An Interest in Conflict?

The 'conflict of interest' policy of the General Medical Council and the fitness to practice hearing of Dr Andrew Wakefield, Professor Walker-Smith and Professor Simon Murch.

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Conflict of interest has become a major area of regulatory, academic and legal concern over the last decade. Most of the concern has focused on the links between academics, experts, PR consultants and industry in a variety of legal and medical fields.[i] The area today does, however, stretch to the interests of newspaper and television reports and politicians. To simplify, it is possible to say that conflict of interest and declaration of conflict of interest, affects, or could affect anyone who appears to be speaking independently.

Britain has not necessarily been behind, in grasping the nettle of declaration of conflict of interest but unfortunately the critical issue has often been replaced by a rather blasé approach to the whole matter. When I disclosed that the late Sir Richard Doll, perhaps the world's most famous epidemiologist[ii] had taken large amounts of undeclared money from Monsanto, whilst working on studies, and writing critical articles about other epidemiologists involved in researching chemical causes of cancer, a number of 'eminent' scientists (some of them intimate with Sense About Science) wrote to the Guardian newspaper claiming that Sir Richard's research would not have been influenced by such payments. In relation to pharmaceutical companies and regulatory bodies, it has now become commonplace to take for granted a wide range of conflicting interests.

In 1999, the Committee on Safety of Medicines, began publishing edited minutes of its meetings on its website, including details of any members who declared links with pharmaceutical companies. This came after a long and tenacious campaign by Charles Medawar, a conscientious campaigner in relation to antidepressant drugs. The committee is one of the independent advisory bodies that used to give advice to the Medicines Control Agency. Under the Freedom of Information act, Medawar demanded copies of the minutes of committee meetings held during 1998.The committee refused to give Mr Medawar the information he requested and passed him on to the Medicines Control Agency.

After an unsuccessful sixteen month battle for information Mr Medawar took his case to the ombudsman, who ruled that there was no reason to justify withholding most of the information requested.[iii]

In 2002, the Daily Telegraph reported that the parents of children damaged by MMR were concerned at the links that existed between members of the Committee on Safety of Medicines (CSM) and the Joint Committee on Vaccination and Immunisation (JCVI). An article said that documents produced by two Department of Health committees responsible for reviewing the safety and efficacy of measles-mumps-rubella triple vaccine (MMR), revealed that a significant numbers of members have links with manufacturers of the MMR vaccine. Fifteen of the 36 members of the CSM have declared personal or non-personal links with companies cited in a class action being brought by parents who believe that MMR had harmed their children.

Six committee members had personal shareholdings and/or held consultancy posts with MMR manufacturer GlaxoSmithKline and nine have a past or present association, such as receiving research funding from companies involved. Two members have declared interests in both categories.

David Thrower, a parent who has campaigned for more research into MMR, said: 'The tolerance of potential conflicts of interest in the medical establishment has reached an extraordinary level, both in terms of the scale of the interests involved and the apparent complete disinterest of central government in this issue'. A spokesman for the Department of Health said 'Anyone who declares any sort of interest in the pharmaceutical industry cannot play a part in any decision relating to those companies and has to leave the room when the subject arises.' [iv]

GSK leads the way in infiltrating organisations, handing out shares and generally unbalancing the world of medicine and medical research. In April 2007, Bob Fiddaman of 'Seroxat Sufferers' posted this list of members' interests from the Committee on Safety of Medicines Annual Report in 2004. Fiddaman opened his list with these words. 'I've looked through the pdf file for The Committee on Safety of Medicines Annual Report for 2004 and will show you all those members who have ties with Glaxosmithkline'.[v]

> Member – Personal Interests: Professor A Blenkinsopp - *GSK Specific – Fees*, Professor H Dargie - *GlaxoSmithKline Consultancy*, Dr M Donaghy - *GSK Shares*, Dr J C Forfar - *GSK Shares,* Dr R Leonard - *GSK Fees/ Publicity work*, Prof D J Nutt - *GSK Consultancy Psychotropics and 300 shares*, Professor J F Smyth - *GSK Consultancy*, Professor Christopher Bucke - *SKB Shares*, Prof Nicholas Mitchison - *GSK Shares*, Dr Brian J Clark - *GSK PHD student funding*, Professor Robert Booy - *GSK Consultancy*, Professor S M Cobbe - *GSK Research grant*, Professor J E Compston - *GSK Consultancy*, Dr A Glasier - *GSK Shares (£10,000)* , Dr Andrew A Grace - *GSK Consultancy*, Dr P Hindmarsh - *GSK Consultancy on growth, probably lapsed by now*, Professor P D Home - *GSK Consultancy*, Dr R F A Logan - *GSK Shares*, Professor R MacSween - *SmithKline Beecham Shares*, Professor J O'D McGee - *SmithKline Beecham Shares*, Professor David R Matthews - *GSK Honorarium for advise*, Dr A Smyth - *GSK Conference expenses*, Professor A D Struthers - *GSK Shares*, Professor J C E - *GSK Shares*, Dr A Gerard Wilson - *GSK Consultancy*, Dr Rosemary Leonard - *GSK Fees/ Publicity work*, Mr David P S Dickinson - *GSK Fee paid work*, Dr Charlotte C D Williamson - *GSK Shares*, Professor Anthony H Barnett - *GSK Advisory work and lectures diabetes related products*, Professor V Krishna K Chatterjee - *GSK Consultancy on preclinical research with a Vanillord Receptor antagonist (Consultancy end of 2004)*, Professor Albert - *GSK Shares.*

In the middle of this discourse about conflict of interests, in 2001, the GMC set up what they called a Register of Interests, part of which was described as giving access to the following information:

> Consultancies,directorships or advisory positions relating to any medical, healthcare or pharmaceutical company or organisation, NHS trust or authority, public body or political party.

This would appear to cover a great deal of ground in relation to pharmaceutical companies but in fact it misses out salient matters. Today, the GMC policy on conflict of interests appears to be half-hearted. At the time the particular focus was the Masons.

While the adoption of this policy was obviously a step in the right direction, the rules made no mention of work done in the past or previous remuneration received from pharmaceutical companies, nor any mention for instance of the holding of shares in a pharmaceutical company or a staff post or advisory role on a pharmaceutical funded journal or for that matter a pharmaceutically funded patient group or charity.

What seemed to be missing was a signed pro-forma which asked outright for a declaration such as is signed by the committee membership of the MHRA or the DH. The new policy also appeared to leave any declaration to the subject themselves. [vi]

> Being a Council member or panelist for the GMC carries with it responsibilities. People working in these roles are expected to act impartially and objectively, and to take steps to avoid any conflict of interest arising as a result of their membership of, or association with, other organisations or individuals ... a code of conduct, which includes a requirement to declare relevant interests, as set out in that code. ... Fitness to Practice panelists must notify the GMC as soon as possible if they have, or may appear to have, any interest in or association or connection with any person (whether financial, organisational or personal), which may, or does, give rise to a conflict of interest or the suspicion of a conflict of interest. [vii]

As the GMC is acting as the prosecuting authority in fitness to practice hearings, it would seem that the primary responsibility for weeding out conflicts of interests lie with them and not with putative panellists. I say this on the understanding that industry will always try to infiltrate individuals into positions where they can affect decisions in their interests. This being the case it seems naive to allow the onus of responsibility to rest on individual panellist.

In relation to panel members who might adjudicate in fitness to practice hearings it is clearly important that all interests which might, however tangentially, have a bearing on the panel's findings are declared and stated on the papers for that particular hearing.

At the bottom of most vested interests in the field of medicine, are financial associations with pharmaceutical companies. This is principally the case because it is such connections that imply real conflicts of interest, where individuals receive remuneration from the use of, the advertising for, or promulgation of drugs, procedures or equipment. Of course, direct receipt of money is only half the story because the promulgation of allopathic medicine itself can be a point at issue in some GMC cases.

While looking at this matter, it might be wise to ask ourselves why there is a need for this kind of transparency at the GMC, especially in relation to Fitness to

Practice panel members. The great majority of cases that come before the GMC originate with patients, and complaints about the way that they have been treated by doctors. Inevitably it would rarely be the case that conflicting interests were an issue in these cases. However, a small number of cases are brought over issues of scientific research and issues around non-allopathic therapies. Some of these cases entail questions of importance about the competitiveness of pharmaceutical products and while the pharmaceutical companies should be commended on cleaning up corruption in their industry by using the GMC, there are clearly cases which they support for the sole reason that the accused are people who challenge the pharmaceutical industry.

In all these cases the ABPI (Association of British Pharmaceutical Industry) has its own 'police force' and investigators who work with the GMC preparing cases; the company Medico Legal Investigations. In relation to cases brought by the pharmaceutical industry against doctors challenging it's competitiveness, it is clearly important that the integrity of the hearing is not compromised by individuals who have vested or conflicting interests. Of course many people would go much further than this and suggest that the GMC should not be publicly washing the dirty laundry of the pharmaceutical industry; that it should police itself and its own employees but not be able to become involved on any level in bringing any kind of case through the GMC against doctors who are not directly working for them.

Obviously in any case that is brought by the GMC having come from an outside body, rather than an individual patient or group of patients, the onus on the GMC to investigate and then try this issue and the people involved is considerable. Members of panels hearing cases which even tangentially involve the pharmaceutical industry, should have absolutely no connection with that industry. This is not something which should be open to debate or polite discussion, the matter is clear and fundamental; in the case of anyone brought before a GMC fitness to practice panel, whose case is even tinted with pharmaceutical company involvement, in the substantial matter of the case, in the investigation of the case outside the GMC or in the bringing of the charges, the panel that 'judges' the case must be absolutely free of any influence from pharmaceutical companies. As well as panel members clearly stating their interests and them being printed and made public in detail, all prosecution witnesses should, be required to state their interests before giving evidence.

This matter might also be raised with the GMC in relation to the very structuring of their prosecutions, for while some of them are handled solely by in-house lawyers, a small number are put together by Medico Legal Investigations working with the GMC. It has always been one of the foundations of justice in European countries that the accused is aware in detail of those making the accusation and with whom the prosecution originates. It is of vital importance to the case for the defense that they have detailed statements with regard to this aspect of the charges.

Clearly statements of interests are relative, and while some interests might even potentially aid justice in one hearing, those same interests might seriously hamper justice in another. Take for example, a panel member working in some capacity for the Department of Health (DH). While this would definitely be an interest that had to be taken into account if the case in question involved issues upon which the DH had very definite policies, it might not be a relevant if the issue at hearing was something quite personal to the defendant such as sexual assault.

The case of Dr Andrew Wakefield has been bedeviled by instances of unrevealed vested interests, a number which have been investigated and written about by John Stone, the father of an autistic child.[viii] It might of course have been expected that a case involving vaccines produced by the largest pharmaceutical company in the world would inevitably draw its unfair share of vested interest situations, especially because Glaxo SmithKline appears to be taking over the world at the moment.

- Brian Deer, the journalist who tendered the initial complaint to the General Medical Council, has described himself on his web site as a journalist who investigated claims made by parents of vaccine damaged children. He has written a number of articles in defense of vaccines manufactured by GSK and had been aided in his research into Dr Wakefield by Medico Legal Investigations, a company that is completely funded by the Pharmaceutical Industry. There are clearly matters of conflict of interest even in the initial stages of the prosecution.
- Brian Deer disclosed in his main Sunday Times article about Dr Wakefield[ix],

after he had presumably spoken to him, that the then Minister for Health, John Reed had called for the 'case of Dr Wakefield' to be referred to the GMC. Given that Dr Wakefield's research suggested a link between MMR and Inflammatory Bowel Disorder (IBD) and a putative link between measles virus, IBD and states of regressive autism in a sub-set of children and given that the New Labour government had underwritten any costs against GSK claimed in damages for adverse reactions caused by the MMR vaccination, Reed's shunting of Dr Wakefield's case into the GMC represents the most serious conflict of interest and manifest corruption.

- In 2007, it was revealed that the Chair of the Panel for the Wakefield hearing, *chosen by the GMC,* was Professor Dennis McDevitt. Just before the hearing began Professor McDevitt was challenged by parents over undisclosed interests when previously unseen minutes of a meeting revealed that Professor McDevitt had been present at the 1988 JCVI meeting that approved Pluserix-MMR as safe for a product license. McDevitt continued to sit on the JCVI through 1991 when SKB were forced to withdraw Pluserix after serious adverse reactions were reported in a number of countries.

- In 2004, the High Court Judge Sir Nigel Davis, in a closed hearing, rejected the appeals made on behalf of vaccine damaged children whose legal aid had been withdrawn for a coming court case, which would ultimately represent some 2,000 cases. Weeks after this decision had been made, John Stone reported that the Judge had failed to disclose that his brother was a non-executive board director of GSK, defendants in the case. The case had been in progress for nearly ten years and was only months away from it's hearing in the High Court. The science lobby groups funded by the drug companies and especially Lord Dick Taverne the founder of Sense About Science and previously a major PR handmaiden for the pharmaceutical industry had campaigned heavily to get legal aid taken from the parents. After John Stone publicised the conflict of interest, Brian Deer accused him of being 'cruel' to the scions of the Davis family.
- During Dr Wakefield's defense case the fact that Richard Horton's line manager at the *Lancet*, the Director of the Elsevier publishing company, was

also a non executive director of GlaxoSmithKline, was reinforced. Dr Horton gave evidence claiming that Dr Wakefield had failed to provide him with evidence of his conflict of interest in relation to money that the Legal Aid Board had granted the Royal Free Hospital. This evidence did not seem to coincide with the historical record.[x] Dr Horton made no declaration at the beginning of his evidence that he was on speaking terms with one of the GSK directors or indeed that such a person acted as his line manager at the *Lancet*.

Dr Surendra Kumar

Dr Kumar is the Chair of the GMC fitness to practice panel that is hearing the case of Dr Wakefield, Professor Walker-Smith and Professor Simon Murch. He was chosen by the GMC as Chair following the 'stepping down' of the previous incumbent, Professor Dennis McDevitt. The full panel consists of five members, three 'medical' members and two lay members; they are aided by a legal assessor Mr Nigel Seed QC. There is no conflict of interest information annexed to the papers which describe the charges against the three defendants.

For anyone who takes the trouble to go to the GMC web site and look at the declarations of putative panel members, they can ascertain that Dr Kumar is connected to the following organisations:

> Principal General Practitioner. President, British International Doctors Association (formerly ODA). Interests: Medical Defense matters & Medico-politics. Member: General Practitioner's Committee (BMA), UK National Screening Committee (Dept of Health). Fellow: Royal College of GPs (FRCGP). Fellow BMA. Member Independent Review Panels of MHRA (Medicine & Health Care Regulatory Agency). Member of Clinical Executive Committee (CEC) of Halton & St Helens PCT. Member of Medical Protection Society.

I want to make clear from the start of this analysis of what I have called Mr Kumar's 'vested interests' that almost the sole responsibility for this state of affairs lies with the GMC. I have no evidence at all to suggest that Mr Kumar himself has been responsible for trading on any vested interests he might have and which have not been disclosed by the GMC. The great bulk of Mr Kumar's disclosed public work show him to be a dedicated and hard working doctor who is much concerned with local, national and even international medical matters. However, being the fair minded and

honourable man he appears to be, I am sure that he would not be happy to keep the following matters undisclosed in the context of the particular 'fitness to practice' panel which he presently chairs.

It was very noticeable that at the beginning of this hearing in 2007, there was no structured mechanism for introducing conflict of interest information. Mr Kumar did make a point of telling the hearing, in general terms and quite hastily, that he has previously sat on committees that were part of the Medicines Control Agency (MCA). In 2003, the Medicines Control Agency became the Medicines and Healthcare products Regulation Agency (MHRA). It also has to be said that at any point in the hearing when a named person known to Dr Kumar, or a particular place of work, has cropped up, he has immediately told the hearing that he knew or had worked in the vicinity of this person or this location.[xi]

It goes without saying that the GMC, the prosecuting agency in this case was duty bound to summon all its resources in testing all panel members in this hearing in great detail in order to discover and make public any possible conflicts of interests. This was inevitably the case after the debacle of Professor McDevitt and the other circumstances of interest conflict that have come to light, especially in relation to GlaxoSmithKline (GSK) in its present and previous incarnations. It has also to be stressed, that from the beginning, the case against Dr Wakefield has been perhaps the most contentious scientific and medical case in Britain in the last half century. Added to this it was obviously important for the GMC to consider, first, the current discourse in Britain and the US about conflict of interests and second, the ironic fact that non-declaration of vested interests in the mid nineties is one of the most serious charges leveled against Dr Wakefield.

In looking at what might be considered Dr Kumar's vested interests that might have been declared at the start of the Wakefield, Murch and Walker-Smith fitness to practice hearing, I will concentrate on four areas; his previous involvement with the GMC, his work on two committees of the MHRA, his work for the Department of Health, his work as Chairman of the British International Doctors Association (previously the ODA), and the previously declared information about his shareholdings in GSK

The GMC

Dr Kumar has been a consistent activist within the GMC between 1999 and 2003 and has, as he makes clear in his list of posts and affiliations on the GMC site, prior to 2004 been a GMC council member and served on the following committees; the 'registration committee', the 'health committee', the 'professional conduct committee', and the 'racial equality and diversity committee'. As an Associate of the GMC since 2003 has also been a panel member on 'fitness to practice' hearings.

We have to consider, that in this highly sensitive case, the General Medical Council is the prosecuting authority and although Dr Kumar's committee experience falls conveniently one year short of 2004, the time when the complaint was laid against Dr Wakefield *et al*, it might be said that being so intimately involved with the business of the GMC it is hardly likely that he has not been au fait with the GMC's position on the prosecution of Dr Wakefield, Professor Murch and Professor Walker-Smith. Being privvy to such information might make it hard to sit impartially in judgement on a case that is clearly so crucial to the GMC. It is in effect no different from the Crown Prosecution Service ensuring that it gets one of its staff on a jury in a criminal trial.

The MHRA

Since the late 1990s Mr Kumar has been involved in two British medicines regulatory bodies, the Medicines Control Agency (MCA) and its committee, the Committee on the Safety of Medicines (CSM). The MCA became The Medicines and Health Care Regulatory Agency (MHCRA) and in 2005 the CSM became the Commission on Human Medicines. Although it is quite difficult to back track and gain a record of the participants on this and other similar committees, Mr Kumar can be found to be definitely on the CSM in 1998 and this is probably the committee membership that he alluded to at the beginning of the hearing.[xii] This committee discussed the safety of drugs and vaccines.

Following the restructuring of the MCA after it became the Medicine and

Health products Regulatory Agency (MHRA), Dr Kumar began sitting on two of the most influential committees of this body. The Independent Review Panel for Advertising (IRPA). and the Independent Review Panel for Borderline Products (IRPBP). [xiii] Both the advertising of pharmaceutical products and the definition of what is a medicine are two of the hottest topics presently involving pharmaceutical companies in Britain. Meetings are held, in virtual secrecy at the headquarters of the MHRA, in Nine Elms, South London.

The Independent Review Panel for Advertising, primarily considers written representations from pharmaceutical companies as to the conformity of their advertising and promotional material with the Regulations, and to advise Health Ministers on the conformity of advertising and promotional material with the Regulations before a final decision is made by Health Ministers. I do not know whether the advertising of vaccines comes under discussion in the IRPA.

Both the IRPA and the IRPBP has a policy of members declaring personal and non-personal interests. The latest declaration of interests that can be found on the internet for both these committees are for 2004 and 2005.[xiv] It is frequent and common practice with both the MHRA and the DH, that they let site access to declared interests lapse over long periods.

In the years 2004 and 2005 Dr Kumar, in the declaration of interests demanded by these two committees, makes known shareholdings in GSK, although the number and contemporary value of these shares is not stated. Of the ten members of IRPBP, six had share holding in pharmaceutical companies, while five held GSK shares. In 2005, the committee consisted of only five members. Three of these had shares in pharmaceutical companies, Dr Kumar logged personal and non-personal interests in four companies, including GSK. Two other members declared interests in GSK, besides Dr Kumar.[xv]

The IRPBP is an important committee within the MHRA. The committee decides which treatments are considered medicines and which are not allowed to call themselves medicines. In terms of pharmaceutical industry competitiveness, this committee is very important. One of the issues in the fitness to practice hearing held

for Dr Wakefield *et al*, involves the use and prescription of Transfer Factor. I do not know whether this product has at any time been discussed by the IRPBP.

Dr Kumar made a declaration for the IRPBP in 2004, however, it is not possible to gain information of members interests on this committee after that date. There are five members listed for this committee and two members, including Dr Kumar have interests in GSK amongst other pharmaceutical companies. Two other members have interests in alternative health companies.[xvi]

Membership of committees overseen by the MHRA, and membership of previous committees overseen by the MCA, raise considerable questions about conflict of interests, independence, loyalty and truth. On hearing of the MHRA for the first time, it might seem to many people that the MHRA is a 'normal' government regulatory agency. Few people would guess that the MHRA, while being the most important regulatory body for medicines in Great Britain, the organisation which, for example, processes Yellow Cards that notify the DH of adverse reactions to drugs, is actually *a trading company completely subsidised by the pharmaceutical industry*.

The history of the medicines regulatory agencies in Britain is a story of how the medical chicken crossed the road, from government participation and control of regulation to total immersion in the pharmaceutical industry. Thalidomide provoked drug regulatory legislation in many countries. In Britain, the Medicines Act was published in 1968, originally this Act was prosecuted by the Medicines Division of the Department of Health, and it was not until 1989, that the regulation of pharmaceuticals was given its own agency, the Medicines Control Agency (MCA). However, the Medicines Division of the DH, even within its short life, became notorious for its 'revolving door' approach to staff; long serving pharmaceutical executives happily swapped jobs with top civil servants ensuring a continuity of protection for the industry.[xvii] This revolving door philosophy has continued throughout the latter development of the regulatory agencies, until in fact with the MHRA the revolving door has spewed out the whole department into the foyer of the pharmaceutical industry.

The MHRA took over from the MCA in 2003. The MHRA is a Government Trading Fund; it might just as well be called a business or a corporation. A Trading Fund is an almost entirely separate economic entity which earns money by the provision of services and like any kind of company, it must balance the books at the end of each year. A trading fund is a government department, or an executive agency or part of the department, which has been established as such by means of a Trading Fund Order made under the Government Trading Funds Act 1973 (as amend the Government Trading Funds Act 1973, 26th July 1990). Typically, trading funds operate in very specialised fields and rely on their ability to derive income from their activities in order to cover their costs. Examples of trading funds are the COI and Ordnance Survey.

However, unlike a number of other Government Trading Funds, which provide services, earn money and accept fees from diverse 'beyond government' sources, the whole of the MHRA income is provided by one funder; the pharmaceutical industry. Further, a percentage of staff and executives of the agency, have come into it from the pharmaceutical industry. It is therefore not surprising, that funded and partly staffed by the industry, its policies are shaped to please this sector.

The MHRA has the largest policing and enforcement department of any European medicines regulation agency, a part of the Enforcement & Intelligence Division (E&ID) of the Agency. Although contemporary government in Britain is characterised by quangos, and the attachment to Government of private vested interests, the MHRA is, as has been explained above, a business in itself which makes profit from the provision of services to the pharmaceutical industry. Inevitably there exists a high level of cynicism and some anger in the world of alternative medicine that, in effect, non-pharmaceutical treatments, which have not on the whole been proven harmful and against which no complaint has been levelled, are now regulated by a commercial concern which is managed, staffed and funded by the pharmaceutical industry. The cynicism is inevitably greater amongst those who realise that the pharmaceutical industry are also charged with overseeing the adverse reactions of their own medicines, which kill and maim many thousands of people.[xviii]

From a legal point of view, perhaps the most worrying aspect of the MHRA, is that like the Atomic Energy Authority,[xix] it has its own police force, in this instance, paid for by the pharmaceutical industry. The two Divisions of the MHRA which are important in relation to the tracking of supplements and compliance and legal enforcement are firstly, the Medicines Borderline Section and the Enforcement and Intelligence Group, which gathers information on individuals who promote suspected medicines.

The Group raid premises, make and take statements and confiscate products, computers and paper work. Although they are not police officers they can obtain warrants for raids from Magistrates and Judges. Enforcement often links up with Trading Standards Officers in local areas. 'Officers' in the enforcement group have their own powers conferred by the Medicines Act 1968 and subordinate legislation applying to the Act. These powers include the right to enter any premises to inspect, to take samples, to require production of any books or documents and to take copies of, or of any entry in, any such book or document. 'Officers' are bound by the Police and Criminal Evidence Act (PACE) and PACE codes of practice. It is a criminal offence to obstruct an enforcement officer. However, this particular police service stands well outside the discursive apparatus of accountability which exists either within the London Boroughs or at County level outside London. These enforcers are literally a law unto themselves – or more specifically, the law of the pharmaceutical companies.

When considering conflict of interests, the workings of the MHRA have to be seen in light of the fact that the agency is completely beholden to the multinational pharmaceutical industry.

The Department of Health

Dr Kumar sits on the UK National Screening Committee that is chaired by the Chief Medical Officer for Scotland and advises Ministers and the NHS in all four UK countries about all aspects of screening policy and implementation. Screening programmes are of immense importance to the contemporary drugs industry as the

present embittered battle over the Gardasil vaccine against human papillomavirus (HPV) for pre-pubescent girls is showing. This of course is in no way a reflection of Dr Kumar's work on this committee but I have pointed to this to show how in certain circumstances the NHS can be deeply involved with the pharmaceutical industry.

The most important fact about Dr Kumar's involvement on this committee is that it shows his access to the NHS and the Department of Health at a relatively high level. The Department of Health has been at the very forefront of the battle against Dr Andrew Wakefield. Even the lowest grade officers in the Department toe the government line. Anyone seeking information about MMR from the DH web site, is directed through links to Brian Deer's web site and, apparently speaking for the New Labour government and the Department of Health, Deer gives his version of the crimes of Dr Wakefield. The DH gives no links to other web sites of a similar kind and there is not the slightest attempt at balance.[xx]

If you go to 'MMR the facts' and put Brian Deer in the search box, the site will serve you 50 items which mention Deer's work. The first item is this:

> 'MMR news:14-Nov-04: Sunday Times: MMR scare doctor planned rival vaccine, Doctor whose work provoked a worldwide scare over MMR failed to reveal that he was developing his own commercial rival to the vaccine.' 'MMR scare doctor planned rival vaccine, Sunday Times - Brian Deer. 'It has emerged that a patent was filed on behalf of Dr Andrew Wakefield for a measles vaccine and other products that would have stood a better chance of success if public confidence in MMR's safety was undermined. To read the full Brian Deer article in the Sunday Times, please visit Times Online'.

Now the fact is, this story is not true. Of all the allegations made by Brian Deer, this is surely the most prejudiced. The competitive vaccine was Transfer Factor which Dr Wakefield experimented with in the hope that it might help children overcome serious adverse reactions to MMR. The GMC enquiry, was so little enamoured of this 'evidence' that it dismissed it almost entirely, concentrating instead on whether or not Dr Wakefield, or either of the other

two defendants were acting ethically in prescribing Transfer Factor to one particular child who had been referred to the Royal Free hospital by his GP. The child was suffering from gastrointestinal problems that, his parents reported, had begun immediately after he received the MMR.

If you move on past Deer into the DH MMR site, everything becomes vaguely hilarious. It sights under its MMR research time-line, first the *Lancet* paper.[xxi] You are prepared for this paper by a refutation of it by Professor Simon Murch, one of the defendants in the ongoing Fitness to Practice Hearing.

> The overwhelming weight of evidence shows that MMR is the safest way to protect against measles, mumps and rubella, and the number of studies demonstrating this is growing.
>
> A list of the key studies looking at MMR are listed below.
>
> In November 2003 Dr Simon Murch - one of the authors of the 1998 paper (Wakefield A J et al) suggesting a possible link between MMR and autism - stated in a letter to the Lancet that there is now *'unequivocal'* evidence that there is no link between MMR and autism.

This first citation of the Lancet paper, which is incidentally headed 'Research suggesting **link** between MMR and autism' is then followed by pages of references headed 'Key research showing **no link** between MMR and autism' - LOL**!** The first page has 12 citations.

If you travel to Brian Deer's web site through 'MMR News' you will find an analysis of the *Lancet* paper by Professor Trish Greenhalgh. This off the cuff analysis repeats almost word for word the prosecution case put by the GMC. As anyone who has been following the GMC hearing will know, the prosecution that is the GMC, fell hook, line and Murdoch owned Sunday Times sinker for Deer's story that had been concocted with the help of Medico-Legal Investigations. This fable suggests that the Lancet paper case-series review, is in fact a failed full blown research project organised to prove that MMR causes autism in all vaccinated children.

Greenhalgh's explanation of the Lancet paper[xxii] is quite extraordinary in that it follows Deer's line rather than the paper itself. To be fair to her perhaps she hadn't

read the paper or perhaps she's an absent minded professor. [xxiii] It is worth quoting some of Greenhalgh's sentences because they give a very clear view of how Dr Wakefield's detractors from the beginning, tried to portray the Lancet paper as the record of a full blown study, rather than a short 'case series review'. It also gives us an insight into the case that the GMC is prosecuting and how this case is broadcast by the DH.

Readers of the passages below, should bear in mind that Dr Richard Horton, the editor of the *Lancet* contended in his evidence to the GMC hearing, that the Wakefield paper was an excellent piece of scientific reporting of a new syndrome. He compared it to early case reviews of aids related illnesses, where various scientists and doctors had attempted to trace the aetiology of the illness and detail a new diagnostic pattern. In Horton's opinion there was absolutely nothing wrong with the science in the paper, which was in his opinion only let down by Wakefield's lack of declaration of conflict interest; that being money which he *did not receive* from the Legal Aid Board.

> *If the hypothesis was that there is a causal link between MMR and autism-bowel syndrome, this study design was incapable of proving that link one way or the other.* [xxiv]
>
> This was not the hypothesis that the paper tested, in fact the paper did not test a hypothesis, it reported on a series of cases.
>
> *The sample was highly selected – that is, the authors deliberately picked out the tiny number of children who had been referred to a major specialist centre because they had both bowel symptoms and an autism-like syndrome. So the fact that these rare conditions occurred together proves nothing at all.*
>
> There was no sample, just 12 consecutively referred children who seemed to have similar gastrointestinal symptoms and a regressive autistic disorder.
>
> *The fact that children with diarrhoea or other chronic gastro-intestinal symptoms have microscopic evidence of inflamed bowels is also, in itself, unsurprising.*
>
> This is an absolutely amazing statement because it echoes in every nuance the words of the prosecutor Miss Smith. It is in effect what the prosecution have based their whole case on and the main reason why there has been no chance for the parents to give evidence; because they would argue that this was not a true picture of their children's illnesses. And let's not forget, that the evidence of inflamed bowels was at the time given and is at the hearing being given by one

> of Europe's most experienced specialists, Professor Walker-Smith. With 40 years paediatric work under his belt he might just have more experience of these things than the newspaper reporter Deer and the academic scientist Greenhalgh.
>
> *The sample was extremely small. I would expect a scientific study claiming a causal association between two events (in this case, giving MMR vaccine and developing autism-bowel syndrome) to have a formal statistical calculation of the number of individuals that ought to be looked at. This is known as a power calculation. The reason why the Lancet does not normally publish studies on just 12 individuals (the usual number of research participants is several hundred, and not uncommonly, several thousand) is that the smaller the study, the more likely it is that an apparent causal link will turn out to be due to chance association.*
>
> The *Lancet* paper did not set out to prove a causal link between MMR and autism or anything else. It was a case series review which reported on 12 consecutively referred children.

I'm afraid that we have to leave Brian and the Prof. here because I am getting upset and we are drifting off the point of this essay. Hopefully the above demonstrates how the NHS and DH vaccination sites slavishly follow the prosecution line in the Wakefield story and how any attempt to reason with them or engage in a dialogue that might uncover the truth would be as the younger generation say, well pointless. We have to ask ourselves whether or not a man working closely with the DH and NHS could remain unaffected by this propaganda.

To show how far up the system this honesty paralysis goes, we might quote John Stone:

> After the publication his (Brian Deer's) story the Chief Medical Officer, Sir Liam Donaldson remarked to the BBC Today Programme (23 February): 'Now a darker side of this work has shown through, with the ethical conduct of the research and this is something that has to be looked at'. On the same day the Prime Minister said to ITV: 'I hope now that people see the situation is somewhat different from what they were led to believe'.[xxv]

BIDA

Since 2002 Dr Kumar has been the National President of the British International Doctors Association (BIDA). Prior to that he was, from 1990-1996, the General Secretary of the organisation.

BIDA was established in the United Kingdom with the objective of promoting the medical, dental and allied sciences. The main objectives of BIDA are: to protect and promote the interests of Ethnic Minority Doctors and Dentists working in the United Kingdom, to highlight the current issues and problems facing ethnic minority doctors and dentists, to grapple with all issues that effect ethnic minority doctors and dentists and to promote better representation of ethnic minority doctors and dentists on medical and national bodies.

However, what doesn't become clear on the BIDA web site unless you look closely is the fact that the organisation is funded not only with membership fees but also by pharmaceutical companies. BIDA's magazine is also subsidised by drug company advertising. This information is declared by Dr Kumar in his conflict of interest declaration for the MHRA and no doubt would have been for the GMC had they a thorough policy on conflict of interests.

GlaxoSmithKline

During 2003, 2004 and 2005, that is for at least two years after the complaint was made against Dr Wakefield, Dr Kumar held shares in GSK. These shares are only traceable up until 2005 because after that year, as often happens, the MHRA has failed to post any information about the committees on which, Dr Kumar, amongst others, sits.

Not only is it the case that anyone adjudicating in the Wakefield fitness to practice hearing has the power to raise or lower the price of the shares, there is inevitably a question that has to be answered about the individuals commitment to that company and how they came by these shares; it is well known that shares are GSK's considered method of payment for work done for the company.

Clearly this matter should have been cleared-up with the requisite declarations before the beginning of the GMC hearing. It could, however, be the case that Dr Kumar has got rid of his shares in the last three years. Although this would not exempt Dr Kumar from a declaration about the shares, I am sure that a clear statement from him to this effect would go some way towards satisfying those critical of this

GMC prosecution. Other matters will of course remain and perhaps an inquiry into the other matters raised in this essay might be settled by an independent investigation into how it was that both Professor McDevitt and Dr Kumar came to be selected for this particular fitness to practice hearing.

ENDNOTES

[i] Hardell L, Walker MJ, et al. 'Secret ties to industry and conflicting interests in cancer research' *Am J Ind Med* 2007 50:227-233

[ii] Sir Richard Doll: Death, Dioxin and PVC. published on the Science and Democracy site http://www.dipmat.unipg.it/~mamone/sci-dem/sci&dem.htm.

[iii] *BMJ* 1999;319:939 (9 October) CSM takes small step towards openness Jacqui Wise , London.

[iv] Parents unhappy with MMR safety experts' links to drug firms. Lorraine Fraser, Medical Correspondent (Filed: 25/08/2002) http://www.telegraph.co.uk/news/main.jhtml?xml=%2Fnews%2F2002%2F08%2F25%2Fnmmr25.xml

[v] Hardell L, Walker MJ, et al. 'Secret ties to industry and conflicting interests in cancer research' *Am J Ind Med* 2007 50:227-233

[v] *BMJ* 1999;319:939 (9 October) **CSM takes small step towards openness** Jacqui Wise

[v] Parents unhappy with MMR safety experts' links to drug firms - By Lorraine Fraser, Medical Correspondent (Filed: 25/08/2002) http://www.telegraph.co.uk/news/main.jhtml?xml=%2Fnews%2F2002%2F08%2F25%2Fnmmr25.xml

[v] http://fiddaman.blogspot.com/2007/04/committee-on-safety-of-medicines-gsk.html

[vi] http://www.gmc-uk.org/about/register/panellists.asp

[vii] email to the author from Sarah Crack, Media Officer, General Medical Council. 28th August 2008.

[viii] Silenced Witnesses.

[ix] Brian Deer, The Sunday Times, February 22 2004

[x] Last year it was also revealed that the present editor of the New England Journal of Medicine had share holdings in Glaxo Smith Kline.

[xi] This practice coincides with a note about spontaneous declaration that I was sent by the GMC after making an equiry about their policy:

There are, however, occasions relating to Fitness to Practice hearings when a conflict, or potential conflict, of interest may arise and which would not be recorded in the Register of Interest. This would include occasions where the doctor appearing before the panel, or a witness, was known to one of the panelists or where one of the panelists had prior knowledge of the events that led to the doctor's appearance before the panel. You will appreciate it is impossible to list such conflicts in the Register of Interests. The procedure on those occasions is that panelists are required to declare those interests as soon as they are aware of them. Panelists are usually able to declare such interests in advance of the start of the hearing but there are instances where conflicts only become apparent during the course of a hearing e.g. as the evidence is adduced or when a witness is called.

[xii] 1998 SUMMARY OF THE MEETING OF THE COMMITTEE ON SAFETY OF MEDICINES HELD ON 11th FEBRUARY 1998

[xiii] The Medicines (Advertising and Monitoring of Advertising) Amendment Regulations 1999, SI No. 267, came into force on 5 April 1999 and completed the implementation of Directive 92/28/EEC Regulation 13 and the Schedule contain a procedure for a review of the Health Minister's preliminary decision on whether an advertisement complies with the Medicines (Advertising) Regulations 1994, as amended ("the Regulations"). The Health Ministers proposed that the review will be undertaken by an Independent Review Panel.
[xiv] 15 Jul 2004 Independent Review Panel for Advertising. Latest documents for the Independent Review Panel for Advertising http://www.mhra.gov.uk/Committees/Medicinesadvisorybodies/IndependentReviewPanelforAdvertising/index.htm (last dated 2008)

[xv] 2005. Independent Review Panel for Advertising: Declaration of members current personal and non-personal interests. http://www.mhra.gov.uk/Committees/Medicinesadvisorybodies/IndependentReviewPanelforAdvertising/AnnualReport/index.htm

[xvi] Independent Review Panel for Borderline Products Declaration ofInterests PERSONAL INTERESTS NON-PERSONAL INTERESTS. http://www.mhra.gov.uk/Committees/Medicinesadvisorybodies/IndependentReviewPanelontheClassificationofBorderlineProducts/index.htm

[xvii] In another context, that of testing drugs in North America, Monsanto engineered one of their top executives into a regulatory post just for the duration of a drug trial which tested one of their drugs, after which he left and returned to the company.

[xviii] The initiation of legal cases against pharmaceutical companies for death and damage, is in Britain a matter of civil claim, for which legal aid has to be provided, while prosecution for the use or misuse of alternative treatments which have been labelled as medicines, even without any complaints of death or damage, is a criminal matter prosecuted by the MHRA.

[xix] Other agencies such as London Underground and British Rail have their own police service, but here these officers and these laws are on the whole general criminal matters such as theft and assault and the officers in these forces act with the national police in all matters.

The police of the AEA and the MHRA, not only have considerable power, but they are in specialised areas normally not traversed by the accountable constabulary.

[xx] http://www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/index.htm ....to.... MMR Explained ... to... http://www.mmrthefacts.nhs.uk/

[xxii] http://www.mmrthefacts.nhs.uk/search.php?keywords=Wakefield
[MMR news]: Analysis of the 1998 Lancet Wakefield paper
Professor Trisha Greenhalgh explains why the Wakefield 1998 Lancet paper should never have been published on scientific grounds.

[xxiii] :http://briandeer.com/mmr/lancet-greenhalgh.htm Full investigation available at:http://briandeer.com/mmr/lancet-summary.htm

[xxiv] http://briandeer.com/mmr/lancet-greenhalgh.htm

[xxv] cited by John Stone in his bmj response

http://www.bmj.com/cgi/eletters/328/7438/528#56300