## An Inquiry by the UK House of Commons Health Select Committee

## into the Influence of the Pharmaceutical Industry

## **Margaret Williams**

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Given the well-known and long-term involvement with the pharmaceutical industry of certain medical advisers prominent in the ME world, the international ME community may be interested in this Inquiry. The House of Commons Health Select Committee under the chairmanship of David Hinchliffe MP is taking submissions and hearing oral evidence detailing concerns about the power, bias and influence of the pharmaceutical industry (and flowing from this, upon those doctors who are financially linked to it) and the effect of such influence upon patients. There have already been two evidence sessions and there is to be another on 11<sup>th</sup> November 2004 at which various Royal Colleges (including the Royal College of Psychiatrists) will be giving evidence, with the possibility of a further evidence session in December. The Inquiry is held in the Wilson Room at Portcullis House, just across the road from the House of Commons. There has been great interest in this Inquiry, with the room being packed. The Select Committee Report is not expected before Christmas.

The Clerk to the Committee can be contacted on 0207-219-6182. Reports of this Select Committee, minutes of the oral evidence and press notices can be accessed at <u>www.parliament.uk/parliamentary\_committees/health\_committee.cfm</u>

The written submissions from many interested parties and the transcripts of the oral evidence make lengthy and disturbing reading.

In conjunction with this Inquiry, there is to be a Conference in London on  $4^{\text{th}}$  November 2004 at Friends House, 173 Euston Road from 9am - 5 pm at which some of those who gave evidence to the Select Committee Inquiry will be speaking. Another speaker will be the internationally renowned author and psychologist Dr Dorothy Rowe (contact <u>millie@april.org.uk</u> or telephone 01992-813111). The conference will provide a forum for sharing knowledge and will be a rare opportunity for communication between the industry, research analysts, health care professionals, regulators, policy makers and the public.

On 11<sup>th</sup> September 2004 the BMJ published a piece by Ray Moynihan setting out the response of the pharmaceutical industry to this parliamentary Inquiry:

"The House of Commons Health Committee is investigating drug companies' influence on medical research, the education of doctors, health information and drug evaluation. It will specifically look at the industry's influence on the NHS, the National Institute for Clinical Excellence (NICE) and other regulatory authorities, universities, professional societies and the media. For its part, the Association of the British Pharmaceutical Industry (ABPI) strongly cautioned the committee against tougher restrictions on the industry's communications and marketing".

Without doubt, this is an explosive issue. Evidence given to the Health Select Committee told of payments to medical consultants by the pharmaceutical industry of £5,000 plus expenses for a one hour talk (with the audience being unaware that speakers were in the pay

of the industry) and of senior doctors receiving consultancy fees from drug companies of more than £20,000 for a few hours' work. A senior consultant (Dr Peter Wilmshurst, consultant cardiologist, Royal Shrewsbury Hospital) told the Inquiry that this was common practice, and that the sums offered to him for a few hours work were £22,000, this being the level of payment made by drug companies to consultants such as himself, but professors could earn "considerably more". The same consultant told the Inquiry he had been offered a bribe of two years' salary not to publish research on a new drug that was not in the interests of the drug company that produced it.

MPs were informed that the industry arranged for doctors in their pay to receive free massage and to have their portrait painted, and that the most important "opinion-leaders" are taken abroad by drug companies and offered fees for consultancy work.

MPs were told that family doctors' practices can make profits of over £50,000 per year from drug companies and that doctors are inundated with gifts from the pharmaceutical industry. Professor David Healy, Head of Psychological Medicine, University of Cardiff, said "People like me come out of meeting halls with our arms stuffed full of bags of free gifts".

Explaining about such payments, Professor Healy said: "The industry is very clever at how they organise these things. If I am working in a consultant capacity for one of the pharmaceutical companies, I will have had media training often. Let's say some issue blows up and the media gets told 'You can approach Dr Healy'. I will be able to say, and the media and the pharmaceutical company will be able to say, 'No money passed hands'. The money comes from elsewhere; it actually comes from the trips to the Caribbean; it comes from being asked to chair meetings which involve no work at all; it comes from having my papers written for me and then I am paid as though I have written the papers. That is where the money comes from".

The Select Committee heard of the efforts made by the industry to persuade general practitioners to use products by arranging for the country's leading medical experts ("opinion leaders" in various medical disciplines) to put their name to reports that endorse products and strategies, even though the leading experts had not written the articles concerned. This practice, known as "ghost-writing", is very common. Professor Healy told MPs that doctors maintain they are not influenced by the free gifts but are influenced by "evidence", and that this "evidence" now consists of articles that have been ghost-written, so that when the industry representatives come round, they not only dispense free gifts but also a sheaf of articles. The problem is that such ghost-written articles (handsomely paid for by the industry) do not represent the raw data but do influence physicians (who believe them to be "evidence").

Committee member Dr Doug Naysmith asked Professor Healy: "Are you suggesting that eminent clinical scientists, academics, add their names to papers that they do not really write?", to which Professor Healy replied: "My estimate is that, even in journals like the BMJ, the Lancet, The New England Journal of Medicine and JAMA, it may be worse for psychiatry than elsewhere, fifty percent of these articles are ghost-written. It may be higher. (The) most distinguished authors from the most prestigious universities are approached precisely because they are the most distinguished authors from the most prestigious universities". Dr Naysmith's response was "This is pretty disturbing stuff". The Chairman asked "Do people not see through what is going on?", to which Dr Wilmshurst replied "People do not always know, because people do not always declare their conflicts of interest. Some people were earning considerably more from individual pharmaceutical companies by talking for them every fortnight, twice a month, than they were earning from the university or the NHS that they work for".

When asked about the role of the Royal Colleges in relation to the improper publishing by the industry, Emeritus Professor Andrew Herxheimer (medical pharmacologist) said "I think that the Royal Colleges are not really set up in a way that would make that straightforward", and Professor Healy said "You are trying to force a financial camel through the eye of a scientific needle.....this comes close to fraud".

Concerning the influence of the industry on research, Dr Wilmshurst was explicit: "I think the pharmaceutical industry influences the research that is published". He went on to provide evidence of outright fraud, telling of a drug company that had actually altered the clinical record cards detailing side effects of a drug, which the company omitted entirely before providing information to a regulator in The Netherlands, and that documents sent to The Netherlands by the drug company were a forgery. Asked how commonplace such forgery was, Dr Wilmshurst replied: "I suspect it is as common now as it ever was, and I think it was very common".

On the issue of medical research, the issue of publication bias and the use of editorial "spin" was raised by Dr Des Spence, a GP from Milngavie, Glasgow, who questioned why the results from the industry are more likely to show a positive outcome than those sponsored by no profit organisations.

On the issue of medical education, Dr Spence submitted that 'Promotional hospitality masquerading as education' is the best description of the current provision of education by the industry to the NHS. Unfortunately this education for professionals is skewed with agenda setting by the industry and with speakers paid directly by the industry. The written material provided by the industry that is relied upon by many doctors lacks a strong evidence base''.

Regarding medical education, Dr Wilmshurst gave evidence about the major impact of the industry in this field: "There is a requirement for people to undertake a certain number of hours of medical education, 50 hours a year, and most of that is funded by industry, directly or indirectly. Whenever I go to a lecture at the postgraduate institute in my hospital, the room hire is paid by a drug company, as are the meals that you get. Next week there is a conference at the Royal College of Physicians, at which the key speaker is the Deputy Chief Medical Officer, and industry sponsors that meeting: it is £2,000 a time to have your logo on the bag; £6,000 a time to sponsor part of the cocktail reception. Presumably, the NHS is happy that industry sponsors" (*sic*).

Asked what proportion of continuing professional education is typically funded by the industry, Dr Wilmshurst replied "Ninety per cent plus", and Professor Healy said "There are virtually no state-funded clinical trials here in the UK, This is probably very, very important".

In relation to frequency of doctors' contact with the industry, Dr Spence said it could be on a daily basis: "Often, certainly in the areas I work in, they provide lunch on a daily basis to many of the doctors and nurses in the area".

Not only the common practices that pervade the pharmaceutical industry but also the cosy relationship between it and Government are in the spotlight, as is the failure of the regulatory body tasked with protecting the public (the Medicines and Healthcare products Regulatory Agency -- the MHRA, previously called the Medicines Control Agency or MCA and also the Committee on the Safety of Medicine or CSM).

Submissions were received which disclosed that in order to prevent whistle-blowing, the industry relied on threats of legal action to strike fear into civil servants working in the regulatory authorities that were supposed to be safeguarding the public.

In his written submission, Professor Herxheimer stated "The influence of the industry on medical practice and on the regulation of medicine is perverse, overwhelming and relentless".

He continued: "Close collaboration between industry, ministers and civil servants on the principles and details of regulatory policies has continued. During all this time the Ministry of Health and its successors, the DHSS and the DoH have been the sponsoring Department for the pharmaceutical industry, whilst of course being its biggest consumer. Over the years, many personal relationships have grown between regulatory officials and the staff of pharmaceutical companies. Similarly comfortable contacts have existed between many of the members of the Committee on Safety of Medicines and the industry, and this continues. The influence of the industry on medical practice is enormous, but largely intangible and unseen".

One member of the Select Committee, Dr Richard Taylor, said: "We have had such universal condemnation of the MHRA, the only question is, should it be abolished?"

It was asked why there are no lawyers, or people from the Consumers' Association (Which?) on regulatory bodies and Professor Herxheimer provided the answer: "the regulators are funded by industry".

Dr Spence encapsulated the issues succinctly as being: "the current relationship between the industry, health care professionals and government as a whole. It is that close relationship that gives them an undue sway over the health agenda".

He said "I can tell you that I know hundreds of doctors and I know what the industry is like on the ground: (it) is unbelievably vociferous and active in promoting its own message. The amount of hospitality received by the medical profession compared to other public services is, in my view, a complete disgrace".

The Inquiry was told by Dr Spence that those he represented (The No Free Lunch Organisation) certainly believed that the industry has a major influence over health care policy and that it has a "very clear agenda, which is predominantly that of profit" and that this agenda is "in direct conflict with the responsibilities of the NHS". He informed the Inquiry that the industry is worth £9 billion per year and said: "The pharmaceutical industry has been the most profitable industry throughout the 1990s. They are unbelievably profitable".

Dr Wilmshurst said "I think there are the issues around the influence on doctors, but there is also a more important influence, and that is the influence on government". Asked about this, Dr Wilmshurst said "I had a meeting with the Chief Medical Officer two years ago and gave him other examples of serious research misconduct. I have written to him repeatedly since then asking what he has done about it, and I get a postcard acknowledging my letter".

The Inquiry also heard evidence about the deliberate creation by the industry of so-called "lifestyle" conditions that could lead to unnecessary use of medicines and to distorted prescribing behaviour and it heard of the indoctrination of the public that they need drugs (such as anti-depressants) in order to cope with their lives.

It also took evidence of the move to make ever more drugs available by "Direct to Consumer Advertising" (DTCA), currently permitted in only two developed countries (the US and New Zealand.

The Select Committee took evidence about the re-marketing by the industry of old generic drugs under new names (with the new named drugs being far more expensive), which are advertised by the industry as being of superior efficacy or safety when there is no evidence of this.

One submission to the Inquiry was from a group of consultant psychiatrists calling itself "Critical Psychiatry Network"; it was founded in Bradford in 1999 and the submission bears the name of a Dr Philip Thomas. Whilst the submission will raise a few hackles within the ME community (for example, the belief of its members that "the practice of psychiatry must recognise the primacy of social, cultural, economic and political contexts" and the fact that members "disagree with the emphasis placed on biological research and treatments"), nevertheless the submission states what the ME community knows only too well: "The problems of definition and validation of illness in psychiatry mean that the field is more open to manipulation by commercial interest than other areas of medicine. Psychiatry is unlike any other branch of medicine in that patients may be compelled to take medication for lengthy periods of time against their consent. The government is about to introduce new legislation to replace the 1983 Mental Health Act, in which these powers of compulsion will be extended into the community. This change in the law has major ethical implications. Perhaps more so than any branch of medicine, psychiatry is open to the influence of external interests. This can be seen in the influence that the industry has on the design, conduct and reporting of psychiatric research. We are deeply concerned about the influence of the pharmaceutical company representatives in shaping the opinions of mental health professionals. Their work represents the triumph of the science of marketing over the marketing of science".

The involvement of patient charities with the industry was also under scrutiny, with the Consumers' Association submission stating: "while some have a clear and accessible policy on their links with the industry, in general there is a distinct lack of transparency about such relationships". The same submission states: "Charities, particularly smaller ones that are less well funded, need to be protected from exploitation. We understand the Long-term Medical Conditions Alliance is intending to revise its own guidelines".

In his written submission Dr Spence raised the same issue: "We are concerned about motivation of the pharmaceutical industry involvement with patient advocacy groups".

The use of public relations (PR) companies and other "creative techniques" employed by the pharmaceutical industry was exposed to the Inquiry, including the use in promotional campaigns of celebrities who subsequently denied any knowledge of the lobby group.

Significantly, the written submission on behalf of The Consumers' Association states: "We have a particular interest in consumer involvement at all levels of decision-making: CA has researched and published reports on the outcome of a CA inquiry into how well NICE works from the patient perspective. Protecting the public and consumer interest must be at the heart of any regulator's powers, decision-making and actions. Parliamentary scrutiny is necessary, but not sufficient, to ensuring regulators are publicly accountable".

In his written submission, Professor Healy was blunt: "Every patient who enters a clinical trial in the United Kingdom is putting every Member of Parliament in a state of legal jeopardy".

Members of the Select Committee are on record as being "horrified" by the evidence they heard (see "Drug companies are accused of putting patients' lives at risk" by Colin Brown, Deputy Political Editor, The Independent, 15<sup>th</sup> October 2004).

The evidence to be presented at the next session and the publication of the Health Committee's Report on the influence of the pharmaceutical industry are awaited with keen interest.