knowledge base", if it is to mean anything useful at all, means knowledge that the treatment is effective. If it doesn't mean that, what does it mean?

### **Medicines and Healthcare products Regulatory Agency (MHRA)**

The MHRA should be a top-level defender of truth. Its strapline is, "We enhance and safeguard the health of the public by ensuring that medicines and medical devices work and are acceptably safe."

The MHRA did something (they won't tell me exactly what) about one of the most-cruel scams that I've ever encountered. The scandal involved the company Esperanza which produced and sold a Homeopathic Neuropeptide for multiple sclerosis at an outrageous price (£6,759 for 12 month's supply). Needless to say there was not a jot of evidence that it worked (and it wasn't actually homeopathic).

Astoundingly, Trading Standards officers refused to do anything about it. The MHRA admit that there is precious little evidence that any of the herbs work, and that homeopathy is



nothing more than sugar pills. Their answer to that is to forget that bit about "ensuring that medicines work". Figure 2 is the MHRA's [Traditional Herbal Registration Certificate](#)<sup>54</sup> for devils claw tablets.

Figure 2: MHRA's Traditional Herbal Registration Certificate for Devils Claw



The wording "based on traditional use only" has to be included because of European legislation. Shockingly, the MHRA have allowed them to relegate that to small print, with all the emphasis on the alleged indications. The pro-CAM agency NCCAM rates devil's claw as "possibly effective" or "insufficient evidence" for all these indications, but that doesn't matter because the MHRA requires no evidence whatsoever that the tablets do anything. They should, of course, added a statement to this effect to the label. They have failed in their duty to protect and inform the public by allowing this labelling.

## Conclusions

The regulation of alternative medicine in the UK is a farce. It is utterly ineffective in preventing deception of patients. Such improvements as have occurred have resulted from the activity of activists, and sometime the mainstream media. All the official regulators have, to varying extents, made things worse. The CHRE proposals promise to make matters worse by offering "accreditation" to organisations that promote nonsensical quackery. None of the official regulators seem to be able to grasp the obvious fact that is impossible to have any sensible regulation of people who promote nonsensical untruths. There are adequate laws that make such deception illegal, but they are not being enforced. The CHRE and its successor should restrict themselves to real medicine. The money that they spend on pseudo-regulation of quacks should be transferred to the MHRA or a reformed Trading Standards organisation so they can afford to investigate and prosecute breaches of the law. That is the only form of regulation that makes sense.

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