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From: Brian Deer <mailbrian@briandeer.com>
Subject: Wakefield, Walker-Smith, Murch
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The General Medical Council,
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2733564 Andrew Jeremy Wakefield

1700583 John Angus Walker-Smith
2540201 Simon Harry Murch

Following an extensive inquiry for The Sunday Times into the origins of the public panic over MMR, I write to ask your permission to lay before you an outline of evidence that you may consider worthy of evaluation with respect of the possibility of serious professional misconduct on the part of the above named registered medical practitioners.

(A) Events at Royal Free Hospital

1. Background

These matters arise from activities focussed on the paediatric gastroenterology department and the academic department of medicine at the Royal Free Hospital, Hampstead, between approximately June 1996 and December 2001.

During that period, a series of developmentally disordered children with gastric symptoms were investigated by the above-named doctors. During week-long admissions and under sedation or general anaesthetic, these investigations included, among other things, ileocolonoscopies, upper gastrointestinal endoscopies, lumbar punctures, barium follow-throughs and MRI scans. A description of these investigations may be found at <http://briandeer.com/mmr/royal-free-11.htm>

I am not a doctor, but my research leads me to think that some of these investigations - particularly the intubations and lumbar punctures - are highly-invasive procedures, which posed potential risks to the children, and which may be carried out only on the following grounds:

- (a) In a doctor's reasonable judgment, they are likely to be of clinical benefit to the child, and/or
- (b) They are properly authorised by a competent ethics committee.

The precise number of developmentally disordered children who underwent these investigations is not clear, and I believe warrants inquiry beyond my present reach as a journalist. Material apparently

from an initial series of 12 cases was published in the Lancet on February 28 1998 by the three named doctors, and others. A series of 30, including the 12, was published as an abstract in Gut (vol 42, supp 1, TF340), based on a presentation at a conference in Harrogate in March 1998. A series of 60 children, including the others, was published in the American Journal of Gastroenterology in September 2000. I think that some tests were performed on up to 300 children. I understand that up to 150 of these were clients of a single solicitor, Mr Richard Barr.

I believe there are grounds to ask whether the motive for these investigations may have been:

(a) In the case of Mr Wakefield, Professor Walker-Smith and Dr Murch to find what they believed to be a distinctive gut pathology in some developmentally disordered children, in association with evidence of measles virus in the central nervous system. They thought that these together might be evidence of an unrecognised medical condition.

(b) In the case of Mr Wakefield, to advance litigation against drug companies by finding children, pre-screened by solicitors and claimant groups, with a particular constellation of symptoms that might accord with theories of his own which he hoped to place before a court.

2. Were investigations "approved"?

Application was made to the ethical practices committee of the Royal Free Hospital by Mr Wakefield, Professor Walker-Smith and Dr Murch to perform these investigations, and was approved by the committee on November 13 1996. The reference is 17 2-96. This research is described as "A new paediatric syndrome; enteritis and disintegrative disorder following measles/rubella vaccination." I draw your attention to the vaccine, which is not MMR. The protocol further specifies the children to be studied as suffering from disintegrative disorder, or Heller's Disease. The approval letter can be found at <http://briandeer.com/mmr/royal-free-10.htm>

This protocol was then apparently the basis for study of children who were vaccinated with a different vaccine - MMR - and who suffered from autism - a condition related to, but I think different from, Heller's Disease. All children apparently had some form of gastric symptoms, although what these were isn't wholly clear to me. An informed consent document, submitted by Mr Wakefield to the ethics committee, can be found at <http://briandeer.com/mmr/royal-free-12.htm>

In the Lancet paper of February 28 1998, it states: "Investigations were approved by the Ethical Practices Committee of the Royal Free Hospital NHS Trust, and parents gave informed consent."

3. Were investigations "clinically indicated"?

Following publication of the series of 12 in the Lancet, Professor Sir David Hull wrote on July 6 1998 to the dean of Royal Free's medical school, Professor Arie Zuckerman, inquiring into the basis of the ethics committee approval. His letter is at <http://briandeer.com/mmr/royal-free-1.htm> Professor Hull appears to be concerned at the invasive nature of the tests, and asks if they are ongoing.

After making inquiries within the medical school, the dean replied on July 27 1998, reporting the words of Dr Michael Pegg, chair of the hospital's ethics committee, that "the Committee did not approve the investigations".

The dean explains: "The Committee approved data collection from investigations that were indicated clinically and that it is not the role of an Ethics Committee to question clinicians' judgement as to what are and what are not clinically indicated investigations."

The justification for the invasive investigations, therefore, moves from ethical approval to clinical

indication. This line is taken in various communications, particularly following Professor Hull's intervention.

On February 20 2004, the Lancet, without agreement, issued a press release of confidential and embargoed material from discussions between myself, representing The Sunday Times, and the journal. This breach of confidence served to deflect criticism of the Lancet, and its editor, Dr Richard Horton, who apparently previously worked with Mr Wakefield at Royal Free and who published the 1998 paper. Attached to this press release was a statement by Dr Murch, which deals with the ethical issue. This is at <http://briandeer.com/mmr/royal-free-13.htm> Among other things, in the fourth paragraph, Dr Murch explains with regard to the lumbar punctures [my emphases]:

"We had in particular taken advice for the neurological investigations, since **some** of the referrals appeared to have suffered an encephalitic illness... **Several** of these cases had not been investigated to exclude a primary cause of their regression..."

As I have said, I am not a doctor, but I have studied this issue and have taken advice. As a lay person, I respectfully submit to the GMC that it may not be possible to claim that the standardised battery of tests as set out in the protocol, including these specific invasive procedures, carried out together as described in the patient consent document, can reasonably be said to be clinically indicated. It appears that Dr Murch tacitly acknowledges a lack of indication in at least a number of cases in his reference to "some" and "several" children.

Therefore, there was, in my view, neither ethical approval, nor or clinical indication for the invasive investigation of some children.

4. A conflict of interest

The finding from my inquiry which has attracted most attention in recent days is that Mr Wakefield - apparently unknown to colleagues, including Professor Walker-Smith and Dr Murch - had entered into a contract with what was at the time the Legal Aid Board to carry out tests on litigants in a lawsuit against pharmaceutical companies. The contract was dated August 1996 and valued at £55,000.

The Lancet paper states, with regard to financial support: "This study was supported by the Special Trustees of Royal Free Hampstead NHS Trust and the Children's Medical Charity." No mention is made of Mr Wakefield's contract, and, prior to my investigation, this contract was never made public. Mr Wakefield now says that, as the investigations on the children were paid for under the NHS and the legal aid money spent on other things, he did not need to disclose the payment. He says he will disclose it in a paper apparently intended for publication at some time in 2004.

5. Litigants in the case series

I respectfully submit that the power of the Lancet paper, which led to a worldwide panic over the safety of MMR, lay in what appeared to be simple facts:

- (a) Two thirds of the parents of 12 developmentally disordered children with gastric symptoms routinely attending a teaching hospital's paediatric gastroenterology department appeared to blame MMR.
- (b) The recalled onset of behavioural symptoms in the children is reported in the paper as within days (average 6.3) of immunisation.

At outpatients, the parents would have said words to the effect of: "It's the MMR, doctor". Although the series was of only 12 children, such assertions, apparently by parents in eight instances, if

accurate, may have been worthy of report, for debate within the profession.

However, my inquiries have established that some significant number of these parents were either actually suing drug companies when they attended the hospital, or declared such an intention soon after. I think the number may be a clear majority of the case series. Confronted on this point by The Sunday Times, Mr Wakefield has admitted that "four or five" were litigants. The Legal Services Commission may be able to advise.

It is a logical certainty that a parent who is suing a drug company, alleging that MMR damaged their child, will, when asked, blame MMR.

If even "four or five" of the eight children were litigants, it would appear to me to be gravely misleading to imply, and to allow to stand unqualified for six years, that an association between the children's developmental problems and MMR had been found.

6. Scientific fraud

Although I am not medically qualified, I have studied the 1998 Lancet paper, and interviewed two of its authors, and I do not believe, even at face value, that the work can have been carried out in the manner that the public has been led to believe. Documents in my possession, including a 2000 submission to the ethics committee, and statements made to The Sunday Times by Mr Wakefield, Professor Walker-Smith and another author, claim that these children were part of the hospital's routine clinical caseload.

It is quite plain to me, and I believe can be confirmed using the GMC's statutory powers, that the bulk of these 12 children, and much of the continuing series of developmentally disordered children seen in the paediatric gastroenterology department, were in fact orchestrated referrals and, in some cases, active solicitations by the Royal Free team. In one case I know of, Professor Walker-Smith wrote to a consultant paediatrician soliciting a child by name, at Mr Wakefield's instigation, when that paediatrician did not believe that the child warranted referral.

It is my belief that the case series which triggered the worldwide panic over MMR was, in effect, rigged by Mr Wakefield, with at least Professor Walker-Smith turning a blind eye to what was going on.

7. Deception of the profession

I have by no means been the first to become aware of serious shortcomings and anomalies in the work being published by Mr Wakefield and the others from Royal Free. As I understand it, the Department of Health, the American Academy of Paediatrics and the Centers for Disease Control have all sought to question Mr Wakefield. He has rebuffed those approaches and refuses to speak to me. However, on two occasions Mr Wakefield has been asked questions and, in a fashion, has answered them.

The first occasion was a very important meeting convened by the Medical Research Council on 23 March 1998 specifically to discuss the Lancet paper and its growing impact on public opinion. At this meeting, Mr Wakefield was squarely asked where he had got the children. A number of persons at the meeting say they have clear recall of this issue. There is also a confidential minute taken by the MRC staff:

c) How were the patients selected?

Members were interested in how the children had come to be referred to the RFHMS team, as this had a bearing on the issue of bias in the generation of the case series. Mr Wakefield explained that originally the parents of the children had come to the Group without any connection through any other organisation. Latterly, following media attention, parents had

heard of the RFFHMS Group's work, either directly or through other organisations.

In a letter to the Lancet, published on May 2 1998, Dr A Rouse, of Wiltshire Health Authority, raises the issue of litigation and whether there was some element of bias in the selection of the children in the study. Mr Wakefield dissembles in his response and claims "No conflict of interest exists".

8. Misapplication of public money

According to the Legal Services Commission, it paid, as the Legal Aid Board, £55,000 to Mr Wakefield to provide it with a report giving full clinical and scientific details on ten claimant children. However, Mr Wakefield has admitted in response to my investigation that the children's care and tests were paid for under the NHS. The chief executive of Royal Free tells me that, to his knowledge, the legal aid money went to Mr Wakefield's virological interests, and Professor Walker-Smith tells me that it was spent on studies of a wider group of children. I conclude from this that the money was not spent in the manner for which it was given: what I believe the NHS calls "double-billing" or "double-paying", which may be financial fraud.

The GMC may be able to get to the bottom of this, and the precise nature of his contractual obligations arising from the litigation, dealing directly with the Legal Services Commission.

(B) My submission to the GMC

1. With regard to Mr Wakefield, Professor Walker-Smith and Dr Murch

In the light of the material set out above, I submit to the GMC that there may be prima facie evidence that these three may have embarked upon what amounted to a "fishing expedition" into the guts and spines of at least some of these vulnerable, developmentally disordered children without either ethics committee approval or clinical indication. I submit that, if this were found to be the case, that it would be a violation of the rights of these children, in circumstances where parents could not give valid informed consent, and that therefore this may amount to serious professional misconduct.

2. With regard to Mr Wakefield

In the light of the material set out above, I submit that on a matter as serious as the safety of a vaccine, touching on the health of millions of children, and affecting parental decisions of the utmost seriousness, Mr Wakefield was under an absolute duty to make the true position clear, with regard to both his involvement in the litigation and the litigant status of children upon whom he purported to derive findings. Mr Wakefield did not do this, omitting vital information from publications and leaving the public confused with regard to the true implications of the work performed at Royal Free. I submit that this may amount to serious professional misconduct.

I believe there are grounds for the GMC to use its statutory powers to investigate whether the case series published in the Lancet and elsewhere was so loaded with litigant children as to evidence the allegation that the studies were rigged, and the published findings fraudulent. This would, of course, amount to serious professional misconduct.

In Mr Wakefield's responses to the Medical Research Council hearing, he failed to squarely answer straight questions about the source of the children, and I submit that this failure, which could only have been deliberate, may amount to serious professional misconduct. Similarly, a pattern of apparently evasive or deceitful conduct on this matter of great public concern is evidenced in his reply to Dr Rouse in the Lancet of May 2 1998.

Mr Wakefield admits that the money paid by the Legal Aid Board for comprehensive reports on ten children was, in fact, spent on something else. I submit that this may amount to financial fraud, and therefore serious professional misconduct.

Conclusion

As a matter of public duty, I write to offer this outline of my main findings, and to offer the GMC my fullest cooperation in getting to the bottom of these matters.

Yours sincerely,

Brian Deer

<http://briandeer.com>