

## **The Complainant**

Brian Deer, the ABPI, Medico Legal Investigations  
and Dr Andrew Wakefield

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In February 2004, Brian Deer, a well established and capable investigative journalist, authored a front page article entitled 'MMR RESEARCH SCANDAL' for the *Sunday Times*.<sup>1</sup> This apparently independent article focused on what Deer maintained was the unethical research of Dr Andrew Wakefield, the research gastroenterologist who had over the preceding decade questioned the safety of the combined Mumps Measles and Rubella (MMR) vaccine.<sup>2</sup>

Wakefield's analysis of the adverse reactions to this vaccination had come to a head in 1998 with the publication of a case review of 12 children, published in the *Lancet*. Deer followed this

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<sup>1</sup> Brian Deer, MMR RESEARCH SCANDAL. *The Sunday Times* (London) February 22, 2004.

<sup>2</sup> Dr Wakefield and his lawyers soon embarked upon an action for libel against Deer and the Sunday Times. However, as this case proceeded and the start date for the prosecution by the GMC began to get closer, the defendants in the libel action demanded disclosure of all defence material in the GMC case and the judge instructed that they had to comply or forfeit their case. Dr Wakefield was forced to withdraw from the case.

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*Sunday Times* article with a *Dispatches* programme<sup>3</sup> in November 2004.

In Deer's *Sunday Times* article the then Secretary of State for Health, Dr John Reid<sup>4</sup> called for Dr Wakefield to be arraigned before the GMC on unspecified charges. It transpired later that Deer was the sole complainant against Dr Andrew Wakefield, lodging his complaint within days of the *Sunday Times* article being published. Six months after the *Sunday Times* article appeared and a month before the television programme, the General Medical Council (GMC) served notice on Dr. Wakefield to appear before the Council's Preliminary Proceedings Committee (PPC), a necessary step before possibly being brought before the Professional Conduct Committee.

From its very beginning, the case that developed around Dr Andrew Wakefield, inside and outside of the GMC was shot through with vested interests. Nothing about the case has been straightforward, nothing is clean or without the dirty finger marks of conspiracy. However, unlike other similar situations that have unfolded during New Labour's decade of office, the government, because of an apparent moral clarity in any circumstance involving health and medicine, still appears to be winning hands down. Despite the support of a number of able journalists and campaign supporters, no cracks or fissures have appeared in the public façade of New Labour's crucifixion of Dr Wakefield.

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<sup>3</sup> *MMR: What they didn't tell you* - Channel 4 Television, *Dispatches*, November 18 2004.

<sup>4</sup> Secretary of State for Health June 2003 – May 2005

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Ultimately, this failure in the public defence of Dr Wakefield probably hinges on the fact that when it comes to pharmaceutical medicine many commentators immediately suspend critical belief; drugs good all else bad. But it is also because the case of Dr Wakefield and his public criticism of vaccine policy has been the first and most substantial case to fall victim to a new corporate agenda for government in Britain. In the first years of the new century, high ranking corporate lobbyists partly funded by pharmaceutical interests and fated by New Labour embarked upon a strategy of defending corporate science by censoring the media.<sup>5</sup>

Throughout the second half of the 1990s, those cases of vaccine damaged children who had been affected by MMR and MR vaccination introduced in 1988, gained considerable publicity.<sup>6</sup> By the early years of the new century, however, with the new policy of censorship tightening like a noose round the neck of free public debate, these children had vanished and for the children's parents all the doors previously open to expressing criticism of the government and corporate malfeasance had been firmly closed.

This essay analyses perhaps the most singularly important strategic manipulations of the media that has played a decisive end-game role in the case of Dr Wakefield; his appearance with two other doctors before a fitness-to-practice panel at the General Medical Council (GMC) in London. The essay looks with a broad sweep at how Dr Wakefield's prosecution by the GMC was constructed by

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<sup>5</sup> See this author's *Brave New World of Zero Risk*.

<sup>6</sup> See

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Brian Deer, The Sunday Times and a small subsidiary investigation company of the Association of British Pharmaceutical Industry (ABPI).

### Investigating for Whom ?

Deer's article and much of his television programme focused on one of Dr Wakefield's research papers which looked at twelve children who appeared to have been adversely affected by measles virus introduced into their system through vaccination. Dr Wakefield had been writing about the role of measles virus in Crohn's disease since the late 1980s. The review of 12 cases published in the *Lancet*,<sup>7</sup> suggested a link between MMR vaccination, gastrointestinal problems and the onset of autism in some children.<sup>8</sup> In a press briefing that accompanied the publication of the paper, Dr Wakefield had suggested that working on the precautionary principle, it might be better to revert to the single vaccines until research and clinical work at the Royal Free Hospital established proof or rebuttal of the link.

Deer's article presented the case against Wakefield in sensational terms, as if Wakefield was a quack or a charlatan and as

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<sup>7</sup> Wakefield AJ, Murch SH, Anthony A, Linnell J, Casson DM, Malik M, Berelowitz M, Dhillon AP, Thompson MA, Harvey P, Valentine A, Davies SE, Walker-Smith JA. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *The Lancet* 1998; 351: 637-641.

<sup>8</sup> This paper was one of eighty odd papers published by Wakefield between 1991 and 1998. The publications cover different aspects of Wakefield's research as it moved from Crohn's disease specifically to inflammatory bowel disease. A number of these papers mention the part played by measles virus.

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if, he, Deer, had just discovered, astoundingly, that Wakefield's research was biased, unethical and untrustworthy. '*The scandal arises from the journal's publication in February 1998 of a scientific report on the 'findings' in the cases of 12 autistic children, apparently admitted routinely to the Royal Free hospital in North London in 1996-97*' [authors italics].

In fact, Deer was stepping late into one of the biggest controversies in contemporary medical science. He was presenting very serious allegations against a paper which had been published over five years previously by *The Lancet* and which had already faced a barrage of criticism from the vaccine producers and policy makers and their supporters. This assault on Wakefield's integrity was stepped up in 2001 when the Medicines Control Agency (now the Medicines and Healthcare Products Regulatory Agency - MRHA) got together with the Department of Health (DoH), the Royal College of General Practitioners, (RCGP) the British Medical Association (BMA), the Public Health Laboratory Service (PHLS) to publish an unprecedented rebuttal of a later Wakefield paper which suggested that prior to licensing the safety of MMR had not been sufficiently tested.<sup>9</sup> For nine years prior to Deer's article, Wakefield has been victim to a deepening web of intrigue, irrational opposition and dirty tricks.

The nub of Deer's article suggested that Wakefield stood 'discredited for misleading his medical colleagues and *The Lancet*, the

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professional journal that published his findings', having failed to '...disclose he was being funded through solicitors seeking evidence to use against vaccine manufacturers.'<sup>10</sup> In a more temperate academic climate, this charge, were it proven without doubt, something which the newspaper article did not do, might have led to an inquiry into conflict of interest, non disclosure of funding and possible bias. As most medical research funding today comes from industry - particularly the pharmaceutical industry - and the arguments and informal rubrics now introduced by some journals over disclosure are relatively novel, it is unlikely that had this charge been manufactured in 1998 definitely proven, they would have had little effect upon the research findings themselves.<sup>11</sup>

Almost immediately on publication of the *Sunday Times* article, however, *The Lancet* claimed that *The Sunday Times* evidence meant that the finding linking MMR and autism was '...entirely flawed' and should never have been published.<sup>12</sup> John Reid, the

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<sup>9</sup> Andrew J. Wakefield and Scott M. Montgomery. Measles, Mumps, Rubella vaccine: Through a glass darkly. *Adverse Drug React. Toxicol. Rev.* 2000, 19(3) 1-19. Oxford University Press.

<sup>10</sup> The solicitor Richard Barr has been putting together claims on behalf of parents of damaged children since 1992. The cases have faced opposition at every turn from the Lord Chancellor Department and in the year 2000, with the cases not far from a hearing, legal aid was stopped.

<sup>11</sup> The pharmaceutical companies have argued for many years along with other industrial producers, that funding sources do not affect research outcome.

<sup>12</sup> Sir Crispin Davis, Chief Executive of Reed Elsevier plc, publishers of the *Lancet*, and one of Europe's largest publishing company... was appointed as a non-executive director to the board of GlaxoSmithKline - vaccine manufacturers and defendants in the MMR litigation - in July of last year. [Comment by John Stone in his enlightening correspondence with the *BMJ*. 30 September 2004] He was knighted in 2004 for his services to the Information Industry. Two other Board members of Elsevier are also Board members of companies in the Akzo Nobel group which owns Organon one of the manufacturers of HRT. Another Board member is also on the board of Smith and Nephew a large US health care corporation.

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Secretary for Health, who had clearly played a part in the article's make up, called, in the article, '...for an inquiry by the General Medical Council (GMC) 'as a matter of urgency.'<sup>13</sup> Interestingly the inquiry that Reid wanted was into Dr Wakefield's fitness to practice medicine and not into his research findings.

With the support of others, Deer lodged a complaint against Dr Wakefield with the GMC within days of the article appearing. Within six months, evidently needed to prepare the case and draw up the documents, the GMC had opened a case and Wakefield awaited an arraignment before the GMC Preliminary Proceedings Committee. The charges against Wakefield and, as it turned out, two other doctors, Professor Murch and Professor Walker-Smith, stemmed almost entirely from Deer's article.<sup>14</sup>

In the event, it was to take the GMC almost four years to bring Dr Wakefield before a panel and then the hearing was to last for an incredible one and a half years. Throughout this long drawn out trial, and in effect from the first time that Dr Wakefield warned the government about a major public health crisis involving hundreds of adversely affected children, over a 15 year period the government pursued its vaccine policy without publicly announced change, hindrance or any hint of self criticism.

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<sup>13</sup> Although Reid got his 'urgent' complaint to the GMC, he must have been joking about the urgency with which it was pursued, or perhaps the Scots have different temporal notions to the English.

<sup>14</sup> The opportunity has been taken, in preparation for the GMC PPC hearing, to introduce further issues, principally suggesting that Wakefield had various procedures carried out on children for the purposes of pursuing research rather than treatment.

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### From Golden Boy to just 'boy'

Prior to his first findings, published in a number of research papers that measles virus found in the gut of some children after the triple vaccination MMR, *might* be the cause of inflammatory bowel disorders and possibly connected to a regressive autism spectrum disorder, Dr Wakefield had been a much lauded medical researcher.

Most of his work at the Royal Free Hospital (RFH) Medical School in North London between 1986 and 1994 had moved forward the understanding of the cause and treatment of Crohn's disease. He had been royally funded by the biggest pharmaceutical companies and was one of the principle fund earners at the Medical School.

As early as 1992, Dr Wakefield had written to the Department of Health asking for a meeting with David Salisbury, principle medical officer for communicable diseases and immunisation, when he became concerned that measles might be implicated in Crohn's disease. In 1996, Wakefield wrote again to the then Chief Medical Officer Dr Kenneth Calman, asking for a meeting to discuss the possibility that the measles component of MMR was playing a part in the development of bowel disease similar to Crohn's disease. When Wakefield finally did get a meeting in 1997 with Tessa Jowell, then the new Secretary of Health, Calman gave him twenty minutes to make his case for more government funded research and a temporary halt to use of the triple vaccine.

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Following the publication of the 1995 paper about the original MMR trials and his first attempts to get a meeting with the then Secretary of State for Health, Wakefield's career began to unravel. Within a year, all funding for his research from pharmaceutical companies had dried up and in 1998, following the publication of the *Lancet* paper, having declined a non research based position, the RFH Medical School refused to re-new his contract.

All the major institutions of pharmaceutical medicine and supporters of the Government's MMR policy - including the NHS, BMJ, BMA, and the ABPI - began making noises which called into question Wakefield's work, his ethics, his intelligence and his honesty. In the early years of 2000, Wakefield felt forced to leave England to work in North America where it appeared that the monopoly grip of socialised medicine was not strangling independent research into public health.

### **The Description of a Battlefield**

Battles between industries, industrial science and renegade scientists have become relatively common over the last two decades. It seems to be a singular feature of these conflicts that they easily spin out of the academic arena, where the rules of scientific debate used to hold sway, into the domain of the tabloids where a manufactured essence is regurgitated in lurid sound bites.

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Despite the fact that opposition to Dr Andrew Wakefield has consistently argued proof of the *complete safety* of the triple vaccination, no scientific evidence exists for this assertion, nor, logically, could it.<sup>15</sup> In reality, the conflict has been shaped by the forces opposed to Wakefield in almost completely personal terms. He has been depicted as a dishonest anti-vaccine quack, opposed with head-banging partiality to vaccinations and therefore a threat to both parents and the public health. When the charges were eventually framed by the GMC and laid before him, a number of them contained the accusation that he was 'dishonest'.

As is usual with character assassinations conducted by industrial interests, none of the above could be further from the truth. Until 1995, Andrew Wakefield was considered one of the most orthodox of clinical research workers. His medical education was conservative, his early work in the field of immunology and transplantation was classical and he had never voiced even the slightest support for alternative medicine or anti-vivisection.<sup>16</sup> Even with the publication of *The Lancet* paper, he did not voice any anti-vaccine views. Wakefield's dissident status was undoubtedly forced upon him and even then his response has been that of a concerned doctor and not a political subversive. He has only ever raised serious *scientific* questions about the original trials for MMR and the safety of

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<sup>15</sup> Apart from the attempt by the Conservatives to reassure the public that British beef was safe just prior to the BSE crisis, one is reminded of statements by New Labour, voiced on behalf of Monsanto, that GM food is completely safe.

<sup>16</sup> The research of Wakefield and others into inflammatory bowel conditions, has led them to support a nutritional treatment which involves a gluten and casien free diet. For many orthodox doctors, especially those who have supported the processed food industry while denying conditions like allergy, such as Vincent Marks, this treatment does smack of alternative medicine and quackery.

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the present measles virus as it is included in the combined MMR vaccination.

By far Andrew Wakefield's greatest, if not sole concern since the Royal Free was first approached by parents of vaccine damaged children, has been the children and the predicament of their parents. The steady movement over the last decade has been to allow patients increasing access to all the complaints systems within the medical arena.<sup>17</sup> In the case of MMR, with over 2,000 parents involved in legal actions for damages on behalf of their possibly vaccine damaged children, the opposition to Wakefield has had to by-pass parents and public and mount an increasingly ferocious campaign against the doctors, the solicitors and the parents themselves, while completely ignoring the damaged children.<sup>18</sup>

Until Brian Deer's article in 2004, it had never been completely clear what kind of fault we were supposed to find with Dr Wakefield and his work; was he an evangelical anti-vaccine guru, a wrong minded idealist, or a medical mountebank in it for the money? With Deer's article the focus of accusation against Wakefield sharpened. Wakefield was, it seemed, a corrupt and unethical researcher who dabbled in quackery<sup>19</sup> and helped line the pockets of

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<sup>17</sup> This is particularly true of the GMC, which has had to adapt in the aftermath of the Shipman affair.

<sup>18</sup> Some joined up thinking: What might a judge or jury make of a principal witness for the claimants who had recently been found unfit to practice medicine and been struck off the medical register.

<sup>19</sup> Deer 'exposed' the fact that Wakefield was also planning a vaccine treatment for inflammation of the bowel. The patent for this was, however, held by the Royal Free medical school and not by Wakefield. While profiting from research with the

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a firm of solicitors who had helped mislead thousands of parents, convincing them that pharmaceutical companies were responsible for their children's contested illnesses. He is now, as well, depicted within the charges laid by the GMC, as an unscrupulous experimenter upon children, using them for his own research purposes in order to ennoble his care.

While the case for Andrew Wakefield being an unethical quack now settles as a blurred afterthought in the minds of the public, the financial motivation for the government and the pharmaceutical industry in the continued manufacture of compound vaccines, regardless of the cost to public health, is undeniable. Furthermore, the levels of partnership between big pharma and the New Labour government in the production, marketing and distribution of multiple vaccines and other drugs, has never been more sharply in focus.<sup>20</sup>

The Pharmaceutical Industry Competitive Task Force (PICTF), a series of meetings between government and the pharmaceutical industry, deliberated between April 2000 and March

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production of patented processes and treatments is all the rage amongst the medical research establishment it is apparently quackery in Wakefield's case.

<sup>20</sup> In Britain, from the mid nineteen nineties, the ABPI have argued for a joining of venture and purpose in the production of vaccines. Working in partnership with government on production and post-licensing surveillance of drugs, gives the pharmaceutical company a massive advantage. Firstly, the company has an assured market, second, the company is guaranteed consistent Government loyalty over the safety of the drug. Like the companies themselves, it is unlikely that the government, having invested millions of pounds in a project, will act with transparency when it comes to adverse reactions. See, *The Ghost Lobby and Other Mysteries of the Modern Physic*, Wyeth Pharmaceuticals and New Labour. Martin J. Walker MA. 2004

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2001. The first concern of the Association of the British Pharmaceutical Industry (ABPI) was security of UK markets for the distribution of drugs.<sup>21</sup> The concluding of the PICTF was followed by the implementation of another continuing group, to meet once a year, or more, named the Ministerial (Pharmaceutical) Industry Strategy Group (MISG). This group, involving cabinet Ministers, officers from the DoH, the Dti and executives of the major pharmaceutical companies, has continued to meet and refine policy.

Both these groups give evidence of the close ongoing relationship between the New Labour government and the pharmaceutical industry. They also signal the clear and undisputed fact that, while the pharmaceutical industry is in the van of New Labour policy, the thousands of patients suffering from adverse reactions are not to be seen on the medical landscape.

### Government by the Drug Industry

In January 2002, Liam Donaldson, the Chief Medical Officer, published *Getting Ahead of the Curve - A strategy for infectious*

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<sup>21</sup> The Task Force deliberated between April 2000 and March 2001. The co-chairmen were; Lord Hunt, then Parliamentary Under Secretary of State for Health, and Tom McKillop from Astra Zeneca. The Government team consisted of Lord Sainsbury, Baroness Blackstone, Nick Raynsford MP, Stephen Timms MP and the Permanent Secretary at the Department of Health. The team from the Association of British Pharmaceutical Industry (ABPI) was Sir Richard Sykes, of Glaxo Wellcome, J-P Garnier, now Chief Executive of Glaxo Smith Kline, Bill Fullagar, ABPI President and Novartis, Ken Morgan, ABPI Vice President and Pfizer up to June 2000, and Vincent Lawton, APG Chairman and Merck Sharp & Dohme afterwards; finally, Trevor Jones, the Director General of the ABPI. Observers from the Prime Minister's Policy Unit attended all meetings and a variety of officials from government departments were called to meetings to discuss certain issues. The first matter on the agenda was 'Developments in the UK Market', the second and third, 'Intellectual Property Rights' and the 'Regulation of Medicines Licensing.'

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*diseases.*<sup>22</sup> This report set the agenda for ‘modernization’ of the structures within the NHS which deal with infectious diseases and, incidentally, research into bio-warfare agents. The report led to the winding up of the Public Health Laboratory Service (PHLS). The new Health Protection Agency (HPA) was set up and joined with the Centre for Applied Microbiology & Research, a part of the Microbiological Research Authority. As most befits a transparent organization dealing with public health, the Health Protection Agency is based in the Porton Down biological warfare establishment in Wiltshire.<sup>23</sup>

The Health Protection Agency, like many of the other free standing agencies set up under New Labour, has a commercial section which now, rather than muddling through, provides contracted services for pharmaceutical companies as well as

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<sup>22</sup> As a piece of academic work, this report is often lacking. The introductory section, which looks briefly at compromised immunity, begins with the words: ‘Advances in medical treatment, particularly in the fields of cancer therapy and transplantation, have resulted in increased numbers of people living with impaired immunity.’ Despite the fact that drugs and chemotherapy mainly consist of chemicals, Donaldson completely avoids any reference specifically to chemicals in the contemporary phenomena of depleted immunity. The section of the report on vaccines is full of the evasive, unfocused uses of English, for example: ‘Fifty years ago, in this country, there were measles epidemics every year. Hundreds of thousands of children were affected. *Even in the second half of the twentieth century, there were more than 100 deaths associated with many such epidemics.*’ (Author’s italics.)

<sup>23</sup> An irrelevant aside. The Centre for Applied Microbiology & Research, Britain’s research establishment for weapons of mass destruction, which describes itself as ‘An independent public sector body providing expertise and resources for Government and the biopharmaceutical industries worldwide,’ has six non executive directors, and nine executive managers, all of whom are men. Should we assume from this that the writ of equal opportunities does not run in the bio-warfare sector, or simply that most women wouldn’t touch the work with a barge pole?

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developing drugs and vaccines with them.<sup>24</sup> It is clear from the setting up of the HPA, that medicine and health have turned a corner in post-industrial Britain, the mass treatment and the mass creation of ill health by pharmaceutical companies and not the people, is now at the forefront of the government public health programme.

Donaldson's report laid considerable stress on vaccination, which he clearly saw as the future of '...cost-effective health strategy.'<sup>25</sup> In *Getting Ahead*, he committed himself and New Labour to an accelerating pace 'of new vaccines.' Which will not only be new '...but many will be combined'. Inevitably, as a modernizer bent on governing in partnership with industry, Donaldson makes it clear in his report that 'Harnessing this change will require a carefully managed relationship with the research community and the vaccine industry'.<sup>26</sup> From the time of *Getting Ahead*, the British Government entered into an extensive business partnership with the pharmaceutical industry to accelerate the production of '...cost-effective combined vaccines.' Although the public was not informed,

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<sup>24</sup> It was the Centre for Applied Microbiology & Research which supplied the armed forces with anthrax vaccine during the Gulf War and the occupation of Iraq. Who passed this vaccine for safety?

<sup>25</sup> Quoting from the 1993 World Bank Report *Investing in Health*.

<sup>26</sup> The vaccine industry consists of those companies who regularly produce vaccines and are represented within the ABPI, by being an especially named group: The UK Vaccine Industry Group (UVIG) is made up of Aventis Pasteur which is owned by Merck & Co., Baxter Healthcare, Chiron Vaccines, GlaxoSmithKline, Solvay Healthcare and Wyeth. Above the UVIG is the European Federation of Pharmaceutical Industries and Associations and its associated body, the European Vaccine Manufacturers Group (EVM). Both the UVIG and the EVM have the same basic goals: to sell as much vaccine as possible, or in the words of the EVM, to 'promote a favourable climate for expanded vaccine protection and improve vaccine coverage in Europe, and to help sustain the innovative R&D capabilities of vaccine manufacturers in Europe.'

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another major novelty would be that many future vaccines would be based upon genetically modified material.

In most contemporary public disputes over science, there is one side which does not bother arguing the science but simply claims to have the interests of the public at heart; in the debate over the safety of vaccination and especially MMR, it is easy to identify those on this side. Where any crisis in pharmaceuticals overreaches a problem for a specific company, the Association of British Pharmaceutical Industry (ABPI) takes up the cause. The sole interest of the ABPI is the protection of the image, productivity and profitability of the generic drugs industry.

Continuing a programme begun by the Thatcher governments, New Labour has given the pharmaceutical industry 'most favoured industry' status. With the help of government, the industry has made itself almost indispensable to the making of health policy and the functioning of the 'modernised' NHS. Extending their long term strategy of infiltrating areas key to the marketing of their products, the ABPI acts in partnership with a large number of voluntary sector organisations, charities and the NHS. Key figures from the ABPI are now ensconced within all the agencies which might test, need, help manufacture, buy, or use new drugs. In the case of vaccines, the ABPI strategically argues the case for MMR in scheduled meetings with cabinet members and through

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lobby groups which have 'intimate' relationships with Ministers and parliamentary committees.<sup>27</sup>

The pharmaceutical companies are assured of millions of pounds in profit over the coming years with the sale of multiple vaccines to the NHS. The industry needs ongoing programmes of vaccine development and assured sales, not simply to maintain future revenues, but also to shore up economic viability in an industry presently beset by crisis.

Despite feverish attempts by the pharmaceutical companies to invent new illnesses, the time of the patented 'pill for every ill' is coming to a close. The most lucrative future areas of pharmaceutical production will in the future be linked to high technology testing and fertility, mental health assessment and 'treatment', gene manipulation, prophylactic medicine especially vaccines and, heavily in the forefront, mind altering cognitive behaviour drugs . Some pharmaceutical pundits have gone as far as to suggest that it will at some future date be possible to inoculate children against every illness known to humanity; if this situation ever arises, no doubt we can depend on the pharmaceutical industry to find some new ones.

Beyond the specific cause of producing and promoting vaccines and other pharmaceuticals, the ABPI has over the last twenty years become increasingly involved in controlling clinical

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<sup>27</sup> The Ghost Lobby and Other Mysteries of the Modern Physic, Wyeth Pharmaceuticals and New Labour. Martin J. Walker MA. 2004

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research. The move to ring-fence and control clinical research, ensuring that it becomes the domain of industry alone, has been a common theme in all industries which have a legacy of causing environmental illness.

The tobacco industry, the mobile phone industry, the plastics industry, the asbestos industry and the pharmaceutical industry,<sup>28</sup> to name but some, have all fought campaigns to draw epidemiology and clinical research out of the hands of independent scientists and establish it on a footing favourable to industry.

### Brian Deer Vaccine Claims Assessor

In 1989, Brian Deer wrote a number of penetrating articles about the failings of AZT, the anti HIV and AIDS drug developed by the Wellcome Foundation.<sup>29</sup> The articles criticised the Concorde trials with AZT that followed its licensing and introduction.

Following these articles and others contributed by analysts such as Joan Shenton the film maker, the editor of the

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<sup>28</sup> So much good work to choose from, see the following for starters; Rachael's Environmental News; The books of John Stauber and Sheldon Rampton;. Linda Marsa, Prescription for Profits; Sharon Beder, Global Spin; Dr Georeg Carlo and Martin Schram Cell Phones: Invisible Hazards in the Wireless Age; Martin Walker, Dirty Medicine. Also, Martin Walker, Company Men and the Public Health: Part Two, Sir Richard Doll: Death, Dioxin and PVC.

<sup>29</sup> Brian Deer. Revealed: fatal flaws of drug that gave hope. *Sunday Times*, 16 April 1989.

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*Sunday Times*, Andrew Neil, came under considerable pressure to refute the articles and cease to employ Deer. This assault on the independence of the *Sunday Times* was engineered by the very company that manufactured AZT, the Wellcome Foundation, with help from the Wellcome Trust, then the charitable arm of the drug company. In the late 1980s, Wellcome was the major supporter of a new group of Health Fraud activists, the Campaign Against Health Fraud that lobbied and campaigned on behalf of pharmaceutical medicine.<sup>30</sup>

CAHF, which was set up in 1988, argued for good practice in clinical trials and against 'unproven' alternative medical therapies, a campaign which later merged into the one for evidence based medicine and recently was taken over by Sense About Science. Initially, their aims were considered in relation to the ongoing trials for AZT and the growing sub-culture of alternative treatments for HIV and AIDS-related illnesses, which Wellcome saw clearly as a threat to the marketing of AZT.<sup>31</sup>

In 1991, Andrew Neil seemed to collapse under the pressure that was being applied to him. Although to his credit, the *Sunday Times* never distanced itself from the argument that AZT was a useless and dangerous drug, and the case for a heterosexual pandemic of HIV in Europe and America was over-hyped, after pressurising visits to the paper from HealthWatch emissaries, the paper appeared to send Deer to work in North America for a while.

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<sup>30</sup> CAHF has since changed its name to HealthWatch

<sup>31</sup> See this author's book, *Dirty Medicine*.

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On returning to Britain, Deer dropped out of sight for some time while engaged in a battle with members of Healthwatch. When he re-appeared writing for the *Sunday Times* in 1994 he was back on top form, with an information packed guide to the Wellcome Empire, its history and its future. A very long, well-balanced article that had evidently been written with the full involvement of Wellcome's past and present scientific staff.<sup>32</sup>

This wide ranging report did not refer critically to AZT, then making hundreds of millions of pounds for Wellcome, in fact Deer's campaign against this drug seemed to have ended. In its place he now waged a campaign against Wellcome's health destroying anti-bacterial drug Septrin.<sup>33</sup> At the time Septrin, clearly at the end of its life, had damaged thousands of people and was under attack from doctors and following Deer's first article, two independent campaigning groups. One of these groups, The Septrin Action Group

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<sup>32</sup> A personal note about Deer's come-back. When I wrote *Dirty Medicine*, I interviewed Deer and devoted a short section to him in the book. At that time Deer was clearly on the side of those who were critical of AZT and part of a 'collective' campaign that questioned the drugs side effects as well as its ultimate usefulness. During this brief period of writing about Deer, I had a couple of meetings with him and a number of phone calls. All of which were enjoyable, apart from Deer's rather detached presence which I thought was lacking in warmth. I didn't have any contact with him after *Dirty Medicine* came out but when he returned from the States to begin work again for the *Sunday Times*, out of the blue I received a phone call from him. I can't remember now whether the call came before his article on Wellcome or after its publication, but I'm almost sure it was after. When I picked up the phone, Deer didn't even bother introducing himself before embarking on a tirade against me. The purpose of this phone call remained a complete mystery to me until I spoke to someone else with whom Deer had had previous friendly relations. She too had received a rude phone call that clearly signalled an end to any co-operative relationship they might previously have had. It occurred to me then, that these phone calls signalled an end to an old Deer and the birth of a new persona.

<sup>33</sup> Brian Deer, Hard Sell, Part I, The Sunday Times News Review, February 27 1994.

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was determined to take a group legal action while the other, the Victims of Septrin Group, just wanted the drug taken off the market.

Part One of Deer's long article about The Wellcome group, published in February 1994, was accompanied by a hard hitting front page article headed; 'Top selling drug may have killed hundreds in Britain'. This article, and others, was quickly followed by a parliamentary debate introduced by Margaret Hodge in March 1995.

At the conclusion of Deer's campaign the Committee on Safety of Medicines and Medicines Control Agency announced in July 1995 a change in the drug's prescribing indications.<sup>34</sup> This change was reflected in the 'uses' section in its data sheet. According to Deer's web site, the CSM had been pressed into this concession after hearing that the Sunday Times was about to publish another case evidenced expose about Septrin in the The Sunday Times Magazine on July 9 1995.

In this magazine article Deer wrote movingly about the kind of journalist he was, describing how hour after hour, night and day, in and out of the bath, he listened to a continuous stream of incoming telephone calls from people who had suffered serious adverse side effects from Septrin or one of Wellcome's other brand named antibacterials of the same family. Deer says that he listened, sympathized and followed up with all of these calls and in the

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<sup>34</sup> Andrew Herxheimer suggests that this could have been done a decade earlier. See, Side Effects: Freedom of information and the communication of doubt Andrew Herxheimer. The Side Effects of Drugs Annual (SEDA) 19: 1996. The article can be seen in draft form at:

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magazine article he recalls many of them, calling them to mind as if they were important anniversaries in his own experience.

For some reason, Deer did not support the two independent campaigns that had been set up. Perhaps as a journalist he needed a clear field to be able to use the cases that contacted him in the best way for the overall campaign. Perhaps he thought that independent campaigns might press for objectives in which he and the Sunday Times were unprepared to become involved.

There can be little doubt that Brian Deer's Sunday Times campaign against Septrin was one of the most successful campaigns waged against a pharmaceutical product in Britain. Within 18 months of his first article, prescription of Septrin had been restricted in Britain. However, Wellcome seemed to have escaped lightly from the damning evidence accumulated by Deer; in Britain, prescription of the drug was 'restricted' only by data sheet recommendations while throughout the rest of the world the prescription and sales of Septrin remained unaffected; no legal claims went forward on behalf of the many badly damaged or deceased victims of Septrin and the two campaigning organizations set up promptly folded; Perhaps most important of all, Brian Deer became the 'owner' of the Septrin archive that he had accumulated during his investigation. Notes on his web site make it clear that information from this archive can not be used in any way without Deer's permission.

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The prescribing restrictions on Septrin at least provided Deer with a relatively smooth public victory against a major pharmaceutical company. Brian Deer's investigative career, however, was about to take another turn, and again it would involve the Wellcome Foundation.

In 1998, Deer produced another heavy-weight article about drugs in the *Sunday Times Magazine*.<sup>35</sup> The whooping cough vaccine, produced by Wellcome, had come under consistent public attack in relation to serious adverse reactions. Throughout the eighties and early nineties a handful of court cases had each been defeated by Wellcome.

However, following steady and committed campaigning by Rosemary Fox, whose daughter had been adversely affected by the vaccine, aided by the labour MP Jack Ashley in 1979 the Government was pushed into a strategic concession to parents of vaccine damaged children, setting up the Vaccine Damaged Payment scheme. The Vaccine Damage Payment Unit although appearing to be an instrument of hope for parents of vaccine damaged children later became a distraction that could be used by the government to tell parents that a fair system was at hand.

On the legal front, there were no concessions and Britain retained its reputation as the hardest country in the world to get

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<sup>35</sup> Brian Deer: The Vanishing Victims. *The Sunday Times Magazine* November 1 1998. Can whooping cough jabs cause brain damage in children? Brian Deer investigates.

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legal justice against a pharmaceutical company; not one in-court case settlement conceded to a claimant. Until that is, the case of Kevin Best.

In 1994, at the end of a drawn out legal contest, an Irish mother, Margaret Best, was awarded £2.75m, plus costs on behalf of her son Kenneth, whom the court decided had suffered brain damage after receiving the whooping cough vaccine.

Although this ruling cost Wellcome only £10m., a tiny fraction of their profits, the finding threatened to de-rail the marketing of the DTP vaccine while putting the brakes on the government and pharmaceutical combined vaccine programme.

Why Deer was drawn to write his article about Margaret and Kevin Best, we shall probably never know; however, the change in direction, was, for Deer quite startling. On the issue of vaccines at least, Deer now appeared quite firmly on the side of the pharmaceutical companies and the government. It appeared that to Deer, Vaccination was primarily an issue of public health, one in which there should be a balance between individual damage and collective immunity. Serious cases of obvious vaccine damage should be resolved by the Vaccine Damage Payment Unit.

Clearly Deer considered, in concert with the pharmaceutical companies, that each case of vaccine damage that might gain public attention or represent a viable legal case had to be publicly questioned. Despite the clear and quite heroic legal victory

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won by Margaret Best on behalf of her brain damaged son, Deer's article sought to re-enforce the vaccination strategy of the pharmaceutical companies, while introducing into the public mind, retrospective doubts about the validity of her evidence.

The article on Margaret Best reads quite unlike many of Deer's other hard hitting articles. Well written in a contemporary style, it is noticeable that the author had found it difficult to directly accuse Margaret Best of bringing a false claim against Wellcome. The article summed up Best's lengthy battles in the Irish courts with one of the world's largest drug companies in a relatively low-key manner and like a Matador suddenly aware of animal rights, Deer fails to deliver the *coupe de grace*. The article leaves hanging the question of whether the court *had allowed* Margaret Best to be confused about factual evidence which she gave in support of her son's case, or whether she *had lied consistently* to obtain her settlement.

It is worth taking just a sip of the Margaret Best article, and swilling it around the mouth before spitting it out; the bouquet has an interesting musty fullness of hackery. The essential statements of the article give a good idea of how a good journalist can cast doubt upon a legal ruling which has been six years<sup>36</sup> in its distillation, with a *vox pop* article, unsupported by legal or scientific detail.

Margaret was living like a lottery winner in a five-bed roomed house down a maze of country lanes, near the airport. The property had

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<sup>36</sup> It began in April 1989 and finished in July 1995.

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electric gates, a gravel drive, floodlights and barking dogs. Furniture was chunky and fabrics rich.

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On Wednesday September 17, 1969, it seemed, Kenneth was 4.5 months old and received his first DTP vaccination. He apparently had a fit, or "turn", six hours later while eating his tea, and, after that, more than 10 times daily. "His face got very red and his eyes turned in to the right, in to the corners," Margaret had told the Dublin judge. "Both his arms came up to his chest and it was as if his whole body was stiff."

She said that she phoned her general practitioner that night, had taken Kenneth to him next morning, and then at least twice a week for months. Eight months later, a paediatrician diagnosed Kenneth as having West's syndrome, a progressively disabling seizure condition which usually starts at between three and eight months of age, and which is often genetic in origin. The records of this doctor, and those of another consultant, also contained oddities. Neither was told about the DTP and both took down dates for the boy's first fits that were many weeks after his jab.

Such discrepancies were serious: experts who believe in the vaccine damage link say that fits must occur with 72 hours to be plausibly linked to it. The contradictions inevitably raised the question of whether Margaret's story was accurate.

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... one morning in her kitchen, we did a short interview. We talked about her father, a bookie's clerk, about how she left school at the age of 12, and about her first job as a care assistant. Then we discussed her husband, Ken, and their subsequent separation. And finally the fateful night.

"So, where did you phone the doctor from?" I asked, trying to get a picture in my mind. Margaret got up, walked across the kitchen and did something or other at the cooker.

"Well," she said. "There was a neighbour whose phone I sometimes used."

"Um, so is that what you did?"

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She paused. "No," she said, and moved back to the cooker.

I waited until she returned. "So, er, what, you used a phone box?"

"Yes," she said.

It was background colour, of no great consequence. But later I listened to the tape. Why mention the neighbour if she had used a phone box? What was the reason for delaying her reply? Surely, the night which saw her child's life wrecked was indelibly etched on her mind?

The article about Margaret Best appears to be central to Deer's development as a journalist who now came down forcibly against the idea that vaccines could have adverse reactions or cause damage to their recipients and furthermore that claimants are scammers capable of lying about the circumstances of their children's damage.

If this matter of Deer's defence of vaccinations might have seemed merely speculative following the article about Margaret Best, it was to become increasingly concrete with his following articles and finally his *Sunday Times* article on Andrew Wakefield.

By 2004 when Deer was willing to stake his reputation on the anarchic assault on the identity and science of Dr Wakefield, he was also apparently willing to admit to his defence of pharmaceutical and government vaccine policy.

Last November (2003) a Sunday Times journalist who identified himself as Brian Lawrence paid a visit to Kessick's home north of London. He spent nearly six hours questioning her about William's autism, Wakefield

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and the entire MMR controversy. Afterward, she said, she felt like she had been grilled like a witness under cross-examination. She said that Lawrence didn't seem to believe anything she told him.

Her suspicion was not far off. "Brian Lawrence" was actually Brian Deer, a prize-winning investigative journalist with a reputation for breaking stories about the pharmaceutical industry. Deer said he used a false name --Lawrence is actually his middle name -- because he didn't want Kessick to check his web site and find out that one of his specialties was tracking down false claims of damage from vaccines.<sup>37</sup>

Brian Deer posted this part of an article by Glenn Frankel on his web site, where it can still be read, without rebuttal or contradiction. If this is still the case and Deer has given us no information to suggest that it isn't, one unanswered question remains writ large, 'Does anyone other than the *Sunday Times* newspaper, fund Brian Deer to carry out this work?'

## Investigating and Prosecuting in Private Interests

Deer's support for the vaccine industry, while being critical of some selected pharmaceutical industry extreme events, leaves him in an interesting position with respect to Dr Wakefield. For while he might broadcast forcefully in support of the trial subjects terribly damaged in monoclonal antibody trials - a subject that the ABPI would also want exposed<sup>38</sup> - he is forced to portray the parents of

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<sup>37</sup>. He introduced the article that contained the sentences with, 'On Sunday July 11 2004, Glenn Frankel, reported from London for the Washington Post, after interviewing some of the key players in the MMR scandal. His story ran from page A1, under the heading "Charismatic Doctor at Vortex of Vaccine Dispute".

<sup>38</sup> In March 2006, six men were taken seriously ill whilst acting as 'healthy volunteers' in a clinical trial at an independent research facility run by American company Parexel on the site of Northwick Park Hospital, London. This episode of the documentary series *Dispatches* (Channel 4, 28th September 2006) tries to uncover what might have caused an apparently routine safety trial to go so dramatically wrong. As well as discussing the case with a number of experts on clinical trials, investigative journalist Brian Deer spends a lot of time talking with Ryan Wilson, the man most badly affected by the trials. In keeping

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vaccine damaged children as possibly untruthful or mistaken chancers and the professional scientists critical of some vaccines as at best fools and at worst crooks.

Given what appears to be a conflicting stance on some drugs and procedures as against his pharmaceutically supportive approach to vaccinations, it would seem important to view Deer's work within the overall context of the needs of the pharmaceutical industry, rather than take for granted the more focused PR that has now begun to circulate about him as the only journalist in Britain willing to take on the pharmaceutical industry.

The ABPI, like related world bodies of the pharmaceutical industry, is more energetic than any other manufacturing trade association. Its word and its emissaries spread across the country and then the globe like the missionary flocks of the church in nineteenth century Africa. Once members reach positions of prominence within the hierarchy of the industry, they continue serving their masters long into the future, after retirement and sometimes it appears, into the hereafter. Each prominent officer of the ABPI who remains loyal is trained in promiscuity, he joins, infiltrates and becomes intimate with numerous individuals and organisations, in order to gather intelligence and influence people in their belief in, and ultimately their consumption of, pharmaceutical medicines.

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with this genre of reporting, there is also the compulsory pursuit of a representative from Parexel, in the vain hope he might talk on camera. (<http://bioethicsbytes.wordpress.com>).

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Amongst those within this pharmaceutical diaspora, there is no room for liberalism, doubt or the countenancing of weird ideas about alternative medicine. There is no space for critical dialogue. While there might be faults in the family pharma, they are never discussed seriously in public.<sup>39</sup> The survival of the industry rests entirely, believers think, on the rebuttal of any criticism. The kind of jaundiced cynicism which this engenders is inevitably inimical to free scientific investigation.

The control of funding, clinical research and subject cohorts, has become increasingly important to the pharmaceutical industry for a number of reasons. As the industry has colonised larger numbers of patients, research staff in hospitals, medical schools, GP practices and universities to carry out trials, it has developed a need to protect its interests – poor or corrupted research wastes both money and time. Consequently, the industry has developed its own highly selective regulation and policing of clinical research. While the industry argues that they have done this because governments are backsliding, it is clear that the industry is desperate to maintain hegemonous control of regulation and policing of its funded research as far as it is able.

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<sup>39</sup> Over the last couple of years, high ranking pharmaceutical executives and ABPI members have made some statements which appear to cast doubt on the efficiency and ethical basis of the industry. In 2005, Sir Richard Sykes, stated to the *House of Commons Health Committee enquiry into the Influence of the Pharmaceutical Industry*. ‘ Today the industry has got a very bad name. That is very unfortunate for an industry that we should look up to and believe in, and that we should be supporting. I think that there have to be some big changes.’ However, very little does change and a sceptic might suggest that statements like the one above are simply acclimatising statements, off-handedly offered to blunt serious criticism.

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As a consequence of this determination to control clinical research, independent research which hints at industry-created illness has been attacked on every front and is now an almost extinct animal. In those rare cases, such as that of Professor Arpad Puztai whose research found that genetically modified potatoes damaged genes in mice,<sup>40</sup> these independent thinkers are attacked by science in defence of industry with all guns blazing.<sup>41</sup> They are dragged through ignominy in the media, they are stripped in public of their past and all their decorations and they are ceremoniously kicked into the gutter. Their work is publicly torn into confetti and scattered to the winds of history.

By gaining complete control of the Medicines and Healthcare products Regulatory Agency (MHRA),<sup>42</sup> and by fighting to ensure the majority of regulatory body members are allowed interest conflicts as the norm, the pharmaceutical industry is able to present a solid bulkhead against the investigation of health damage from drugs, legal actions for compensation or irregularities in manufacture or prior to licensing. The pharmaceutical industry, to a far greater extent than any other, has become untouchable.

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<sup>40</sup> See Andy Rowell's excellent work on this and other GM scandals, particularly, Ousted Scientist and the Damning Research into Food Safety. Michael Sean Gullard, Laurie Flynn, Andy Rowell *The Guardian* (London) February 12, 1999 at <http://www.biotech-info.net/ousted.html>

<sup>41</sup> There is an interesting overlap between the lobby and spin groups which attacked Puzsti's work and defended his dismissal and those who have attacked Andrew Wakefield. Ex members of the late 'Marxist' sect RCP, have in their post political years become messianic defenders of industrial science. Members of their moribund grouplet, have supported the psychiatric dismissal of ME as an organic illness, supported the pharmaceutical companies over HRT, supported Monsanto on genetic engineering and supported the Government and the ABPI over MMR.

<sup>42</sup> The body which used to be called the Medicines Control Agency (MCA) and is now entirely funded by the pharmaceutical industry.

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If, however, the pharmaceutical industry has gradually gained control over clinical research in Britain and Europe it has wanted for one thing; a regulatory investigative agency tied to a prosecuting function. In cases of law breaking, the police and the courts could be used but, in other cases, British medicine and medical research in particular have always been lacking in a superstructure which contains investigating and prosecutorial agencies. This situation leaves the industry vulnerable and insecure, consistently open to the sudden constitution of an *independent* investigative and policing agency.

### Oiling the Wheels of the GMC

In neither his *Sunday Times* article nor the Dispatches programme nor on his web site does Brian Deer make reference to a company called MedicoLegal Investigations Ltd (MLI). MLI is a private company, controlled and almost completely funded by the ABPI that has an agreed representation on its board. The company played a leading part in Deer's investigation, and helped prepare the case against Wakefield to go before the GMC.<sup>43</sup>

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<sup>43</sup> The GMC has been involved in the MMR conflict on at least two other occasions, the first time when they put allegations to Dr Peter Mansfield accusing him of 'putting children's health at risk' after he offered single vaccines to parents. Sense, however, prevailed in Mansfield's case when the GMC dropped the charges against him. The complaint had been brought by Professor Brian McCloskey, Deputy Director of the Health Protection Agency, Local and Regional Services. The HPA is the new Public Health Laboratory Service (PHLS), the agency which partners pharmaceutical companies in the production of vaccines and has a wide range of commercial involvements with these companies. The PHLS added its name to a condemnation of Wakefield in 2001 when he published *Through a Glass Darkly*. The paper suggested that MMR had not been sufficiently well tested for safety. The second time when they brought Jayne Donegan before a fitness to practice hearing. At the end of the hearing the panel found in her favour on all the charges.

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The overview of MLI's history, personnel and investigations which follows is not intended to point to a *joined up conspiracy*. It will be obvious to most people that a private enquiry agency mainly controlled by the ABPI and managed in part by an ex ABPI staffer, would, in many cases, probably not be impartial. In an investigation into the ethics of a researcher who has suggested adverse reactions to pharmaceutical products, or perhaps alternatives to these preparations, the chance of a fair inquiry would appear non-existent.

The core of this essay, however, approaches an explanation of something more important than this. We live in a world where we really cannot believe everything we read in the papers, where an inquiring mind is an essential aspect of a sane identity. The following section about MedicoLegal Investigations explains to a degree the culture and the parameter of the attack on Andrew Wakefield. It is given also as a lesson, for within this information are revealed, like great rocks before the prow of a ship, the beginning of the questions which we must ask and answer about Wakefield's case, if we believe in fairness and justice.

Recently, a well informed medical activist, who had sat as a lay representative on GMC panels, wrote to a contact of mine rebutting what I had said in one of my essays about Medico-Legal Investigations. She asked, 'What could be wrong with an investigative agency, even if it was backed by the ABPI, bringing cases to the GMC?'. In the past she said they had processed some important cases, much in the interests of patients. If I could have

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been bothered to respond to this enquiry, I would have said simply; 'That's a fair point, but what about the ones they slip in that are entirely in the interests of the pharmaceutical industry?' The case of Dr Andrew Wakefield is obviously one such case and so it is worth looking a little more deeply and perhaps cynically at Medico-legal Investigations and any contact they might have had with Brian Deer and the GMC.

The simple question has to be asked, 'Does the GMC need the ABPI or does the ABPI need the GMC?' The answer of course is obvious, while the GMC in theory doesn't need and shouldn't have anything to do with the pharmaceutical industry, the ABPI needs to be linked to a regulatory system that gives its regulatory strategies authority. How else could it bring dissidents into line and how else could it punish ill discipline in the industry.

In 1996, after eight years of processing cases of clinical research fraud for the ABPI where he was Medical Advisor, Dr Frank Wells<sup>44</sup> set up Medico Legal Investigations (MLI) with Peter Jay, a former career detective with the Metropolitan Police who had retired holding the rank of Detective Chief Inspector.<sup>45</sup>

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<sup>44</sup> Although 1996 was the year Frank Wells apparently resigned from his position at the ABPI, in pharmaceuticals, nothing in the world of post retirement work should be taken for granted. There are numerous ways in which ex-ABPI executives can continue being remunerated by the industry.

<sup>45</sup> **Peter Jay** is Managing Director of Medico Legal Investigations (MLI), a small company which investigates questionable research carried out by doctor. He was previously a Metropolitan Police Detective Chief Inspector and was also a salaried investigator for the General Medical Council (GMC) solicitors for six years.

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Wells' experience in the pharmaceutical industry was of investigating complaints against researchers and following through with their prosecution through the GMC. Jay was experienced in criminal cases, before leaving the Metropolitan Police he had managed the investigation and the prosecution of Dennis Nilsen, until recently the UK's biggest serial killer.<sup>46</sup>

Following his retirement from the Met., Jay worked for several years for the solicitors to the GMC and Dental Council. In this capacity, he investigated cases involving fraud, gross incompetence, negligence, indecency and dishonesty. It was while investigating and prosecuting cases which they took before the GMC that the two men met and decided to set up MLI.

The ABPI had been taking cases involving research misconduct before the GMC since 1988. By 1996 when MLI was set up, the ABPI had referred 16 cases of suspected fraud by doctors in clinical research to the GMC. All 16 doctors were found guilty: two were admonished, five were suspended from the medical register, and nine were struck off.

Almost in passing, it is important to understand both why and how these two regulators related to the GMC and in whose interests it was that they pursued fraudsters inside the pharmaceutical industry? Are there similarities here, for example with the police force that works within the MHRA, completely

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<sup>46</sup> Ironically, Neilsen's place at the top of the serial killer list was taken by Dr Harold Shipman, the murderous doctor whose activities and lack of identification

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subsidised by the pharmaceutical industry and in the main investigating cases that are of benefit to the industry, but spending some of its time investigating alternative medicine practitioners who are brought to 'justice' using the public justice system.<sup>47</sup>

In the late eighties and early nineties, when Duncan Campbell was working with Campaign Against Health Fraud activists, he was helped in getting a number of the cases against alternative practitioners he investigated before the GMC by the newly founded MLI. When in 1996, Campbell wrote his important article, *An MI5 for the Medical Profession*, in the *BMJ*,<sup>48</sup> although his solution was suggestive of an agency for standards with a close link to the State, he wrote flatteringly about MLI, the only investigative agency in the game, at that time.

Medicolegal Investigations, is far more impressive. By July of 1996 17/17 complaints brought to the Council (GMC) by Frank Wells and Peter Jay had resulted in the practitioners being struck off.<sup>49</sup> Medicolegal Investigations is a commercial organisation, working mostly for pharmaceutical companies who suspect research fraud in their trials.<sup>50</sup>

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has caused the GMC no end of problems.

<sup>47</sup> See Walker, Martin J. *The Fate of a Good Man: The investigation, prosecution and trial of Jim Wright by the MHRA*. *Slingshot publications*. 2007. Available from [www.slingshotpublications.com](http://www.slingshotpublications.com)

<sup>48</sup> Duncan Campbell, *An MI5 for the Medical Profession*, *BMJ*, 1996.

<sup>49</sup> This sentence is confusing and should read 'between 1989 and 1996 the ABPI brought 17 cases before the GMC' or 'between 1989 and 1996 Frank Wells helped bring 17 cases before the GMC.' The 17 cases are the record of Frank Wells, who until 1996 was working at the ABPI and Peter Jay who was working for the GMC solicitors Field, Fisher, Waterhouse. MLI was not set up until 1996.

<sup>50</sup> Duncan Campbell *An MI5 for the Medical Profession*, *BMJ*, 1996.

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MedicoLegal Investigations Ltd. ensured that at least three cases which grew out of Campbell's investigations were smoothly prosecuted before the Professional Conduct Committee of the GMC and resulted in doctors being struck off the medical register.<sup>51</sup>

The name of MedicoLegal Investigators or its principle staff, are not mentioned by Brian Deer's accusatory article on Wakefield in the *Sunday Times*. This is odd because in their literature the company appears proud of the part which they played in partnering Deer in his investigation. In an article entitled, *MMR and MLI, MMR Sunday Times Investigation (22<sup>nd</sup> February 2004)* in their internet Newsletter of March 2004,<sup>52</sup> MLI say:

The extraordinary tale of the problems found in the paper by Dr Andrew Wakefield (as published in the *Lancet*) concerning MMR and autism were shared with MLI in strict confidence whilst Brian Deer's fine piece of investigative journalism was under way. *We were asked to advise on matters that were clearly quite alarming.* (authors italics)

So, Brian Deer (and the *Sunday Times*) asked the opinion of a pharmaceutical industry-funded company while investigating Dr Wakefield; why is this not a surprise? This tit-bit purposely fails to reveal whether Deer went to MLI with his investigation or whether they took the idea for the investigation to Deer, or in fact whether the ABPI put Deer and MLI in touch with each other.

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<sup>51</sup> These cases are discussed in the author's book *Dirty Medicine*. Had the subjects of these particular investigations known about MLI at the time, or about the unit run by Frank Wells at the ABPI and MLI's continuing links to the ABPI it would have given them evidence that some HealthWatch activists were working in the interests of the pharmaceutical industry.

<sup>52</sup> MedicoLegal Investigations Ltd. Newsletter March 2004 Issue 10. MMR and MLI.

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In the same short article, the Newsletter makes much of the ABPI concerns about parents who will inevitably have been confused by Wakefield's research. Oddly, the article says nothing at all about Wakefield's supposed ethical infringements but concentrates on the idea that his *wrong conclusions* about MMR would inevitably have confused parents.

Tragically, as in this case, the information provided by Dr Wakefield not only throws doubt on the work of his colleagues within the medical profession it affects the decision making process for parents who became (sic) totally confused about the rights and wrongs of MMR.<sup>53</sup>

It is important not to forget that we are being addressed about the science of MMR by an ex Metropolitan police officer, renowned for their clear thinking on scientific matters, an ex staffer of the ABPI, and an ex member of military intelligence; again, in double blind trials such people have been shown to be very knowledgeable about the science of combined vaccines.

From the beginning, the major funder of MLI, which refers to itself as 'a not for profit organisation,' has been the pharmaceutical industry. Projects have been paid for both by individual companies and the ABPI. The ABPI is superficially open about how it relates to Medico Legal Investigations; in this quote referring to one of Wells' books, the role of the ABPI is fully acknowledged in bringing doctors

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<http://www.medicolegal-investigations.com/index.htm>

<sup>53</sup> Interestingly, this motif which suggests that research critical of pharmaceutical medicines 'confuses' patients, is one of the most pervasive ideas used by big pharma today. When the research results of the Women's Health Initiative were published showing that HRT could lead to breast cancer, stroke, and deep vein thrombosis, Wyeth Pharmaceuticals ran an aggressive campaign against the study claiming that the results would 'confuse' women users and doctors.

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before the GMC. 'Dr Fairhurst was the 16th doctor to be found guilty of serious professional misconduct after referral by the Association of the British Pharmaceutical Industry since the association began actively referring such cases in 1988.'

In another statement, the relationship is again made clear: 'The ABPI, in conjunction with MedicoLegal Investigations will continue to prosecute severe research misconduct and continue to bring investigators to the GMC if necessary.' In 2001, when two board members were nominated by the ABPI to MLI, the company said that the nomination meant that 'The ABPI Board of Management (i.e. the pharmaceutical industry) has demonstrated its support' and on another page of their web site, MLI describe themselves as having 'the full weight of the ABPI behind' them. Jay has written of the MLI in these terms: it 'acts as a bridge between the pharmaceutical industry *and patients*'. According to Jay, the MLI has the support of the GMC, the BMA and the ABPI.<sup>54</sup>

In June 1998, the investigation team expanded when Jonathan Jay became a Director & Company Secretary. According to MLI publicity, Jay was previously a specialist investigator with the Army Special Investigation Branch and had a decade of experience in the detection and prosecution of criminal offences, specialising in criminal deception/fraud investigations.

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<sup>54</sup> Fraud in Medical Research, Peter Jay.  
<http://www.ceres.org.uk/assets/docs/Fraud%20in%20medical%20research.pdf>.

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In 2001, MLI strengthened its board with the inclusion of two nominees from the ABPI.<sup>55</sup> MLI agreed the right of the ABPI to nominate at least two members to the board of the organisation. The first two nominees were Dr Richard Tiner, at that time Medical Director of the ABPI, who assumed the role of a Director of MLI; and Mr Michael Wallace, no lesser figure than a Vice President of the ABPI, became Chairman of MLI.

A penetrating look at members of MLI leaves one gasping at the extensive network of influence built up and acted out by its 'ideological' members.<sup>56</sup> While its investigators evidently have years of experience and technically excel at their jobs, those who guide the organisation and presumably sanction the targets could not be better placed or connected to do the bidding of Big Pharma. If one was looking for an organisation, influential and well connected enough to deliver a death blow to Andrew Wakefield's career, then one need look no further than MLI. If one was looking for an organisation which could organise all the forces of the vaccine industry in defence of MMR one need look no further than MLI.

Private Limited companies are under no pressure at all to declare vested interests. So while MLI could well have instigated, or been from the beginning involved in Brian Deer's investigation which led to charges being brought before the GMC, few would be aware of interest conflicts which might lead to bias in their

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<sup>55</sup> *The Pharmaceutical Journal*. Vol 264 No 7088 p426 March 18, 2000. ABPI formalises links with clinical fraud investigation firm.

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investigation. In February 2002, the organisation invited onto the board Dr Jane Barrett.

### Dr Frank Wells

Dr Frank Wells worked as a GP after training at Barts. A former member of British Medical Association (BMA) Council, in 1981, at the time of its first publication, Wells was joint secretary of the Joint Formulary Committee and the British Medical Association. He was until 1996, Director of Medical Affairs for the ABPI. He founded the Ethical Issues Committee of the Faculty of Pharmaceutical Medicine.<sup>57</sup> The Faculty of Pharmaceutical Medicine is the educational department of the pharmaceutical industry situated within the Royal College of Physicians.

Wells' connections in the pharmaceutical world and the orthodox medical establishment are extensive. He is Chairman of Marix Drug Development Ltd., a professional services firm focussed on all aspects of drug development from preclinical sciences to phase I - IV clinical trials.

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<sup>56</sup> I have used this word to describe the best connected ex and present serving ABPI members of the firm as distinct from their investigators who do not appear to have a record of industry connections.

<sup>57</sup> Under the Chairmanship of Dr Frank Wells, The Ethical Issues Working Group of the Faculty of Pharmaceutical Medicine produced the report *Ethics in Pharmaceutical Medicine*, published in 2000. The other members of the Working Group who produced the Report were: Dr Roger Bickerstaffe Vice President Pharmaceuticals Communications, Solvay Pharmaceuticals; Dr Peter Brock Medical Director, European Vice-President, Medical Affairs, Wyeth Lederle and Member of ABPI Medical Committee; Professor Jean-Marc Husson, Consultant Pharmaceutical Physician, President of IFAPP, and formerly Medical Director, Roussel-Uclaf, Paris; Professor David Lawson, Chairman, Medicines; Dr Ian

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Wells is Vice-Chairman, of the Society of Pharmaceutical Medicine and in the 1990s was a prominent member of the Research Ethics Committees (REC). He currently chairs the Ethical Issues Committee of the Faculty of Pharmaceutical Medicine and serves on two research ethics committees. With Michael Farthing, Frank Wells is the author of *Fraud and Misconduct in Biomedical Research*,<sup>58</sup> published by the BMA Publishing group. Wells is also the author of *Pharmaceutical Ethics*.<sup>59</sup>

### **Dr Richard Tiner**

By the end of the 1990s, it was becoming clear that a higher spin had to be put on the self-regulating protection of the industry. While the industry had managed to hold off government intervention or any kind of independent regulatory inspection of clinical research, the industry was about to be faced with EU Directives. The Directives were to make clinical trial inspections mandatory.

In 1999, a ten year study of over 800 clinical trials, mainly in Britain, uncovered low standards and many concerns about the risks to trial members. In an editorial for the industry journal *Clinical Research Focus*, one of the authors of the study, Dr Bohaychuk, wrote: 'Frankly, after 10 years of detailed auditing, I would never go into a

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Rubin Chief Executive Officer, Matrix, formerly Medical Director, Fisons Pharmaceuticals.

<sup>58</sup> *Biomedical Research*, 3rd Edition edited, by Stephen Lock, and, Hardcover, 6" x 9.5". BMJ Books (An Imprint of the BMJ Publishing Group), BMA House, Tavistock Square, London WC1H 9JR, UK. Publication Date 2001. xii + 268 pages, ISBN 0-7279-1508-8. Price £40.00.

<sup>59</sup> *Pharmaceutical Ethics*. Edited by S Salek, A Elgar. John Wiley & Sons, 2002, £45.00, pp 210. ISBN 0471490571.

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clinical study myself and I would certainly try to discourage anyone in my family from doing so.'

The argument which followed threw into sharp relief the view of the researchers that further independent auditing of clinical trials was needed and that further regulations, like the EU standards about to come into force, were to be welcomed. The ABPI however seemed determined that enough regulations already hampered their industry and it was more than capable of self-regulation.

Replying to an article about the study in the Guardian,<sup>60</sup> Dr Richard Tiner, then the Director of Medicine at the ABPI, defended the pharmaceutical industry in the broadest terms:

It is not true to suggest that people taking a part in UK clinical trials are at risk (Drug trials risk to patients, July 27). Stringent safeguards are in place throughout the different phases of clinical trials to ensure that any unwarranted side-effects of a new medicine are immediately reported. If necessary, the trial will be stopped.

It is suggested that pharmaceutical companies and investigators may cut corners. Quite apart from ethical considerations, no company can afford to do that. It takes 10-12 years and some £350m to research and develop a new medicine. This investment would be thrown away if the regulatory authorities had cause to believe that guidelines had not been followed.

Your leader (July 27) suggested more regulation. There is no real need for further regulation - indeed, the pharmaceutical industry is already one of the UK's most regulated industries. Contrary to the impression given by your article, the Association of the British Pharmaceutical Industry (ABPI) has

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<sup>60</sup> Sarah Boseley, Drug trials risk to patients Audit shows flawed tests are a danger to health, *The Guardian*, 27 July 1999.

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no problem with the development of a European directive on good clinical practice.<sup>61</sup>

Wendy Bohaychuk PhD, the lead author of the paper, was scathing about Tiner's defence of the industry.<sup>62</sup>

Dr Tiner (Director of Medicine, Association of the British Pharmaceutical Industry), in response to an article describing some of our clinical trial audit findings, wrote that stringent safeguards are in place throughout clinical trials to protect study subjects. According to our data, they are not stringent enough.

The industry has always complained about too much regulation, but given that our health is at risk, surely the whole situation deserves tight control. Anyway, who is checking that these "safeguards" are effective - certainly not the ABPI ... As far as we know, the ABPI has inspected no studies, so we wonder on what grounds Dr Tiner makes his statements assuring us that all is well ... self-regulation did not work ten years ago and it does not work now . . . who is checking that new rules are working? Certainly not the overworked ethics committees in this country which review lots of paper but do not have the time and resources to visit study sites and confirm that the studies they approve are running properly and meeting "exacting standards". And certainly not our government which is still waiting for legislation (why?) to conduct mandatory inspections.

Ten years ago, a senior ABPI spokesperson reported to a European-wide audience at a meeting in France that all clinical trials in the UK were safe . . . Our reaction then, as it remains today, is "how do you know"? The ABPI, the ethics committees and the government were not conducting inspections at that time either.

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<sup>61</sup> Dr. Tiner, letter to the Guardian

<sup>62</sup> Letter to The Guardian (unpublished), 31 July 1999, from Wendy Bohaychuk PhD. Director, GCRP Consultants; Editor-in-Chief, Quality Assurance Journal

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This exchange between Tiner and Wendy Bohaychuk gives us a good picture of a strategic plan which was to be played out by the ABPI over the next five years: Fight the introduction of any further regulation, make as deep a penetration of the area of clinical research ethics as possible, helping to shape and control its future direction and stave off government or independent agency inspections at all costs while creating an agency which, while being under industry control, would appear to be policing standards.

Within a year of this public conflict, Tiner had been placed on the Board of MLI. The industry, already close to MLI, chose to promote it as a 'safe' watchdog which could appear to clean up the industry's clinical research image while protecting the deeper interests of the drug companies. Not only was Tiner a serving executive in the ABPI, but he brought with him to MLI a large number of network connections upon which MLI could draw.

Both Mike Wallace and Dr Richard Tiner, the nominees placed in the MLI board by the ABPI, have been deeply involved in the developing partnership between the pharmaceutical industry and the NHS. Both of them were in prime positions to protect and progress the agreement between the New Labour government and the industry in relation to combined vaccines.

Dr Richard Tiner qualified in Medicine in 1974 and following junior doctor posts in Kettering and Taunton, worked as a principal in general practice in Somerset for 17 years. In 1996, he took over the post, given up by Frank Wells, of Director of Medicine at the ABPI.

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His current responsibilities include the development of child vaccines and work on the ethics of research, trials and production of child medicines.<sup>63</sup> He sits on the ABPI Current Controlled Trials Advisory Group. Clearly Dr Tiner would be at the forefront of any discussion around adverse reactions to childhood vaccination.

Tiner is a member of the NHS General Medical Services Committee's prescribing subcommittee, which also has a considerable interest in take up of vaccines and post licensing surveillance.

Tiner was the Clinical Trials Strand representative from the ABPI on PICTF, the Cabinet level meetings held between the government and the pharmaceutical industry. He was a participant in the formulation of NICE Clinical Guidelines for the NHS and the regulation of clinical trials.<sup>64</sup> Tiner is a firm believer in partnership between the government and the pharmaceutical industry, in his view '...through PICTF the Department of Health in particular and the pharmaceutical industry are now beginning to see each other as partners rather than on opposite sides of the fence.'

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<sup>63</sup> The issue of child medicines is a big contemporary problem within the pharmaceutical industry because it has only recently become public knowledge that for years, children have been given lower doses of pharmaceuticals which have only been given to adults in trials and only licensed for adults. At the same time that this information surfaced it was revealed that children prescribed the SSRI anti depressants had suicidal ideation which one company at least had failed to report prior to licensing.

<sup>64</sup> *Current Issues in Paediatric Clinical Trials*, Meeting Report 2005-05-01.

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Tiner is a member of the Executive Committee of The Society of Pharmaceutical Medicine of which Frank Wells is also a member,<sup>65</sup> and in this capacity very close to the Association of Research Ethics Committees.

Dr Tiner is also a member of the Council of the NHS R&D Forum,<sup>66</sup> a network for those involved in planning and managing research in health and social care. The aim of the Forum is to improve the environment for research in health and social care by facilitating and encourage sharing of best practice. A senior manager from the Department of Health also sits on the Council and the Council 'interacts' with the Department of Health.

The ABPI launched its Paediatric trials guide, *Current Issues in Paediatric Clinical Trials*<sup>67</sup> on 23rd Feb 2005 in a move, they said, to ensure that children benefit from medicines especially tailored to their needs. On the book's launch, the ABPI claimed that the difficulty in conducting trials in young age groups is behind a current shortfall in the range of medicines specifically formulated for children.

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<sup>65</sup> The Society of Pharmaceutical Medicine is a pharmaceutical industry front. Besides Dr Tiner from the ABPI, its Executive Committee includes Dr Martin Lunnion of GlaxoSmithKline, Dr Donna Ellender of Sanofi-Synthelabo, Dr John Pincott of Celltech, Dr Bruce Charlesworth of Pfizer UK, Dr Shaun Kilminster and Dr Andrew Dowson, who are the inventors of the The Short Pain Inventory and directors of a Headachetest.co.uk an on line headache treatment programme.

<sup>66</sup> Other members of the Council include high ranking representatives from the MRC, Institute of Child Health and Great Ormond Street Hospital, NHS Modernisation Agency NICE, COREC, The Wellcome Trust, RCGP and Research Group.

<sup>67</sup> *Current Issues in Paediatric Clinical Trials*. ABPI Publications.

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Tiner, commenting on the publication as the Director of Medicine at the ABPI, rather gave the game away when he said, 'Currently more than 90 per cent of medicines used in newborns and 45 per cent of medicines used in general paediatric care have never been tested or licensed for use in that age group and are used off-label by clinicians. This situation needs to be changed *but clinical trials in so many age groups are expensive ...*'

### Michael Wallace

Mike Wallace, the other nominee to the position of Chairman of MLI, is a Vice-President of the ABPI and, until December 1999, was a managing director of Schering Health Care Limited.

Mike Wallace is a member of the Scottish Medicines Consortium (SMC), a quango set up to advise the Scottish NHS on buying medicines. The first Annual Report, in 2003, created a furore. It included a record of members' interests which revealed that half of the Consortium's members had interests in pharmaceutical companies. Wallace, who is Chairman of the Patient & Public Involvement Group of the Consortium, recorded a financial interest in seven companies.<sup>68</sup>

Wallace is Chairman of Datapharm Communications Ltd, a company established in 1977 and run in co-operation with the ABPI. Datapharm is involved in sales and marketing as well as publishing. The company represents the ABPI Medicines Compendium,

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<sup>68</sup> Conflict of interest fears over fees paid to experts. Sarah-Kate Templeton, Health Editor *Sunday Herald* on Line. <http://www.sundayherald.com/31674>

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Electronic Medicines Compendium, Medicine Guides and Primary Care Drug Dictionary interface.

Datapharm is currently developing Medicine Guides as part of the Medicines Information Project (MIP), and publishes the annual ABPI Medicines Compendium. The MIP is based on partnership between a wide range of organisations including industry and other stakeholders in the provision of patient information. On the MIP Operational Group, collaborators include representatives from NHS Direct Online, Datapharm Communications, the Royal College of General Practitioners (RCGP), The Proprietary Association of Great Britain (PAGB), Royal Pharmaceutical Society of Great Britain (RPSGB), NHS UK Medicines Information (UKMI), NHS Direct, CSM Working Group, MHRA and DH (Nursing). Richard Tiner and Mike Wallace are both on the board of MIP.

Datapharm hosts and supports the NHS, UK Medicines Information web site.<sup>69</sup> Just in case, you are bogged down in this text,

I'll run that by you again, please wake up!:

**Mike Wallace, a Vice President of the Association of British Pharmaceutical Industries and Chairman of MedicoLegal Investigations, which helped Brian Deer shaft Andrew Wakefield is a director of a company allied**

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<sup>69</sup> <http://www.ukmi.nhs.uk/>

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**to the ABPI which runs the NHS medicines information site giving medicines information to patients.**

Hmm, 'I wonder what the site has to say about MMR and autism. Well nothing much, they just refer you to 'Digest' and 'Talk' sheets which have a few items in them about MMR and things;' 'Oh, Yes, look here, it says that there is definitely no link between MMR and autism'. 'And here, it puts you in touch with the NHS site mmrthefacts, and, look if you go through to that, it puts you in touch with . . . Brian Deer's site.' Hmm.

Wallace has over 30 years experience in the pharmaceutical industry and one of his net biographies states quite clearly that as '...a Managing Director of Schering Health Care Ltd ... he developed extensive contacts with government and the NHS.'

### **Dr Jane Barrett**

Dr Jane Barrett MBBS, AKC, FFPM, LLM, is the new girl at MLI, the only girl in fact. She joined MLI in February 2002 as a consultant medical adviser and joined the Board as a Non-Executive Director on 1st April 2002.

Dr Barrett qualified in medicine in 1976 and began work as a family doctor. In 1985 she joined the pharmaceutical industry, working for large and small pharmaceutical companies and then for a global contract research organisation. She founded the Barrett

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Consultancy in 2001, from which she provides medical and legal expertise to pharmaceutical companies.

Barrett was the last Chairman of the British Association of Pharmaceutical Physicians (BrAPP) and is now Vice Chairman. The BrAPP was founded over 40 years ago and is now one of the largest groups of its kind in the world; it draws its membership exclusively from physicians working in or for the pharmaceutical industry. It was previously known as the Association of Medical Advisers in the Pharmaceutical Industry.

Dr Barrett is an executive member of IFAPP. Started in 1970 by three British pharmaceutical physicians, IFAPP was originally called The International Meeting of Medical Advisers in the Pharmaceutical Industry. The aims of the organisation were to bring together physicians and scientists from the pharmaceutical industry with those working in research institutes and academic medicine.

In 1975, the organisation became the International Federation of Associations of Pharmaceutical Physicians (IFAPP). The mission of IFAPP is to promote Pharmaceutical Medicine. Dr Barrett's role as an executive member of IFAPP has led her to head the Advisory Committee for the 2005 European Summit, organised by the journal of IFAPP, *Applied Clinical Trials*, and held in Paris.

Dr Barrett is joined on the Advisory Committee by other pharmaceutical industry luminaries, including Domenico Criscuolo, who joined Lepetit (now part of the Aventis group) in 1975. In 1985

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he joined Roche, moving in October 2001 to Novuspharma where he is Director of Clinical Development. Uwe Gudat a clinical project leader at Novartis Pharmaceuticals; Jean-Pierre Isal, who has experience with Astra, Glaxo and Parke-Davis; Edmund de Maar, who has held positions with Wyeth, Novartis and Pfizer; Johanna Schenk who has had research-based experience with Eli Lilly, Bristol-Myers, Merrell, followed by 13 years work at two global contract research organisations; Daniel Vasmant Scientific Relations Manager, Public Affairs, Aventis Pharma (Dr. Vasmant has years of experience in paediatric medicine). Beat Widler, Global Head of Department for Quality, Ethics and Systems at Roche.

Since 1997, the IFAPP started organising yearly EMEA - IFAPP conferences at EMEA (European Medicines Evaluation Agency). The EMEA, which Thatcher fought so hard to get in Britain, is the major European regulating body for biological medicines. It carries out multi centred trials across Europe and is considerably more powerful than the domestic pharmaceutical regulating agency, the MHRA.

Like Dr Wells, Dr. Barrett is a leading light in the Faculty of Pharmaceutical Medicine, the British Association's college within the Royal College of Physicians, where she is Registrar.

Dr. Barrett is inevitably concerned, as are others in the world of pharmaceuticals, about the use of children in trials. The pharmaceutical companies have tried hard to close off the area of children in research, ensuring that only pharmaceutical company-

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backed research is ethically correct. The introduction to her article, *Why Aren't More Pediatric Trials Performed?*<sup>70</sup> makes it appear that there is no other pediatric research: 'Successful pediatric research requires partnership between the pharmaceutical industry, investigators, ethics committees, and parents'.

### **Andrew Wakefield, Science and the prosecution Process**

Would you trust MLI to support or initiate an unbiased investigation into a doctor, critical of vaccine safety? Would you buy a used medicine from them?

It has become abundantly clear during the Wakefield affair, that the independent scientific community in Britain hardly exists. Only the scientific community can ask questions about ethics of its own number and they are not doing this. The ethical and regulatory vacuum that exists in place of the scientific community in Britain has been filled with careerist politicians, pharmaceutical industry careerists and politically motivated lobbyists. Clearly in these circumstances Dr Wakefield has been press-ganged and subjected to a whole series of corrupt processes masquerading as proper investigation and justice.

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<sup>70</sup> *Applied Clinical Trials*, July 1, 2002.

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The big questions about the work of MedicoLegal Investigations are the same as those which have arisen around the work of the 'quackbusting' organisations such as HealthWatch. When private individuals group together to investigate and prosecute, to whom are they accountable and whose interests are they most likely to serve? Another question is slightly more technical, while anyone can set themselves up as an investigator, unless someone prosecutes on their behalf they will inevitably fail to be effective.<sup>71</sup>

It would be difficult to disagree with Duncan Campbell's overall plan for a policing agency which investigated doctors and others involved in medical research, put forward in his article, *An MI5 for Medicine*. Campbell asked for a policing strata which was as interventionist as the constabulary, as technically well equipped as the secret service and as relentlessly investigative as he himself was. However, involved as he was in a strenuous campaign against what he termed those at the 'disreputable end' of alternative therapies, Campbell appeared to be blinded to the broader issues and the power relations implicit in his plan. For example, who was to initiate investigations and would it be made clear in the process who had initiated the investigation? If it was not clear and if investigators were acting on behalf of powerful interests, how would we assess the balance of the investigations?

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<sup>71</sup> In 1993, HealthWatch, then the Campaign Against Health Fraud, made a doomed attempt to become a part of the NHS. They saw themselves as integrated into government and using all these resources to prosecute those on the fringes of medicine with whom they disagreed. When the Department of Health declined their offer of partnership they spent some years drifting before they made enough headway with various local trading standards offices, to get them to front their prosecutions for them.

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After all, the complex rules which govern the conflicting interests between public safety and individual human rights, embodied in policing systems in the developed world, have taken centuries to evolve. These systems make it difficult for either government ministers or executives of multinational companies to procure police services to investigate people with whom they are themselves in competition with. Where would such an organisation stand in relation to doctors who failed to diagnose adverse reactions, or in relation to corrupt dealing and research practices which originated with pharmaceutical companies rather than trial investigators?

Campbell made the point that the investigative service would ultimately result in prosecution by an independent agency such as the GMC. Such an agency would, he said, work on behalf of 'vulnerable medical complainants' while protecting them from 'retribution at the hands of powerful members of the profession.' In saying this, he failed to imagine a circumstance where the complainants were powerful and the subjects of their complaint people whose competition they might wish to eradicate.<sup>72</sup>

Campbell, perhaps because he is a journalist, also skipped over another essential aspect of the plan to have an investigative agency which led to the prosecution of medical researchers and practitioners. We have, as well, to ask ourselves whether journalists

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<sup>72</sup> Duncan Campbell. Medicine needs its MI5. *BMJ* 1997;315:1677-1680.

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are necessarily the best people to follow up complaints brought to them by 'vulnerable medical complainants.' The politics, finances and methods of most contemporary newspapers do not encourage journalists to take up popular causes, certainly not on behalf of patients.

In the present climate of angry scepticism between those involved in alternative ideas and multinational industries, many people who become the subject of investigative journalism refuse to give interviews. This lack of regulatory power leads to an unfortunate and damaging hole in the prosecuting process. While the police are duty bound to interview suspects and make themselves aware of alibis and explanations, journalists are not.<sup>73</sup> In spirit, though not necessarily in practice, this break in the processes of prosecution undermines one of the most important aspects of any justice system. The investigative journalist often acts, as it were, like a secret policeman, not revealing his investigation to the subject and the subject often unaware of the charges has therefore no recourse to a defence. Even worse in Wakefield's case, the investigation didn't appear to be secret at all, but appeared to have been shared during its progress, with those who would gain from his prosecution.

One of the consequences of this is that when cases are announced by bodies like the GMC, the case is set for a hearing with all the damage which this does to the subject, without there being

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<sup>73</sup> In this investigation, Brian Deer did get together on 18 February 2004 with Richard Horton, Andrew Wakefield and other authors of the paper, in the Lancet offices. At this meeting Deer was told the assumptions at the centre of his investigation were wrong and they were corrected by the papers' authors. Deer chose not to believe the authors.

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any public record of the subjects defence. Of course, it might be that the defendant does not wish to give even a broad outline of a defence. However, in those circumstances where subjects of a complaint might wish to put on record certain issues or even give documentary evidence to investigators in the early stages of an investigation, they are often denied this opportunity and if they do, the accused is not to know what happens to this evidence.

This is perhaps the most substantial reason why unregulated investigators, like journalists working outside the strict letter of the law, should not be able to present their cases to bodies like the GMC. In Wakefield's case, we also have to ask a most important question, who put the case together for the GMC in its formal legal terms? It couldn't possibly have been Brian Deer, who appears legally illiterate; this service is, however, one of those that MLI advertise.

Secret investigations *which do not originate with disadvantaged complainants* are the tools of tyrannical regimes. In developed societies, charges should not be brought to hearing without the subjects of the complaint having the opportunity in a formal setting, with their rights protected, of understanding who is investigating them, with whom the complaint originates, and having an opportunity to refute the charges.

In Duncan Campbell's opinion, because any investigative agency would be separate from the prosecuting agency which it fed, '...the new agency could not be accused of being judge and jury in

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the cases it handles.’ But again this statement lacks the clear thinking necessary when discussing agencies of policing and prosecution. One of the most corrupting links that can be melded in any juridical system is between complainant, investigator and prosecutor. Private investigative and policing systems can be fuelled by hidden motives and if in turn these are linked to prosecutors with similar motivations any sense of independent or clear-sighted justice has usually collapsed. In the case of Brian Deer’s ‘investigation’ into Wakefield, the Department of Health were involved, even the Minister for the DoH. When MLI became involved, so did the ABPI and finally so did the GMC, in a continuous chain of investigation, prosecution and ultimately judgement.

While it does not appear strange that the ABPI would want to infiltrate voluntary organisations, patient groups, clinical research groups, Hospital Trusts and Primary Health Care Trusts; while it might not appear strange that they want to organise the NHS as a market for their drugs, it might, at first, appear odd that they would want to own an agency through which they could investigate and discipline doctors. However, the strategic sense is there, clearly, for while the ABPI want to sell drugs they also want to eliminate critical discourse over those drugs, their trials, their manufacture and their post surveillance observation. They certainly want to eliminate embarrassing cases of corruption involving doctors who don’t properly conduct their trials. They might also want to run covert assaults on professionals who offer conflicting opinions about the effect of their products.

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As the disparity in power between multinational companies and citizens grows, these companies draw to themselves many of the agencies and structures of the civil political administration which used to be, or perhaps should be, in the public domain. As society has become more privatised, democracy has suffered and increasingly these agencies and structures drift beyond accountability. This has clearly happened in relation to the pharmaceutical industry in the case of the governance of their trials and the safety of their products.

The rules of post industrial society are quite different from those of industrially-based social democracy and we have to educate ourselves to them. Most importantly, now, we have to read between the lines in relation to conflicts of interest and become quickly sceptical of politicians and large industries.

When only a whisper floats by about the adverse reactions caused to children by combined vaccinations, but a great furore is unleashed about a doctor who tries to treat those children and so challenges the pharmaceutical monopoly grip over health care, our sense of inquiry should immediately be alerted.

Deer's primary and as yet unproven charge against Wakefield was that he failed to disclose that he had used Legal Aid money - acquired to develop a case against the pharmaceutical companies - to carry out research. If Deer believed that this was ethically unconscionable, why did he not reveal that his 'expose' had in part been aided by an ABPI funded organisation? Why did he not

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inform parents of autistic children whom he interviewed that he considered one of his roles to be *the investigation of false claims of vaccine damage?*

In the final analysis, we have to ask whether Brian Deer was acting independently when he 'investigated' and wrote about Andrew Wakefield. In his article about Margaret Best, Deer puts considerable emphasis on how, when and from where she telephoned her doctor. We will, no doubt, have to wait many decades before we find out what pattern of telephone calls and emails lay behind the initiation and construct of Brian Deer's original *Sunday Times* investigation, in the meantime, because the GMC has covered his tracks, we can only guess.