

To: tcobrown@gmc-uk.org
From: Brian Deer <mailbrian@briandeer.com>
Subject: Wakefield, Walker-Smith, Murch
Cc:
Bcc:
Attached:

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Brian Deer
c/o The Sunday Times, 1 Pennington Street, London E1 9XW
mailbrian@briandeer.com

The General Medical Council,
178 Great Portland Street,
London W1W 5JE

February 25 2004

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

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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 172-96. 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

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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 RFHMS 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.

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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>

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In reply please quote: FPD/2004/0671

8 April 2004

Mr. Andrew Wakefield
43 Taylor Avenue
Richmond
Surrey
TW9 4EB

GENERAL MEDICAL COUNCIL

*Protecting patients,
guiding doctors*

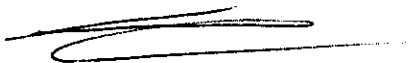
Dear Mr. Wakefield,

I am writing further to your telephone conversation with Blake Dobson in February, and my subsequent letter to you. Please accept my apologies for our delay in contacting you again.

I am writing to confirm that we have received complaints about you from a number of sources. These complaints raise complex issues and we have, therefore, asked our lawyers to analyse the information we have received and to advise us in respect of the matters raised in the complaints.

We will write to you again in due course, although I hope you will appreciate that this may not be for some time. Please do not hesitate to contact me should you have any further queries on this matter. Please note that I will be away from the office after today until 19 April 2004.

Yours sincerely,



Tim Cox-Brown
Caseworker, Fitness to Practise Directorate
Direct Line: 0161 923 6427; Fax: 0161 923 6401
E-mail: tcoxbrown@gmc-uk.org

01925 264156

In reply please quote FPD/2004/0671

Please address your reply to Juliet St Bernard, Conduct Case Presentation Section,
Fitness to Practise Directorate
Tel: 020 7915 3400
Fax: 020 7915 3696

27 August 2004

Special Delivery

Mr. Andrew Wakefield
43 Taylor Avenue
Richmond
Surrey
TW9 4EB

**GENERAL
MEDICAL
COUNCIL**

*Protecting patients,
guiding doctors*

Dear Mr. Wakefield,

A screener who has been appointed to give initial consideration to cases has asked me to notify you that the GMC has received information which appears to raise a question whether, as a registered medical practitioner, you have committed serious professional misconduct within the meaning of section 36(1) of the Medical Act 1983. A copy of the relevant provisions of the Act is enclosed, together with copies of the Procedure Rules, the GMC's publication "Good Medical Practice" and of a paper about the GMC's fitness to practise processes.

In the information it is alleged that:

1. At all material times you were a UK registered medical practitioner employed by the Department of Academic Medicine of the Royal Free Hampstead NHS Trust and as a Senior Lecturer at the Royal Free Medical School (now the University College London Medical School);
2.
 - a) On 16 September 1996, you signed an application to the Ethical Practices Sub-Committee of the Royal Free Hampstead NHS Trust for the approval of a project entitled "A New Paediatric Syndrome: Enteritis and Disintegrative Disorder Following Measles/Rubella Vaccination" (Project 172 96),
 - b) Project 172-96 named you, Professor John Walker-Smith and Dr Simon Murch as the responsible Consultants and aimed to explore the link between the emergence of a new syndrome which involved disintegrative disorder (Heller's disease) and the measles or measles/rubella vaccine,
 - c) Project 172-96 was approved at a meeting of the Ethical Practices Sub-Committee, which took place on 18 December 1996, and confirmed in a letter from the Chairman of the Ethical Practices Sub-

Committee to Professor John Walker-Smith dated 7 January 1997, the letter confirming that the approval was to last for two years, commencing 7 January 1997,

- d) Between 6 August 1996 and 1999, you made no further applications to the Ethical Practices Sub-Committee for ethical approval in connection with Project 172-96 or in connection with any other research that you were conducting,
- e) On 28 February 1998 you and 12 other doctors, published an article in the Lancet medical journal entitled "*Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children*" ("the Lancet article"),
- f) The Lancet article reported the findings of your research on 12 children, consecutively referred to the Department of Paediatric Gastroenterology at the Royal Free Hospital with chronic enterocolitis and regressive developmental disorder,
- g) The majority of the children who formed the basis of the research reported in the Lancet article had a behavioural diagnosis of autism or an autistic spectrum disorder,
- h) The Lancet article made numerous references to the MMR vaccine,
- i) The Lancet article stated that all investigations were approved by the "Ethical Practices Committee of the Royal Free Hospital NHS Trust" and that parents had given informed consent,
- j) The research reported on by you in the Lancet article was substantially different from that for which approval was granted by the Ethical Practices Sub-Committee in that it related to:
 - i) children with a diagnosis of autism and not disintegrative disorder (Heller's disease),
 - ii) the MMR vaccine and not the measles or measles/rubella vaccine,
- k) Despite your assertions to the contrary in the Lancet, you therefore failed to obtain ethical approval from the Ethical Practices Sub-Committee for the research that you carried out and later reported in the Lancet,
- l) Over a period of two years between August 1996 and the publication of the Lancet article, you carried out a number of invasive procedures on children without the necessary ethical approval from the Ethical Practices Sub-Committee,
- m) Your actions as set out in heads 2 a) – l) were:

- i) inappropriate,
- ii) not in the best interests of patients,
- iii) not in accordance with your professional ethical obligations,
- iv) likely to bring the medical profession into disrepute,
- v) fell seriously below the standard of conduct to be expected of a registered medical practitioner;

3.

- a) In the Application for Approval of Ethical Project 172-96 you described a series of tests that would be carried out on children who formed part of the study,
- b) These tests included highly invasive procedures such as lumbar puncture,
- c) The Ethical Practices Sub-Committee granted its approval for these invasive tests on the basis that they be carried out only as clinically indicated for the children concerned,
- d) These tests were however determined and routinely carried out on children who formed part of the study without consideration of the individual history, diagnosis, symptoms and clinical needs of the children and without an adequate evaluation of the necessity of the tests,
- e) Vulnerable children with developmental disorders were therefore subjected to invasive investigations in the interests of your research rather than in their best clinical interests,
- f) Your actions as set out in heads 3 a) to e) were:
 - i) inappropriate,
 - ii) not in the best interests of your patients,
 - ii) fell seriously below the standard of conduct to be expected of a registered medical practitioner;

4.

- a) The Ethical Practices Sub-Committee approval granted in January 1997 for Project 172-96 stated that only children enrolled at the Royal Free Hospital after 18 December 1996 should be included in the study,
- b) You included at least one child, William Kessick, in the study in relation to whom findings were published in the Lancet article, who was seen at the Royal Free Hampstead NHS Trust prior to the 18 December 1996 start date, in September 1996, and who should not therefore have been included in the study;
- c) Your actions as set out in head 4 b) were:
 - i) inappropriate,

- ii) taken without the approval of the Ethical Practices Sub-Committee,
- iii) not in the best interests of your patient,
- iv) fell seriously below the standard of conduct to be expected of a registered medical practitioner;

5.

- a) The Application for Approval of Ethical Project 172-96 stated that children considered for the study would be referred by their GP or via the Vitamin B12 Unit at the Chelsea and Westminster Hospital with manifest disintegrative disorder and symptoms and signs of intestinal disease,
- b) The Lancet article stated that the children used in the study published were all consecutively referred to the Department of Paediatric Gastroenterology at the Royal Free Hospital,
- c) Despite these statements, the study that you carried out and the research later published in the Lancet included some children:
 - i) sourced by Mr Richard Barr, a solicitor acting on behalf of litigants seeking to institute action against pharmaceutical companies who manufacture vaccines, and various vaccine pressure groups,
 - ii) children from outside the NHS area including, a child from the USA and one from Jersey,
- d) Your actions as set out in heads 5 a) to c) were:
 - i) inappropriate,
 - ii) intended to mislead the public and the medical profession,
 - iii) fell seriously below the standard of conduct to be expected of a registered medical practitioner;

6.

- a) At some stage prior to August 1996, you entered into a contract with Mr Richard Barr, a solicitor acting on behalf of a number of litigants seeking to institute action against pharmaceutical companies, to conduct research on behalf of his clients' behalf,
- b) On the strength of a research proposal drafted by you, Mr Barr obtained funding from the Legal Aid Board (now the Legal Services Commission) to support this research,
- c) The funding obtained was to study children whose parents believed they had been injured by the measles/rubella vaccine,
- d) No separate application was made by you to the Ethical Practices Sub-Committee for ethical approval of a study funded by the Legal Aid Board,

- e) The Legal Aid Board approved funding for your research on 22 August 1996,
- f) The funding was paid out by the Legal Aid Board in two instalments of £25,000 paid in late 1996 and in 1999 respectively,
- g) In your Application for Approval of Ethical Project 172-96 you made no reference to the funding provided by the Legal Aid Board,
- h) No mention of the Legal Aid Board funding is made in the Lancet article,
- i) In applying to the Ethical Practices Sub-Committee for approval and in publishing your research in the Lancet you did not disclose your potential conflict of interest having received Legal Aid Board funding to conduct research on behalf of potential litigants,
- j) Your actions in respect of heads 6 a) to i) were:
 - i) inappropriate,
 - ii) intended to mislead the public and the profession,
 - iii) fell seriously below the standard of conduct to be expected of a registered medical practitioner;

7.

- a) In an interview with Mr Brian Deer, a freelance journalist, you later denied that a conflict of interest had arisen saying that the research published in the Lancet had been funded by the NHS and that the Legal Aid Board money was used for other research interests,
- b) You have not published any further research crediting the Legal Aid Board funding,
- c) You failed to account for the public money provided to you by the Legal Aid Board in connection with your research,
- d) You failed to use the money supplied to you by the Legal Aid Board for the purpose for which it was intended;
- e) Your actions as set out in paragraphs 7 a) to d) were:
 - i) dishonest,
 - ii) intended to mislead the public and the medical profession,
 - iii) fell seriously below the standard of conduct to be expected of a registered medical practitioner;

8.

- a) Information generated as part of research which lead to the publication of the Lancet article was subsequently used as part of the litigation

instituted against vaccine manufacturers by Mr Richard Barr and other solicitors on behalf of their clients,

- b) Your purpose in conducting research was therefore not solely as set out in the application for approval of Project 172-96 or as stated in the Lancet article but was also to further litigation,
- c) Your actions set out in heads 8 a) and b) were:
 - i) inappropriate,
 - ii) designed to mislead members of the medical profession and the public,
 - iii) fell seriously below the standard of conduct to be expected of a registered medical practitioner;

9.

- a) In February 1998 you attended a press conference following the publication of the Lancet article,
- b) During the course of the press conference you expressed your personal views regarding the safety of the MMR vaccine and recommended that the three vaccines making up the MMR vaccine namely measles, mumps and rubella, should be given separately,
- c) Your actions stimulated public concern regarding the MMR vaccine and had serious public health consequences for the government's immunisation programme,
- d) You made this statement without clear, substantiated evidence that the MMR vaccine caused harm to children which could be avoided by administering the three vaccines separately,
- e) Your conduct set out in heads 9 a) to d) was:
 - i) irresponsible,
 - ii) designed to mislead the medical profession and the public,
 - iii) fell seriously below the standard of conduct to be expected of a registered medical practitioner;

10.

- a) On 23 March 1998, following the publication of the Lancet article, you attended a meeting specifically convened by the Medical Research Committee to discuss the Lancet article,
- b) At this meeting you were asked to explain the source of the patients used in the study published in the Lancet,
- c) The minutes of this meeting reflect that you stated that parents of the children involved in the study initially came to the Royal Free Hospital without any connection through any other organisation but that later,

following media attention, parents heard of the work carried out the Royal Free Hospital either directly or through other organisations,

- d) This statement was incorrect in that some children who formed part of the study were sourced by Mr Richard Barr, a solicitor acting on behalf of potential litigants, and through anti-vaccine pressure groups,
- e) Your actions as set out in heads 10 a) to e) were:
 - i) dishonest,
 - ii) intended to mislead members of the public and the medical profession,
 - iii) intended to conceal the true purpose of your research,
 - iv) fell seriously below the standard of conduct to be expected of a registered medical practitioner;

11.

- a) In February 2002 you published a paper in the J. Clin. Pathol: Mol. Pathol medical journal (2002, 55; 0-6) in which you reported on a number of children with autism and bowel disease as well as a group of children who were used as controls,
- b) Within this group of children used as controls were 27 children whose tissues had been obtained at appendectomy,
- c) You failed to obtain the consent of the parents of these children for the use and retention of the tissues for purposes of your research,
- d) Your actions as set out in heads 11 a) to c) were:
 - i) inappropriate,
 - ii) not in the best interests of your patients,
 - iii) fell seriously below the standard of conduct to be expected of a registered medical practitioner;

12.

- a) In 2002 the Chief Medical Officer wrote to you in response to your proposal that a meeting be convened with you, Professor Walker-Smith and Mr Richard Barr,
- b) In the letter, the Chief Medical Officer posed a number of questions including whether you and your colleagues had obtained informed consent from patients used as controls within the study, for the use and retention of control tissues,
- c) The Chief Medical Officer also asked that these samples be made available for independent testing,
- d) You failed to respond substantively to the questions posed by the Chief Medical Officer,

- e) Your actions as set out in heads 12 a) to d) fell seriously below the standard of conduct to be expected of a registered medical practitioner.

The information is supported by various documents. Copies of these documents are enclosed.

The screener has directed, in accordance with the Procedure Rules, that the information received be referred to the Preliminary Proceedings Committee of the Council. That Committee will consider the complaint and any written explanation provided by you, to determine whether the case should be referred to the Professional Conduct Committee of the Council for inquiry into a charge against you.

You are invited to submit at your earliest convenience a written explanation of the foregoing matter. The next meeting of the Preliminary Proceedings Committee will be held on **15 October 2004**. It is in your interests that the Committee should have time to give careful consideration to any explanation you may wish to offer. You may therefore find it helpful to know that any explanation received by the Council before **6 October 2004** will be circulated to the Committee before the meeting. Any explanation received between **6 October 2004** and **15 October 2004** will be placed before the Committee on the day of the meeting.

Please address your explanation for the attention of Juliet St Bernard, Conduct Case Presentation Section, The General Medical Council, 178 Great Portland Street, London W1W 5JE or fax it to the following number: 0207 915 3696.

If you intend to consult your medical defence society, or to take other legal advice, you should do so without delay.

In accordance with Section 35A(2) of the Medical Act 1983 (as amended), you are required to inform us, within 10 days of receipt of this letter, of the following:

- The name and address of all of your current employers,
- the Health Authority with which you have a service agreement,
- any locum agency or agencies with whom you are registered,
- the hospital or surgery at which you are currently working.
- If you engage in any non-NHS work, you are also required to notify us, within the same period of time, of the name of the organisation or hospital by which you are employed, or have any working arrangements. Please forward this information directly to me. Upon receipt of these details, your employers will be notified of the Committee's consideration of the matter.
- If you are approved under Section 12 of the Mental Health Act, or Section 20(b) of the Mental Health (Scotland) Act 1984, you must also notify us of this fact.

A pro forma is enclosed for you to complete and return in the envelope provided.
Failure to comply with this statutory requirement to provide the above information may result in further proceedings against you.

The documents enclosed with this letter may contain confidential material. This material is sent to you solely to enable you to respond to the allegations in this letter: it must not be disclosed to anyone else, except for the purpose of helping you to prepare your defence.

Please will you write personally to acknowledge receipt of this letter quoting the reference shown above.

Yours sincerely,




Blake Dobson
Assistant Registrar

Encs.

1. GMC Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988.
2. Good Medical Practice booklet.
3. Conduct Procedures.
4. Disclosure of employer details pro forma.
5. Section 36 (1) of the Medical Act.
6. Screener's memorandum of reasons.
7. Indexed bundle of supporting documents.

THE LANCET

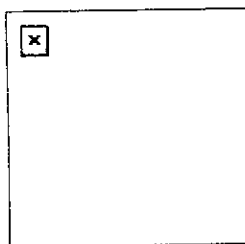
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Volume 351, Number 9103
28 February 1998 [Back to results](#) 

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Early report

Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

A J Wakefield, S H Murch, A Anthony, J Linnell, D M Casson, M Malik, M Berelowitz, A P Dhillon, M A Thomson, P Harvey, A Valentine, S E Davies, J A Walker-Smith

Inflammatory Bowel Disease Study Group, University Departments of Medicine and Histopathology (A J Wakefield FRCS, A Anthony MB, J Linnell PhD, A P Dhillon MRCPPath, S E Davies MRCPPath) and the University Departments of Paediatric Gastroenterology (S H Murch MB, D M Casson MRCP, M Malik MRCP, M A Thomson FRCP, J A Walker-Smith FRCP), Child and Adolescent Psychiatry (M Berelowitz FRCPsych), Neurology (P Harvey FRCP), and Radiology (A Valentine FRCP), Royal Free Hospital and School of Medicine, London NW3 2QG, UK

Correspondence to: Dr A J Wakefield

[Summary](#)[Introduction](#)[Patients and methods](#)[Results](#)[Discussion](#)[References](#)**Summary**

Background We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder.

Methods 12 children (mean age 6 years [range 3-10], 11 boys) were referred to a paediatric gastroenterology unit with a history of normal development followed by loss of acquired skills, including language, together with diarrhoea and abdominal pain. Children underwent gastroenterological, neurological, and developmental assessment and review of developmental records. Ileocolonoscopy and biopsy sampling, magnetic-resonance imaging (MRI), electroencephalography (EEG), and lumbar puncture were done under sedation. Barium follow-through radiography was done where possible. Biochemical, haematological, and immunological profiles were examined.

Findings Onset of behavioural symptoms was associated, by the parents, with measles, mumps, and rubella vaccination in eight of the 12 children, with measles infection in one child, and otitis media in another. All 12 children had

Tim Cox-Brown (0161 923 6427)

From: Brian Deer [REDACTED]
Sent: 01 Jul 2004 10:16
To: Tim Cox-Brown (0161 235 6422)
Subject: Wakefield, Walker-Smith, Murch

To: Tim Cox-Brown,
Fitness to Practice Directorate,
General Medical Council.

This emailed letter is attached with a printed version of the same document.

Re: Andrew Wakefield, John Walker-Smith, Simon Murch

Dear Tim,

Following my previous communications, I wish to report to the GMC claims made by the above doctors in statements published by the Lancet under the editorship of Dr Richard Horton, a former Royal Free hospital colleague of the above, on February 20 2004.

I submit that these statements - which the doctors knew would be widely disseminated both to the profession and to the public at large - sought to mislead on matters of the gravest concern. In addition, analysis of these statements sheds further light on the substantive issues of this disturbing affair.

At the heart of this affair, I submit, was the operation of a scheme, between early 1996 and late 2001, under which desperately vulnerable parents of 200 or more autistic children, some as young at three years old, were enticed by Dr Wakefield and his colleagues into offering the use of those children for medical experimentation involving hazardous procedures which, in most cases, lacked either valid ethical research approval or clinical justification. Medical investigations, including ileocolonoscopies and, in some cases, lumbar punctures and upper gastrointestinal intubations, were performed while the children were under sedation or general anaesthetic in pursuit of this scheme, which was devised by Dr Wakefield in pursuit of a lawsuit to advance speculative and unsubstantiated theories concerning measles virus, inflammatory bowel disease and developmental disorders. In these circumstances, I submit that, in many cases, parental consents to those procedures may have been invalid, and the experiments on the children common assaults.

Derived from this scheme, and furthering its execution, was the creation by Dr Wakefield of a wholly unwarranted scare over the safety of the MMR vaccine, based on no compelling research evidence, and where profound conflicts of interest - which should properly have been disclosed for publication in the Lancet and to the public generally - were concealed. This scare led to parental decisions which placed millions of children's lives and health at risk. Children have suffered as a result.

This present communication deals only with the February 20 statement of Dr Simon Murch. I submit that this statement is false and disingenuous, and that its publication alone constitutes a matter for investigation by the GMC. It's impossible for me to judge whether, in some instances, Dr Murch himself contrived the falsehoods, or whether he is ignorant of the basis of his own work and merely parrots what he has been told. In due course, I hope to supply analyses of statements issued on the same day by Dr Wakefield and

Professor Walker-Smith, which also contain multiple falsehoods on matters of serious concern.

I realize that this is complex, time-consuming, material, but I don't believe that the mere complexity should obscure these doctors' conduct. To get to the bottom of this affair will obviously require a great deal of effort by the GMC and its professional staff. Nevertheless, I think the importance of the MMR issue for parents and for public policy, the paramount need to safeguard children's health, and the GMC's duty to protect standards in medical research, justify the investment.

I have annotated the Murch statement, published by the Lancet.

A STATEMENT BY DR SIMON MURCH

These allegations concerning our 1998 study are extremely serious, and clearly require immediate clarification. I welcome the opportunity to do so. My comment relates to the alleged lack of Ethical Practices Committee approval. I refute the allegation absolutely on the basis of extensive documentary evidence.

Much of the documentary evidence referred to in Dr Murch's statement appears to have been supplied to him by Dr Richard Horton, editor of the Lancet and a former colleague of the investigators at the Royal Free hospital, who obtained it in circumstances of confidence from Brian Deer. In this statement, Dr Murch signally fails to refute anything whatsoever.

The protocol for the 1998 Lancet paper was submitted on September 16, 1996, to what was then termed the Ethical Practices Sub-Committee. It was entitled "A new paediatric syndrome: enteritis and disintegrative disorder following measles/rubella vaccine". It was signed by Andrew Wakefield as lead investigator.

The protocol and pro-forma document, available at <http://briandeer.com/mmr/royal-free-11.htm> is dated 6th August 1996, and is signed by Professor Roy Pounder, Dr Peter Harvey and Dr Mark Berelowitz.

Named consultants were John Walker-Smith and myself, with signed collaborators Peter Harvey, for the department of neurology, and Mark Berelowitz, for the department of child psychiatry.

The application was initiated due to findings at colonoscopy of two children with behavioural disorders, which would now be classified within the autistic spectrum, and a history of chronic gastrointestinal symptoms, and recognition of a broadly similar clinical history among other referred patients.

This is false. While there is no reason to doubt that two or more such children may have been seen at this major teaching hospital prior to the research, that research was initiated in direct execution of an agreement between Dr Andrew Wakefield, Mr Richard Barr, a solicitor then with the law firm Dawbarns, and a collaborating parent, Mrs Rosemary Kessick, now operating a group called Allergy Induced Autism. These three agreed together that the Royal Free hospital would be used to investigate children for the purpose of gathering evidence for a lawsuit against three drug companies, alleging that measles-virus-containing vaccines caused neurological

This claim directly contradicts Dr Murch's assertion above that "the application was initiated due to findings at colonoscopy of two children with behavioural disorders," since the protocol submission, signed by Professor Pounder, is dated the month before this child was colonoscoped (August 6). Also in the month before this child was colonoscoped, a contract was awarded, on 22 August 1996, after submission in June, for Dr Wakefield to carry out "clinical and scientific" tests on 10 children for Mr Barr, financed by the Legal Aid Board.

This child was William Kessick, who became one of the four "best" test-case litigants, selected from more than 1,600 children with legal aid certificates, in the now apparently failed High Court action against the drug companies.

In a recorded interview with me, Mrs Kessick says that she contacted Dr Wakefield in 1995 at the suggestion of Jackie Fletcher of the anti-vaccine group JABS.

In fact, William Kessick's inclusion in the study was improper. He should have been excluded from the research, under a directive from the hospital's ethics committee - available at <http://briandeer.com/mmr/royal-free-10.htm> - stipulating that no child may be enrolled in the study prior to the date of ethical approval. In addition, this child didn't satisfy the admissions criterion of disintegrative disorder, approved by the committee - an issue to be discussed below.

Following this diagnosis, the child had been entered in good faith by our inflammatory bowel diseases fellow into an ongoing (ethically approved) study of polymeric enteral nutrition.

This may or may not be correct.

He had already made remarkable symptomatic improvement, including apparent cognitive advance. We, thus, appeared to be dealing with a condition of significant severity, and had seen clinical improvement unprecedented in this child's history.

The "condition of significant severity" was constipation with encopresis, a staple of paediatric gastroenterology, and in no way mysterious. Encopresis is described at <http://www.medicine.uiowa.edu/uhs/enco.cfm> or can be researched via Google. As any standard reference source will show, this condition often involves a mass of impacted stool in the colon, which commonly affects children's behaviour. It is intractable to treat, even with good parent-child communication, in developmentally normal patients. Both Mrs Kessick and Professor Walker-Smith have given me evidence that this child's behaviour improved directly upon preparation for colonoscopy, indicating the severity of the constipation and the beneficial consequences of directly dealing with it. I submit that the doctors were under a professional duty to treat this constipation problem, rather than to exploit it to give cover for experiments they wished to perform on autistic children.

In a letter to the Lancet published on March 21 1998 (page 908), Murch, Thomson and Walker-Smith report that the autistic children, in fact, suffered from a condition that indicated no invasive procedures whatsoever: "Plain radiography confirms severe constipation with acquired megarectum in almost all affected children... Most parents note a honeymoon period of behavioural improvement after the bowel preparation for colonoscopy..." Thus, the doctors were under a duty to X-ray these children and to attempt to treat their constipation as part of their clinical care before advancing to any

invasive procedures.

It is outrageous that Dr Murch should seek, in this formal statement, to obfuscate the child's gastric problems. In fact, the "syndrome" the Royal Free doctors claim to have discovered, which was used to generate the MMR scare, appears to be nothing more than constipation and consequential gut inflammation with immunological changes in a group of autistic children, pre-selected by lawyers and anti-MMR groups as likely to have mundane gastroenterological symptoms. This true state of affairs was concealed, and both the profession and public hoodwinked by claims of the discovery of a new medical syndrome.

News of this improvement was rapidly disseminated among parents of autistic children, which I believe led to many further referrals.

No doubt news was disseminated - among the parents organisations campaigning for money from the drug companies and against MMR: Allergy Induced Autism and JABS. Jackie Fletcher of JABS told me that all of the initial 12 children seen at Royal Free, and whose details were published in the Lancet on February 28 1998, were members of her group. Eleven became legally-aided, and the twelfth was a US citizen. The Royal Free was conducting research designed from the outset to fish for evidence to present in the litigation.

This child was included in the study, with additional investigations performed after ethics approval was obtained.

"This child", William Kessick, shouldn't have been included in the study, according to the ethics committee's formal direction, noted above. Ethics approval was obtained for a study of children for which this child did not meet the admissions criteria.

In fact, seven of the twelve children reported in the Lancet were colonoscoped *before* ethical approval was given (for a different study to the one reported, as will be explained). Nine had legal aid certificates to sue the drug companies at the time the Lancet paper was published.

The title of this submitted application is a point of contention, and should be clarified. Having taken initial advice from our psychiatric colleagues on the basis of referral letters, it was considered that these children demonstrated a form of autism called disintegrative disorder (Heller's disease).

This is false. The description of the project as an investigation of disintegrative disorder, or Heller's disease, was determined before any referral letters were received, with the *possible* exception of a single letter re William Kessick, who was not suffering from this disorder and whose referral letter did not claim that he did.

It's not plausible, within any generally accepted standards of medical practice, to mistake autism for disintegrative disorder (Heller's disease) in the numbers of children seen before ethical approval was given, in the age group for which MMR is routinely administered, and for whom clinical details were published by the Wakefield group. The difference between autistic disorder and disintegrative disorder is well known, and set out here at <http://briandeer.com/mmr/autistic-disorder.htm>

The Wakefield group knew this distinction before commencing the study, and set it out clearly in the protocol at part 5 of <http://briandeer.com/mmr/royal-free-11.htm>

The investigators plainly intended to carry out a study of children with disintegrative disorder, and obtained approval for this, citing specifically the profound problems of such children. At <http://briandeer.com/mmr/royal-free-9.htm> Professor Walker-Smith describes the children's prognosis as "hopeless" - a prognosis that could not be determined for a group of young autistic children. The study proposed was for disintegrative disorder, not autism, and the researchers knew it.

Part 5 of the protocol document states with regard to disintegrative disorder: "This rare disorder can sometimes be linked to **measles encephalitis...**" [investigators' emphasis]

Having clearly set out their intentions, they then executed a study of a different group of children to that specified in the protocol. This different study, in fact, was well underway before approval was obtained to do anything.

The truth, which contradicts Dr Murch's formal statement, is that the group chose to investigate precisely what the protocol says: disintegrative disorder, in an older group of children than that which was subsequently reported in the Lancet. This decision was reached in execution of the agreement with Mr Barr to pursue the litigation, as will be explained further below.

After full psychiatric assessment of each child seen, it was later concluded that the more accurate description for the submitted paper should be pervasive developmental disorder.

This paragraph admits - as do documents such as the table at <http://briandeer.com/mmr/royal-quiz.htm> - that psychiatric assessment took place *after* children were subjected to inappropriate invasive procedures, such as lumbar punctures. The investigators were, at least in the first series of children, determined to perform lumbar punctures, irrespective of the patients' clinical circumstances.

Our working title for these cases had, however, remained disintegrative disorder, while some parents referred to their child as autistic, and others did not.

This paragraph dissembles. The "working title" remained as it was because this title was approved by the ethics committee, and any other title was not. Dr Murch seeks to imply that some parents referred to their children as suffering from disintegrative disorder, when they did not.

The whole area of nomenclature in autistic spectrum disorders was notably difficult at that stage.

Apart from general matters not relevant to this research, this statement is false. Clear diagnostic criteria were in place and understood by the investigators when they submitted the application for ethical approval. If anything, "nomenclature in autistic spectrum disorders" has become more, not less, difficult with the passage of time.

As we saw more patients, we moved towards a more inclusive label of autism,

The label "autism" was adopted in the Lancet paper because the children actually admitted to the trial were in the main suffering from autism, and not suffering from disintegrative disorder, as described in the protocol. In fact, some children in the

study were neither suffering from autism, nor disintegrative disorder. "Autism" is not a "more inclusive" label. [nb: "Autistic spectrum disorder" and "autism" are not interchangeable terms.]

which was used in subsequent correspondence after February, 1998, to the Ethical Practices Committee.

This misleadingly implies that correspondence was initiated by the investigators. The correspondence after February 1998, when the research was published, arose from an intervention by Professor Sir David Hull, chair of the joint committee on vaccination and immunisation, and past president of the Royal College of Paediatrics and Child Health. Sir David had read the published Lancet paper and evidently did not believe that an ethics committee acting responsibly could have authorised the invasive tests on the children described. His letter to the dean of the medical school is indexed at <http://briandeer.com/mmr/royal-free-1.htm>

Measles and rubella were singled out in the application since these conditions, but not mumps, had been linked to autism in previous isolated reports.

This statement is so egregiously false that it requires extended consideration. Measles and rubella were "singled out in the application" because they were the specific two components of the specific individual vaccine product targeted - quite explicitly and deliberately - by the investigators for study.

Under the legal contract with Mr Barr, Dr Wakefield agreed to study children who they believed were injured by the double measles-rubella vaccine, MR - not by the triple MMR. This double vaccine was used only in an intensive three-week vaccination drive in November 1994. (At the time, there was a worldwide shortage of mumps vaccine, which is the reason it was not included.)

The MR vaccine campaign - sometimes dubbed in the press "operation safeguard" - involved 7.1m school-age children, given MR. This is eleven times the average annual take-up of MMR, and was expected by the investigators to yield a bumper crop of "vaccine victims". These children were in age groups in which disintegrative disorder, or Heller's disease, is diagnosed - as correctly stated in the protocol approved by the ethics committee. This vaccination campaign is described in a parliamentary answer, giving England's figures, reported at <http://briandeer.com/mmr/measles-rubella.htm>

Mr Barr explained the rationale for the study - which he frankly tells me he commissioned from Dr Wakefield - to The Sunday Times magazine in 1995. On 17 December 1995, the magazine published an article (which will have been some months in production) where Mr Barr was quoted as stating the reason why the MR vaccine was singled out for investigation. On page 22, the magazine reports: "In Britain, hampered by a lack of 'hard scientific fact', the link between vaccination and serious adverse reaction has been successfully established only once in court. Now, Operation Safeguard might offer unexpected help. All of the MMR group were babies when they were vaccinated; the Operation Safeguard children are much older. 'Say a child has been alive for 10 years - 3000 days,' says Barr. 'Suddenly, within days after the vaccination, he develops an acknowledged adverse effect. "Coincidence," say the consultants, but we believe it gives us a much stronger case to argue a causal link, often helped by an established history of good health - which babies for obvious reasons, lack."

This fully explains the commission by Mr Barr of a study of MR and disintegrative disorder from the Royal Free hospital investigators.

Having prepared a protocol for a study of MR and disintegrative disorder, however, the requisite number of children could not be found from the ranks of solicitors' clients and parents alerted by media reports, such as The Sunday Times magazine feature (which itself principally showcased alleged MR victims).

Although the researchers explicitly hypothesised that childhood disintegrative disorder, or Heller's disease, was caused by a vaccine, this disorder is extremely rare. An estimate used by the US National Institute of Mental Health, relying on four surveys of autistic spectrum disorders, found only 2 cases of disintegrative disorder per 100,000 autistic spectrum children. The gut surgeon and his gastroenterology colleagues may not have known it, but this extreme rarity, combined with the fact that the disorder is not caused by vaccines, meant that under any foreseeable circumstances they would have found it impossible to recruit a cohort to fit their protocol, or to submit for litigation. The project submitted to the ethics committee could only have foundered.

With regard to the 1994 MR campaign, according to a journalist called Janine Roberts who maintains a website, Jackie Fletcher of the anti-vaccine group JABS had received "80 reports of alleged vaccine damage" from MR as of September 1995. Considering that, in the now-abandoned lawsuit, the claimants couldn't find four convincing vaccine victims for trial from 1,600 with legal aid certificates, it is evident that the grievances identified regarding MR would not be anything like sufficient to produce the results the investigators wanted. The web url for Roberts' information is at <http://inquirer.gn.apc.org/fraud.html>

In this situation, Dr Wakefield, Dr Murch, Professor Walker-Smith and their colleagues, unilaterally changed the admissions criteria for the study, without notifying the ethics committee - and therefore without obtaining approval - and instead recruited children with autism. According to the NIMH calculation, such children are 50,000 times more common than those with disintegrative disorder.

Finally, with regard to Dr Murch's false claim in this respect, it has, in fact long been a prominent feature of Dr Wakefield's theory of how vaccines are supposed to cause autism that vaccine-delivered measles virus may in some way interact with, or be potentiated in its effect by, *mumps* virus.

In summary on this point, Dr Murch's attempt to explain, in a formal statement for publication by the Lancet, the reason why measles and rubella were "singled out in the application", is both false and ridiculous.

This application (172-96) was for permission for in-depth analysis of 25 patients, referred either by general practitioners or the vitamin B12 unit at the Chelsea and Westminster Hospital, who had been studying B12 absorption in children with regressive neurological disorders.

According to press reports, the B12 unit at the Chelsea and Westminster was shut down following allegations concerning the work of Dr "Ray" Bhatt. According to a report in The Independent of July 22 1996, funding for Dr Bhatt's work was "withdrawn in 1995... managers asked for evidence that his work had been peer-reviewed and submitted for ethical approval." It appears that Dr Bhatt's patients were

then directed to Dr Wakefield at the Royal Free, and Mrs Kessick confirms that William Kessick has previously been a patient of Dr Bhatt's.

The selection criteria explicit in this application were the presence of disintegrative disorder, symptoms and signs suggestive of gastrointestinal disease, and parental request for investigation.

"Parental request for investigation" is a revealing criterion.

All patients reported met these criteria.

This is false. Only one of the 12 children reported in the Lancet paper of February 1998 is reported with a - queried - diagnosis of disintegrative disorder. It beggars belief that Dr Murch could make such a claim in a statement to the Lancet.

The consultant paediatricians responsible for the children's care decided on the investigations, although advice was taken from colleagues at other centres.

The investigations were decided upon by the paediatricians before children was even seen, with the exception of one - William Kessick - who had been seen only by Professor Walker-Smith at an outpatient appointment at a different hospital (Barts). No advice could be taken from "colleagues at other centres" on allegedly clinically-indicated investigations of children who had never been seen.

Decisions about the battery of investigations performed on the children were based on extrapolations from information obtained on the telephone by Dr Wakefield from the parents of children that Mr Barr and Mrs Kessick had determined should be sent to the Royal Free. One example of this conduct is reported at <http://briandeer.com/mmr/wakefield-panorama.htm> I submit that it is misconduct to make medical diagnoses, or prescribe clinical procedures, on the basis of telephone conversations with patients' relatives by a gut surgeon with a non-clinical contract.

We determined that these investigations were required clinically, not only to characterise gut inflammation but also to exclude primary neurological diseases.

This is false. The investigations were set out as a research project, and were to be carried out regardless of the children's individual histories, prior diagnoses and symptoms. Many of the children in the study came to the Royal Free with pre-existing diagnoses of autism, as explicitly acknowledged in the Lancet paper, and after extensive screening at other medical centres. In many cases, primary neurological diseases had already been excluded by other doctors, generally better qualified for the task than the Royal Free's gastroenterologists.

Only after the investigations were challenged in the ethics committee's pro-forma did the Wakefield, Walker-Smith and Murch team claim that these investigations were "required clinically" - a judgment that cannot, as a matter of professional standards, be reached before a patient is examined. To do so would, in my submission, be misconduct.

We had in particular taken advice for the neurological investigations, since some of the referrals appeared to have suffered an encephalitic illness,

It follows from this that, according to Dr Murch's words, some of the referrals did not suffer from such an illness, and that therefore to carry out tests on them in the absence of an indication could not be clinically justified.

and specifically the inclusion of lumbar puncture was suggested to us as important for assay of cerebrospinal fluid lactate, to exclude mitochondrial cytopathies that can cause both neurological regression and bowel disease.

The protocol approved by the ethics committee gives a clear statement on the reason the investigators wanted to perform lumbar punctures on children. CSF lactate - very occasionally assessed by specialists for evidence of certain extraordinarily rare genetic conditions - is not mentioned. The protocol states at (4): "Lumbar puncture for measurement of CSF antibody and cytokine profiles." In other words, they were looking for measles virus.

In fact, precisely these tests - looking for measles virus, which Dr Wakefield's speculative theory claimed persisted in the gut, blood and CSF of these autistic children - were carried out, as per the protocol. Speaking at an Institute of Medicine meeting on March 8 2001 in Washington DC, Dr Wakefield referred to these tests. "And here we have a site of persistent viral infection in which to start to look. Clearly that doesn't exclude the presence of virus in the brain. In the first set of children we did lumbar punctures. We looked for viral antibody titres. We did MRI scans, EEGs. We could find no evidence of active inflammation, or local IGG synthesis in the brain. After that it became too expensive and too invasive to continue doing that."

When no virus was found, the investigators did not publish this information in the Lancet paper, which would have contradicted the Wakefield doctrine, but instead retrospectively shifted to CSF lactate as a purported reason for having carried out lumbar punctures in a cohort of autistic children without either ethical approval or clinical indication.

Several of these cases had not been investigated to exclude a primary cause of their regression,

It follows from this that, if "several" had not been investigated, the others had. Therefore to carry out tests on them could not be clinically justified. According to the published Lancet paper (see "patients and methods: clinical investigations") "four children did not undergo psychiatric assessment in hospital; all had been assessed professionally elsewhere, so these assessments were used as the basis for their behavioural diagnosis." Therefore, by the researchers' published admission, one third of the children reported in the Lancet had no conceivable clinical indication for lumbar puncture.

and we thought it important to ensure that we were not missing underlying metabolic or genetic abnormality.

These decisions were taken according to a predetermined plan, without the children first being seen by a psychologist, psychiatrist or neurologist - or indeed by anybody at the Royal Free hospital.

Proposed investigations thus included ileocolonoscopy and upper endoscopy, barium follow-through if ileitis was identified, lumbar puncture (if sufficient fluid remained after lactate assay, serology and/or cytokine testing would be

performed),

This claim regarding the lumbar punctures is disingenuous, as indicated above.

magnetic resonance imaging of the brain to exclude structural defects, electroencephalography to exclude covert epilepsy, electrophysiological testing, and a panel of standard laboratory tests, with isolation of DNA for complement genotyping, since C4 deficiency had been reported to be an association.

The subjects of the research were almost wholly autistic children with constipation and encopresis, as indicated above. These tests were agreed upon before the children were ever examined at the hospital, or their medical records consulted. Doctors in relevant specialties only saw the children *after* such tests had been carried out. A timetable of the investigations carried out is available at <http://briandeer.com/mmr/royal-quiz.htm>

The protocol was referred back at first submission in September, 1996, with clarifications and amendments required, and was approved in December, 1996. Specifically, members of the committee challenged the lumbar punctures and intubations, and were assured, falsely, that these were only performed where clinically-indicated.

This protocol formed the basis for all children investigated in the 1998 Lancet paper, and all were investigated.

This is false, as this analysis shows. A comparison between the approval and the Lancet paper is set out at <http://briandeer.com/mmr/royal-table.htm>

We had no idea at the time of our Ethical Practices Committee application that lymphoid hyperplasia would prove so common, although it was a prominent part of the final report.

This may or may not be so.

It is important to document where the protocol differed from the submission. First, neither I nor my fellow endoscopist, Mike Thomson, eventually considered it justified to perform upper gastrointestinal endoscopy in most patients - there was then no published evidence of upper gastrointestinal pathology,

Dr Murch's statement does not document "where the protocol differed from the submission", as he claims, at all, but in fact serves to conceal the differences. The reference to published evidence is a non sequitur. There was at the time no published evidence of any of this.

and we were performing these procedures under sedation, as was then our practice.

According to the informed consent document, the procedures would be performed under sedation, or general anaesthetic if the child "becomes distressed". This document is available at <http://briandeer.com/mmr/royal-free-12.htm>

Getting the precise level of sedation is not easy in children with such behavioural difficulties, and we felt this was not appropriate at that time, although our policy altered in later years.

It is unclear what this sentence means.

Second, in the event, we did not continue with this extended protocol for the full 25 patients, again because of the clinical concerns of myself and my colleagues, since we had found no evidence of underlying metabolic abnormality in any case and did not consider that lumbar puncture of further cases was indicated.

Either this claim is false, or the investigators have published false information in the scientific press. An abstract published by the journal Gut, and presented in March 1998, refers to 30 children undergoing this protocol. The abstract is available at <http://briandeer.com/mmr/wakefield-gut.htm>

Other children subsequently seen were thus not subjected to this extended protocol, and investigated by testing of inflammatory markers and abdominal X-ray, with endoscopies performed if thought clinically indicated, unless there were clear clinical reasons to perform additional tests.

This claim is false and disingenuous, for reasons dealt with elsewhere in this analysis.

Following the publication of the initial report, John Walker-Smith sought guidance from the Ethical Practices Committee about further investigation of future cases, stating "I would like formally to request Ethical Committee approval for our clinical research analysis of these children who we are continuing to see by clinical need".

This is grossly disingenuous. Professor Walker-Smith "sought guidance" seven days after the Royal Free medical school received the letter from Sir David Hull on July 8 1998. The sequence of correspondence is at <http://briandeer.com/mmr/royal-free-index.htm>

In a letter to the ethics committee, further studies were referred to under the title "autism and non-specific colitis and Lymphoid Nodular Hyperplasia" since that was the clinical entity that the earlier study had defined. This was reviewed on July 22, 1998, and data collection from clinically indicated investigations was approved.

Again, the ethics committee review was triggered by Sir David Hull.

This was for study of subsequent patients investigated on the basis of gastrointestinal symptoms and initial assessment, and in no way relevant to the 1998 Lancet paper,

This appears to be correct. The fishing expedition continued for years, claiming all the while to be clinically-indicated. Children found to have LNH were fed directly into the litigation process.

which had been conducted entirely according to the 1996 approval.

This is false. The Lancet paper barely resembles the protocol submitted to the ethics committee.

Thus, there was no change in the name of the ethical approval requested for the 1998 paper, as mistakenly alleged.

I am not aware of anyone alleging that any change was sought from the ethics committee whatsoever. The committee was simply not notified of wholesale alterations, or of critical matters which the investigators had a duty to bring to its attention.

A local review initiated by the Royal Free medical school in July, 1998, confirmed that the application had been fully considered by the ethics committee, and that assurance had been given that the investigations were clinically indicated. It was also apparent that the continuing investigation of those children had been reviewed by the ethics committee in July, 1998, and appreciated that investigation of children seen after publication had become less extensive, and usually restricted to gastroenterological testing as thought clinically appropriate.

This review and matters following from it were as a result of the approach by Sir David Hull, as indicated above. Nobody has ever doubted that the committee "considered" the application, or that the committee was given the "assurance" that the investigations were clinically indicated. I submit, however, that this assurance was false.

I submit that as a matter of law, doctors cannot simply determine what is clinically indicated and make it so by virtue of that decision. Were this the case, a gynaecologist, a GP, or indeed a gastroenterologist, could with impunity determine that all female patients should, on clinical grounds, have their breasts massaged. I believe the public would be shocked if the GMC punished a medical practitioner in such circumstances, and overlooked any mistreatment of profoundly vulnerable autistic children.

We contended then, and still contend now, that these were standard and appropriate gastroenterological and neurological investigations for the symptoms reported given the current state of knowledge at that time.

I don't believe that Dr Much will be able to find much support for this claim among paediatricians, gastroenterologists or neurologists.

Undoubtedly we now perform endoscopy less frequently, but that is based on extensive experience. Similarly, a child with coeliac disease in the 1970s would have had three diagnostic biopsies compared to the one, or even none, now performed.

By the time Dr Wakefield left the Royal Free in December 2001, he says in a recorded interview with Sunday Times journalists, at least 200 autistic children had undergone colonoscopy.

Mr Barr tells me that up to 150 children seen at the hospital were his clients. Other children were clients of additional law firms involved in the litigation.

Thus, I can confirm that the patients presented in the Lancet study were investigated in accordance with the ethics committee approval of December, 1996,

This is false. The protocol describes a study with a different title, a different admissions criterion, a different number of subjects, different controls, a different rationale for lumbar punctures and a different hypothesised environmental trigger, to what was published in the Lancet. The ethics committee chair and the dean of the medical school explicitly deny the claim in the Lancet that the committee approved the investigations. A comparison of the two studies is available at <http://briandeer.com/mmr/royal-table.htm>

and that no attempt was made to seek retrospective approval.

I am not aware of anyone alleging that the investigators sought retrospective approval. They never at any time sought approval for the study they carried out.

Dr Simon Murch

Senior Lecturer and Consultant in Paediatric Gastroenterology, Royal Free and University College Medical School

I submit that the complex contradictions in this analysis emerge from something very simple: that these doctors carried out an unauthorised and unethical fishing expedition in pursuit of non-clinical goals. When challenged, they dissembled. In the statements published in the Lancet, they misled the medical profession and the public on a matter of grave concern, which is, in itself, I submit, worthy to go before the GMC's fitness to practice committee for investigation.

I hold copies of any documents not available at my website, and am willing to provide them to the GMC, or to give any other help that may be required.

I trust that you will notify me, in whatever way is appropriate, of how my concerns are progressed.

With best wishes,

Brian Deer

<http://briandeer.com>

This page is from a collection of materials indexed at this website arising from an investigation Brian Deer for The Sunday Times of London into research by Dr Andrew Wakefield and others at the Royal Free hospital, London, published in the Lancet medical journal. Go to The Lancet MMR fiasco homepage

The Lancet MMR fiasco: summary of a scandal

On February 28 1998, the Lancet medical journal published a five-page research study of 12 developmentally disordered children, aged 3-10, authored by Dr Andrew Wakefield, Professor John Walker-Smith, Dr Simon Murch and ten others, based at the Royal Free hospital, London. [Lancet 1998; 351: 637-41]

The published study's principal finding was an alleged association between measles, mumps and rubella vaccination (MMR) and the onset of autism. Publicity for this finding caused a worldwide scare over MMR's safety, leading to falls in immunisation rates and a rise in diseases which can kill and disable children.

The Lancet paper reporting the study contained errors, inconsistencies and omissions, which might properly have been challenged by the journal's editor, Dr Richard Horton, a former Royal Free colleague of Wakefield's. These shortcomings, and a principal finding which, at face value, appeared unbelievable, caused widespread concern among doctors, and alerted Brian Deer to the need for an investigation into the research which lay behind them.

The Lancet paper:

1. Among other things, the paper said: "**Findings.** Onset of behavioural symptoms was associated by the parents with measles, mumps, and rubella vaccination in eight of the 12 children..." Under "results", the paper added: "In these eight children the average interval from exposure to first behavioural symptoms was 6.3 days (range 1-14)."

2. Under "acknowledgements", the paper said: "This study was supported by the Special Trustees of Royal Free Hampstead NHS Trust and the Children's Medical Charity".

3. Under "Ethical approval and consent", the paper said: "Investigations were approved by the Ethical Practices Committee of the Royal Free Hospital NHS Trust, and parents gave informed consent."

Brian Deer's findings:

1. Wakefield maintained that the eight children whose parents blamed MMR were routine hospital admissions, but in fact most were solicitors' clients in a lawsuit against vaccine manufacturers. These parents had been sent to Wakefield, and were bound to blame the vaccine. Others in the study were associated with organisations campaigning against MMR. To launder these parents' claims into the medical literature as a "finding" or "result", while concealing their status, was to grossly mislead the public.

2. Unknown to colleagues, Wakefield had negotiated for himself a contract valued at £55,000 with the UK government's Legal Aid Board to perform "clinical and scientific"

tests on ten claimant children. This contract was not disclosed in the Lancet paper, despite signed undertakings to disclose conflicts of interest. This non-disclosure served to conceal Wakefield's relationship with the lawsuit, and bias in the study's execution.

3. After the Lancet publication, the claim that "investigations were approved by the Ethical Practices Committee" was denied, explicitly and in writing, by the chair of that committee and by the dean of the hospital's medical school. The committee had been assured that the investigations - including a uniform battery of invasive and hazardous procedures determined before the children were seen - would have been carried out even if there had been no study. This was untrue. The committee, in fact, never approved any study as described in the Lancet.

Results to date:

Following Deer's intervention, the Lancet said it regretted publishing the paper. By a majority of 10 to 3, the paper's authors, including Walker-Smith and Murch, formally retracted their finding of a possible MMR-autism link. The UK's General Medical Council announced that it would conduct an inquiry into the affair. Brian Deer called for the resignation of Lancet editor Richard Horton.

April 2004

REVEALED: MMR RESEARCH SCANDAL

The Sunday Times (London) February 22 2004

By Brian Deer

FULL details are disclosed today of the four-month Sunday Times investigation that has uncovered a medical scandal at the heart of the worldwide scare over MMR.

Andrew Wakefield, the doctor who champions the alleged link between measles, mumps and rubella vaccine and autism in young children, stands discredited for misleading his medical colleagues and The Lancet, the professional journal that published his findings.

The investigation has found that when he warned parents to avoid MMR, and published research claiming a link with autism, he did not disclose he was being funded through solicitors seeking evidence to use against vaccine manufacturers.

The Lancet said yesterday that The Sunday Times's evidence meant that the finding linking MMR and autism was "entirely flawed" and should never have been published. Last night, John Reid, the health secretary, called for an inquiry by the General Medical Council (GMC) "as a matter of urgency".

Evan Harris, a Liberal Democrat MP who sits on the British Medical Association's ethics committee, said the GMC had inadequate powers and pressed the government for a full independent inquiry. After reviewing The Sunday Times's findings, Richard Horton, the editor of The Lancet, said he should never have published Wakefield's article linking MMR to autism. It was "fatally" flawed.

Wakefield was not contactable yesterday, but he said last week when confronted with the investigation findings that he was unrepentant. He denied misleading his colleagues or The Lancet. 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.

Wakefield was the lead author of the report. He wrote that the parents of eight of the 12 children blamed MMR: they said symptoms of autism had set in within days of vaccination. The Sunday Times has now established that four, probably five, of these children were covered by the legal aid study. And Wakefield himself had been awarded up to £55,000 to assist their case by finding scientific evidence of the link.

Wakefield did not tell his colleagues or medical authorities of this conflict of interest either during or after the research. The children were subjected to a battery of invasive procedures, including colonoscopies and lumbar punctures. In the months that followed the examination of the first children, many more were channelled through the hospital. The parents of many were clients of one solicitor, Richard Barr, of King's Lynn, Norfolk, who was leading the legal attack and had organised Wakefield's funding from the Legal Aid Board (now the Legal Services Commission).

The research paper published in The Lancet contained no scientific evidence of a link with MMR, only the "association" made by parents. But at the unprecedented press conference to launch the report, attacked the three-in-one jab as posing risks of causing autism and bowel problems.

"It's a moral issue for me and I can't support the continued use of these three vaccines given in combination until this issue has been resolved," he said. Neither in the report nor at the conference did he disclose the legally-funded work he was doing for Barr's clients. Asked his opinion of this non-disclosure last month, Barr said: "I remember noting at the time that the funding acknowledgment wasn't there, but it didn't seem to be a big deal . . . things have moved on since then."

Barr added yesterday: "My role is to do the best for my clients. Clients came to me and told me what was happening to their children."

In March 1998, as public alarm took off over the safety of MMR, a meeting of the Medical Research Council squarely asked Wakefield about the source of the children he had analysed in the Lancet report. Wakefield failed to take the opportunity to reveal his interest. Six weeks later he was faced with a letter in The Lancet raising the question of litigation. All children, Wakefield claimed, came through "formal channels" and that "no conflict of interest exists".

The medical establishment has long rejected Wakefield's claims about MMR, and in 2001 he left the Royal Free. He now travels between Britain and America, lecturing about the dangers of the vaccine.

Last weekend, aware of The Sunday Times's investigation, he flew back to Britain. He was represented by Abel Hadden, a top PR man at Sir Tim Bell's Bell Pottinger company. At a tense confrontation on Wednesday at Bell Pottinger's headquarters in Mayfair, a red-eyed Wakefield denied any wrongdoing. He said any conflict of interest in his work was "a matter of opinion". "I believe that this paper was conducted in good faith," he said. "It reported the findings. There was no conflict of interest. Do we have any reasons [now] to change our opinion? No, but then again it's a debate."

As he was speaking, the findings of the investigation were also being shown to Horton at The Lancet. Shocked, Horton later called in Wakefield and visited the Royal Free on Thursday to talk to Wakefield's former colleagues and inspect records. By Friday, Horton and his fellow editors were faced with a dilemma: should they respect The Sunday Times's confidence and wait for the storm to break today? Or rush out a press release criticising Wakefield and taking credit for disclosing his fatal conflict of interest? They chose the latter. Simon Murch, one of the leading doctors involved with Wakefield's research at the Royal Free, said yesterday that news of the £55,000 legal funding was "a very unpleasant surprise". "We didn't know. We were pretty taken aback. The timing of it before the paper is something we have all been shocked by. If you have a colleague who has not told you, if you have not been informed you are going to be taken aback."

He went on: "I am not going to join the queue of people rushing up to kick Andy. But it is right that this has come out: there has been a complete conflict of interest."

Murch said it was never made clear that the payment was in place before the report was published. "We never knew anything about the £55,000 — he had his own separate research fund," said Murch. "All of us were surprised . . . We are pretty angry."

He added: "This is not personal corruption. But there was a clear conflict of interest — it was not declared to us and it was not declared to the journal, and it should have been." Murch said he believed that if Wakefield had made clear his interest, The Lancet would have asked for the report to be rewritten to focus on hard fact and to "leave the speculation, leave the measles story out of there".

Another of Wakefield's 12 co-workers in the study said: "I am very, very angry. I would never have put my name to the study if I had known there was this conflict of interest, and had I not done so it would never have got published."

Another author, Dr Peter Harvey, a board member of Visceral, a registered charity set up to support Wakefield, spoke out in his defence. Harvey said he did not think the funding was relevant and he would have still have put his name to the study if he had known. "I don't think there was any conflict of interest," he said.

Dr Richard Smith, editor of the British Medical Journal, said, however: "That MMR paper is the best example there has ever been of a very, very dodgy paper that has created a lot of discomfort and misery."

FOCUS: MMR - THE TRUTH BEHIND THE CRISIS

The Sunday Times (London) February 22 2004

Six years ago Andrew Wakefield linked MMR with autism. It sparked a national health scare that could yet see children die. Brian Deer reveals the doctor's secret

To call a national press conference in order to announce the results of a scientific trial is rare. For a prestigious teaching hospital to do so for a study involving just 12 children is unprecedented. So when journalists were called to attend an urgent press briefing at the Royal Free hospital in London in February 1998 they arrived expecting a scoop.

Under television lights, five doctors, including the dean of the medical school, lined up to make their announcement. They had, they informed the hushed room, important news from the front line of medicine: injections of the combined measles, mumps and rubella vaccine (MMR) had been linked for the first time to a bowel disorder and the onset of a severe form of regressive behaviour, generally known as autism, in children.

Richard Horton, the dapper young editor of The Lancet, waited expectantly in his office for the reaction. It was shocking news by any standards.

Government policy dictated that every child should receive the first of two MMR inoculations between 13 and 15 months. Thousands of jabs were being given daily. Now parents were being told that the vaccination might be associated with a form of serious brain damage in children.

Advance copies of The Lancet's sensational study were quickly distributed. "Twelve children were referred to (the hospital) with a history of normal development, followed by a loss of acquired skills, including language, together with diarrhoea and abdominal pain", read its remarkably media-friendly opening page. "Onset of behavioural symptoms was associated, by the parents, with measles, mumps and rubella vaccination in eight out of the 12 children."

Eight out of 12: it was a stunning proportion. Worse, the damage had become evident on average just "6.3 days" after the jabs were given. Professor Arie Zuckerman, dean of the medical school, then sounded a word of caution. It was "absolutely essential" that public confidence in MMR was not damaged by the publication of the study. Eight children did not, after all, provide proof of a link between MMR and autism, he noted.

However, if Zuckerman was cautious, others were not. At the centre of the speakers' table sat the principal author of the study, Dr Andrew Wakefield. Cutting a dashing and charismatic figure, the young gastroenterologist had a very different message to impart. Yes, it was just one study and yes, there was no proof, but he personally believed that action was needed.

"One more case of this is too many," he declared. "It's a moral issue for me and I can't support the continued use of these three vaccines given in combination until this issue has been resolved." He wanted single jabs. Until then the emerging public debate over MMR had been based on little more than anecdote. Now it had been given the imprimatur of The Lancet and an urgent call for government intervention. The result was explosive. "Alert over child jabs" shouted the front page of The Guardian the next day. "Ban three-in-one jab urge doctors" said the Daily Mail. Thousands of similar newspaper stories, television and radio broadcasts followed over the next few months.

GPs' surgeries were inundated with calls from parents and vaccination rates started to fall. Six years on and an epidemic of measles, which can maim and even kill, now threatens. Overall, the inoculation rate has fallen to just 79% — well below the 95% needed to confer "herd immunity" in crowded schools, nurseries and playgrounds.

David Elliman, a consultant community paediatrician at Great Ormond Street hospital, warned last week that with almost half of children unvaccinated in some parts of London, the risk of a death from measles had become real. He said that outbreaks of the disease caused by inadequate vaccine coverage in Italy, Ireland and Holland had led to deaths in recent years.

"The worry is that the coverage here is so low in some areas that this could happen here, and people should be made aware of that," he said.

At the Department of Health and in the wider medical establishment, experts were deeply concerned by the reaction to The Lancet study. Yes, the journal had pushed it and yes, officialdom had gained little in the way of public trust after the debate over "mad cow" disease, but Wakefield appeared not so much an objective scientist, more as a man with a mission. He had even written to the department attacking the MMR vaccination before his own research was completed.

"I am writing to you in order to express formally my anxieties over your intention to re-vaccinate all pre-school children," he wrote on September 6, 1996 to Sir Kenneth Calman, then the government's chief medical officer. The letter closed with the blunt instruction: "Do not re-vaccinate."

Now a Sunday Times investigation has revealed that Wakefield's Lancet report was not the objective piece of science that it had appeared to be. All along he has kept a secret from the public, from The Lancet and even from his colleagues. His secret was this: in August 1996 — the month before he dispatched his letter to Calman and a month before he applied for ethical approval for the Lancet study — he had secured up to £55,000 from the Legal Aid Board specifically to investigate a possible link between MMR and autism in respect of 10 named children.

Of the eight children whose parents were eventually reported in The Lancet as having associated the jab with the onset of their child's autism, "four, perhaps five" were covered by the legal aid contract. Not only did Wakefield know at the time of publication that the parents of these children had an interest in seeing a scientific link between MMR and autism established, but he was also being funded to investigate that possibility. Only if he were successful in establishing that link would the children's parents be able to sue for compensation. He knew all this but declared none of it in the Lancet study, to his principal co-authors or to the public.

All the public got was Wakefield's warning against MMR and the concluding paragraph of his study which stated: "In most cases, onset of the symptoms was after measles, mumps and rubella vaccination." Through the offices of public relations advisers and lawyers, Wakefield continues to maintain that he acted properly. But the revelations do more than cast his original study in a new light; they taint his findings.

Even Horton, a former colleague of Wakefield, said last week that in retrospect The Lancet should never have published his study. Late on Friday, after being shown the evidence in confidence by The Sunday Times, he chose to make a public statement.

"If we had known the conflict of interest Dr Wakefield had in his work, it would have been rejected. As the father of a three-year-old who has had the MMR, I regret the adverse impact this paper has had," Horton said.

HOW did Wakefield end up publishing something so potentially misleading in a highly respected medical journal? "Andrew always wanted to be a surgeon," recalled his mother Dr Bridget Wakefield, a retired GP in Bath who is married to a neurologist and is the daughter and granddaughter of doctors. "He's very like my father. If he believed in something, he would have gone to the ends of the earth to go on believing."

After qualifying in medicine and training as a surgeon in Canada, Wakefield joined the Royal Free as a research scientist. Among the bowel problems that he had seen during his training was Crohn's disease, an ulcerating inflammation of the gut. The more he studied it, the more he suspected that it was caused by a common virus: measles.

In the early 1990s Wakefield published several studies proposing a measles-Crohn's link. Although the studies did not lead very far, he kept the faith and persevered. At the same time Richard Barr, a solicitor in Norfolk, was developing a practice in litigation against drug companies. Barr had pursued some cases against Opren, an arthritis drug, and in the early 1990s he learnt of concerns about MMR, which had been introduced in Britain in 1988. A number of clients came to him concerning legal action against three drug companies which manufacture MMR: GlaxoSmithKline, Aventis Pasteur and Merck.

Barr identified clients through newsletters and publicity. "Vaccine damage is not some capricious concept," he claimed in one pamphlet, "but is very real and is demonstrable using scientific principles."

Jackie Fletcher, one of Barr's clients, ran a campaigning group called Jabs which involved concerned parents. It is not clear exactly when Wakefield and Barr first came into contact. Barr thinks he met Wakefield in 1994. A colleague in Dawbarns, the firm where Barr then worked, says it was in 1995. Last week Wakefield said it was 1996, but then conceded that it might have been 1995.

What is clear is that when the two met, a flurry of activity ensued. Damaged children in Barr's network started to be referred to the Royal Free. This was an "unusual" pattern, The Lancet said on Friday.

According to Barr, he and Wakefield began to talk regularly by telephone. Between the two of them a hypothesis was taking shape: that measles from MMR was damaging the gut, causing inflammation. Harmful chemicals were then getting into the blood, resulting in brain damage and autism. It was a neat idea but little more than that. Then, sometime in the first six months of 1996,

Barr and Wakefield approached the Legal Aid Board to fund the clinical investigation of 10 apparently brain-damaged children. In August 1996 the board granted them £55,000 to investigate possible links between MMR and autism, The Sunday Times has established.

Wakefield's clinical colleagues at the Royal Free — who physically examined the children — say they were not told of the Legal Aid Board contract by Wakefield. All the children were presented to them as ordinary patients referred by their GPs. Soon afterwards these same doctors — surprised at what they had seen in the children — applied to the Royal Free's ethics committee to undertake a study for publication on up to 25 children with behavioural disorders who had had measles vaccine.

Wakefield's name was also prominent on the proposal which was submitted in September 1996. It was this study that would give rise to the Lancet article. There was no disclosure on the ethics application form of the legal aid contract. A few of the children were already under investigation but now the numbers increased. Each was subjected to a battery of tests, some highly invasive: one involved manoeuvring a 4ft fibre-optic endoscope deep into the bowel; another was to hunt for measles through a lumbar puncture or spinal tap.

Wakefield says these investigations were judged to be "clinically indicated" by his medical colleagues and therefore justified. They did not know, however, about the £55,000 legal aid contract. Barr was delighted for his clients at the way things were going. Indeed, when interviewed by The Sunday Times last month, he said: "We weren't trying to get an independent paper published under the carpet. I remember noting at the time that the funding acknowledgment wasn't there, but it didn't seem to be a big deal . . . things have moved on since then."

The issue of funding aside, there is another, perhaps more fundamental, issue. After lengthy investigations by The Sunday Times, Wakefield finally admitted last week that "four, perhaps five" of the children in his Lancet study were among the 10 named in the legal aid contract. Was it four or five? "Let's make it five," he said. The questioning went on. Were they litigants? Yes. Was he being paid to help them to build their case? Yes. Were his colleagues told that they had ended up in the Lancet sample? I don't recall. Did he reveal the conflict of interest to The Lancet as its rules explicitly require? No. Why not? "I believe that this paper was conducted in good faith. It reported the findings. There was no conflict of interest. Do we have any reasons (now) to change our opinion? No, but again it's a debate."

The Lancet yesterday described Wakefield's continuing insistence that he had done nothing wrong as "perverse". John Reid, the health secretary, has called for a General Medical Council inquiry. Others are equally bemused. Elliman said he was amazed that Wakefield had used children who were litigating as his subjects.

"These are people with a clear vested interest in the result of the research and it would have been appropriate to let that be known," he said. "Wakefield has got himself into a very difficult position."

Wakefield says that in 1997, as The Lancet study was being prepared for publication, he and his colleagues had another "debate". It was about whether to include the key finding that the parents of eight out of 12 children associated the jab with the onset of brain damage in their offspring.

His co-authors, however, say they did not have the full facts: Wakefield had not told them of the "overlap" of five children or even of the existence of the legal aid contract. When Professor John Walker-Smith, the lead clinician named on the Lancet study, was told of Wakefield's funding, he said that he was "astounded".

"We were seeing these patients by clinical need and we were reporting the first patients we saw," he said. "There was no awareness of any legal involvement when we saw these children."

THERE were several key points at which Wakefield could or should have declared his and the children's involvement in the litigation. The Lancet's rules for its authors are clear: "The conflict of interest test is a simple one. Is there anything . . . that would embarrass you if it were to emerge after publication and you had not declared it? The editor needs to be informed and will discuss with you whether or not disclosure in the journal is necessary." Did Wakefield hold discussions? No. Is he now embarrassed? "I have no regrets," he said. Shouldn't he have disclosed that he was acting for Barr's clients? "I don't agree . . . clearly there is a debate . . . we can argue about this." On Friday, after considering The Sunday Times's evidence, questioning Wakefield and inspecting the Royal Free's records, The Lancet issued a statement which concluded that Wakefield should have disclosed his interest. He should have told the editor about his study for the litigants and its £55,000 funding, even if there had been no children overlapping with the Lancet study. "If we had known then what we do now, we certainly would not have published that part of the paper that related to MMR," the editor added. Wakefield had another opportunity early on to set the record straight. After the Lancet study appeared in February 1998, the Medical Research Council (MRC) convened a meeting to discuss it. Numerous doctors and professors were present, along with officers of the MRC. Minutes of the meeting record: "How were the patients selected? Members were interested in how the children had come to be referred to the (Royal Free) team, as this had a bearing on the issue of bias."

It was an obvious moment for Wakefield to declare his hand, to disclose his interest and put the record straight before the MMR scare that the Lancet study had sparked got out of control. But again he failed to reveal the legal aid contract.

Professor Sir David Hull, chairman of the government's joint committee on vaccination and immunisation, was present. "Certainly the fact that these patients were litigants would be relevant to interpretation of the data," he said. "It was already very questionable whether anyone seriously looking at the data would draw the same conclusions as (Wakefield)." Ironically — and to much less fanfare — Wakefield published a few months later a little noticed study that revealed just how skewed his original Lancet study had been. The brief synopsis, published in a journal called Gut, had data on the original 12 children of the Lancet study and a further 18. Parents of only three of the new children attributed the onset of their children's behavioural problems to MMR. Put another way, the incidence of parental association between MMR and autism had dropped from 66% to just 12%.

Did this undermine the Lancet findings? "You may be right," Wakefield said last week. "I simply don't know. It does seem that as we examined more

numbers the percentage of parents who ascribed (their children's problems) to the vaccine fell away."

EVER since the BSE scare, when the government first declared beef to be completely safe but then decided that it could kill, the public has been distrustful of the health authorities. When Wakefield and The Lancet published his study in that climate, the public was ready to disbelieve government protests that MMR was safe. "After (the study) first came out we were struggling just to get parents to immunise their children," said Dr Michele Hamilton-Ayres, a consultant paediatrician in Cheltenham. "Things got terribly bad."

Immunisation rates have fallen dangerously low and the incidence of measles cases has risen sharply. Meanwhile, legal cases have proliferated: since Wakefield and Barr were granted the £55,000, legal aid for those suing the vaccine companies has reached £15m. Of that, about £5m has gone to Barr's present firm, Alexander Harris, and about £4m has gone to doctors, some earning £100 an hour to study reports.

The Legal Services Commission (successor to the Legal Aid Board) cut off funding last year, but lawyers pursuing compensation claims have taken that decision to judicial review.

Wakefield remains unrepentant. He insists that he and his colleagues have discovered a novel bowel disease in some children with developmental disorders. He claimed last week that the £55,000 study, finally submitted for publication, has found "live" measles in the guts of children with behavioural disorders. But even he admits that this is all a long way from proving that measles, let alone MMR, causes autism. No causal link has been found between them.

Is he embarrassed? Would he like to apologise? Last week, after these questions were put directly to him, the real passion that drives him suddenly broke through. "Should we stop, should we go away, should we stop publishing because it is inconvenient?" he asked. "I've lost my job. I will never practise medicine in this country again. There is no upside to this. "But if you come in to me and say, 'This has happened to my child', what's my job? What did I sign up to when I went into medicine? To look after your child. How many other children does this affect because your child's expendable if it's only your child (suffering damage). That's not my job. I'm not here to make that kind of decision. I'm here to address the concerns of the patient. There's a high price to pay for that. But I'm prepared to pay it." His co-authors, however, feel betrayed. "I am very, very angry," said one of them yesterday. "I would never have put my name to the study if I had known there was this conflict of interest, and had I not done so it would never have got published."

Lancet editor "regrets" research paper which caused worldwide vaccine scare

In February 1998, a five-page research paper by Dr Andrew Wakefield and 12 other doctors from the Royal Free hospital, London, was published in the Lancet medical journal, linking the measles, mumps and rubella vaccine - **MMR** - with autism. This one paper triggered a worldwide scare over the vaccine's safety, and falls in children's immunizations. Six years later, Brian Deer investigated the research, and exposed its finding as a sham. -> Go to the Lancet fiasco for an overview
After a five-hour confidential briefing by Brian Deer to six Lancet senior staff and a member of parliament on Wednesday 18 February 2004, editor Dr Richard Horton broke an embargo agreed with The Sunday Times and rushed out an admission that the journal was wrong to have published the Wakefield research in 1998.

Here is how the BBC reported the story, including Horton's refusal to admit where he had obtained the "allegations". Claims in this news report that the Sunday Times investigation did not "cover the actual findings of the study" are also wrong.

Friday, 20 February, 2004, 19:58 GMT

Journal regrets running MMR study

The medical journal that published a controversial study linking MMR to autism says, with hindsight, it would not have published the paper.

Richard Horton, editor of the Lancet told the BBC the researchers had a "fatal conflict of interest".

But Andrew Wakefield, the researcher at the centre of the study, rejected the journal's claims. The paper prompted many parents to reject the three-in-one jab, even though most experts say it is safe.

The Lancet launched an investigation into the way the study was carried out after receiving "an allegation of research misconduct". It would not reveal who had made the allegations - which do not cover the actual findings of the study.

But in a statement, the Lancet said Dr Wakefield had not said he was carrying out a second study into whether there were grounds for legal action on behalf of parents of allegedly vaccine-damaged children.

Some children were involved in both studies.

The Lancet says it should have been told about this overlap, although Dr Wakefield says he was not involved in the selection process for the second study.

Dr Horton said: "There were fatal conflicts of interest in this paper. "In my view, if we had known the conflict of interest Dr Wakefield had in this work I think that would have strongly affected the peer reviewers about the credibility of this work and in my judgement it would have been rejected."

He said: "As the father of a three-year-old who has had MMR, I regret hugely the adverse impact this paper has had."

Authors retract MMR-autism finding after newspaper investigation nails research

In February 1998, a five-page research paper by Dr Andrew Wakefield and 12 other doctors from the Royal Free hospital, London, was published in the Lancet medical journal, linking the measles, mumps and rubella vaccine - **MMR** - with autism. This one paper triggered a worldwide scare over the vaccine's safety, and falls in children's immunizations. Six years later, Brian Deer investigated the research, and exposed its finding as a sham. -> Go to the Lancet fiasco for an overview
On Wednesday March 3 2004 - ten days after a four month investigation by Brian Deer was published in The Sunday Times of London - ten of the 13 authors of the Lancet paper formally withdrew their claim. Here's how the Associated Press carried the story

By EMMA ROSS, AP Medical Writer

LONDON - Most of the scientists involved in widely discredited 1998 study suggesting a link between childhood vaccinations and autism have renounced the conclusion.

Ten of the study's 13 authors have signed a formal retraction, the text of which was released Wednesday by The Lancet ahead of its publication later this week in the British medical journal.

The retraction follows the recent revelation that the main author was being paid separately by lawyers for parents who claimed their children were harmed by the immunizations. Some of the children involved in the lawsuit were also involved in the study.

The study undermined public confidence in the triple vaccine for measles, mumps and rubella by suggesting it might be linked to autism.

MMR vaccination rates fell dramatically in Britain and several other European nations and have yet to recover, although subsequent studies dismissed a connection between autism and the vaccine. "We wish to make it clear that in this paper no causal link was established between (the) vaccine and autism, as the data were insufficient. However, the possibility of such a link was raised," the scientists said in the retraction.

"Consequent events have had major implications for public health. In view of this, we consider now is the appropriate time that we should together formally retract the interpretation placed on these findings in the paper," the group wrote.

The study, involving 12 children, was conducted about eight years after they had been vaccinated and was based in large part on parents remembering whether the autism symptoms occurred around the same time as the shots.

The main author, Dr. Andrew Wakefield, who at the time was working at the Royal Free Hospital in London, is among those who have not signed the retraction. He could not be reached for comment. However, he has continued to insist the study was valid, despite the findings of authoritative groups such as the World Health Organization and the U.S. Institute of Medicine.

The scientists signing the retraction work for institutions that include the Royal Free Hospital, the Institute of Child Health in Liverpool, England, and Cambridge University.

Tony Blair joins calls to support MMR after Lancet research is denounced

In February 1998, a five-page research paper by Dr Andrew Wakefield and 12 other doctors from the Royal Free hospital, London, was published in the Lancet medical journal, linking the measles, mumps and rubella vaccine - **MMR** - with autism. This one paper triggered a worldwide scare over the vaccine's safety, and falls in children's immunizations. Six years later, Brian Deer investigated the research, and exposed its finding as a sham. -> Go to the Lancet fiasco for an overview
The day after Deer's Sunday Times investigation was published, on February 22 2004, the prime minister joined calls to back MMR, as reported here in The Guardian.

Claim that MMR work mixed science and spin

James Meikle, health correspondent
Tuesday February 24, 2004
The Guardian

Tony Blair yesterday weighed in to the MMR controversy by appealing once more for parents to give their children the all-in-one measles, mumps and rubella jab.

The prime minister, who refused two years ago to reveal whether his son Leo had received the vaccine, stepped in to hammer home his view of the MMR's importance as the General Medical Council paved the way for an investigation into the ethics of Andrew Wakefield's study into autism and bowel disease six years ago which lit the fuse for a series of explosive rows over the vaccine's safety.

Richard Horton, editor of the Lancet medical journal, has said he would never have published the research study in February 1998 if it had known of "a serious conflict of interest", which Mr Wakefield should have revealed at the time.

He and other senior staff conducted an urgent investigation last week following allegations presented by a researcher for the Sunday Times, and concluded that the fact that Mr Wakefield had not revealed he was receiving legal aid funds on behalf of parents seeking to establish a link between MMR and autism was a serious error of judgment and a "fatal conflict of interest".

But Mr Wakefield, who denies any wrongdoing, and former colleagues were cleared by the Lancet of other allegations of research misconduct made about the study which provoked years of argument, serious falls in uptake of the vaccine and repeated warnings of a measles epidemic among young children.

Mr Blair told ITV: "There is absolutely no evidence to support this link between MMR and autism. If there was, I can assure you that any government would be looking at it and trying to act on it. I hope, now that people see that the situation is somewhat different to what they were led to believe, they will have the triple jab because it is important to do it."

Mr Blair, at the height of "did he or didn't he" row over Leo and the jab in 2002, made clear he would never advocate something he did not think safe for his own children.

The government's chief medical officer, Sir Liam Donaldson, speaking on BBC's Today programme, said he had always regarded Mr Wakefield's study as poor science. "If the paper had never been published, then we would not have had the controversy and we wouldn't have had the seed of doubt sown in parents' minds which has caused a completely false loss of confidence in a vaccine that has saved millions of children's lives around the world.

"When Mr Wakefield has been in contact with us, he has often been represented by a PR company rather than communicating directly. "I don't think that spin and science

mix. If they are mixed, it is a very unfavourable position for children's health. Now a darker side of this work has shown through, with the ethical conduct of the research and this is something that has to be looked at."

The GMC confirmed last night that it had spoken to Mr Wakefield and he had indicated his willingness to work with any investigation. Mr Wakefield has been defended by Jabs, a group including members who are trying to pursue legal action over MMR. Its founder Jackie Fletcher said: "Mr Wakefield's original data is not in question at all and the conclusions from it have not changed."

But Sense, the national deafblind and rubella association, said the revelations "further undermine the significance and credibility of Andrew Wakefield's original paper".

Abel Hadden, a PR spokesman at Bell Pottinger, has acted for Visceral, a charity that funds work by Mr Wakefield and others. The Guardian was unable to contact Mr Wakefield last night either by ringing Mr Wakefield's home or Mr Hadden.

Journalist hits back over "inexcusable" journal that "risked children's safety"

In February 1998, a five-page research paper by Dr Andrew Wakefield and 12 other doctors from the Royal Free hospital, London, was published in the Lancet medical journal, linking the measles, mumps and rubella vaccine - **MMR** - with autism. This one paper triggered a worldwide scare over the vaccine's safety, and falls in children's immunizations. Six years later, Brian Deer investigated the research, and exposed its finding as a sham. -> Go to the Lancet fiasco for an overview
After a five-hour confidential briefing on Wednesday 18 February 2004 by Brian Deer to six Lancet senior staff and a member of parliament, editor Dr Richard Horton broke an embargo agreed with The Sunday Times and rushed out an admission that the journal was wrong to have published the research. Here is how the Press Association reported the story

LANCET DOUBTS VALIDITY OF CONTROVERSIAL MMR REPORT;

HEALTH;MMR Substitute

Byline: By Tim Moynihan, PA News

Issue Date: Friday February 20, 2004

Eminent medical journal The Lancet tonight cast serious doubt on the paperit published six years ago which started the scare over the MMR jab.

The publication in 1998 of the study by Dr Andrew Wakefield and colleaguesat London's Royal Free Hospital led to fears of a possible link between themeasles, mumps rubella vaccine and autism, which continue to lead to reducedtake-up of the vaccine today.

Tonight The Lancet said Dr Wakefield had been carrying out studies both forthe Royal Free and for the Legal Aid Board which created the risk of a conflict of interest.

The journal rejected allegations, though, that ethics approval for the investigations on the children reported in the study had not been given.

Its editor Richard Horton told BBC TV News: "If we knew then what we know now, we certainly would not have published the part of the paper that related to MMR, although I do believe there was, and remains, validity to the connection between bowel disease and autism, which does need further investigation, but I believe the MMR element of that is invalid."

Dr Wakefield said in a statement to the editors of The Lancet: "The clinical and pathological findings in these children stand as reported."

He added: "My colleagues and I have acted at all times in the best medical interests of these children and will continue to do so."

The journal's editors said that on Wednesday they were made aware of serious allegations, put to them by investigative reporter Brian Deer working for The Sunday Times, of research misconduct concerning the article.

They rejected claims that ethics approval for the investigations conducted on the children reported in the study had not been given.

They also dismissed an allegation that the children were not consecutively referred to the hospital, but instead invited to participate by Dr Wakefield and Professor John Walker-Smith, thus biasing the selection of children in favour of families reporting an association between their child's illness and the MMR vaccine.

It was also alleged that some of the children in the Lancet study were also part of a Legal Aid Board funded pilot project, led by Dr Wakefield, which had the aim of

investigating the grounds for pursuing legal action on behalf of parents of allegedly vaccine-damaged children.

It was claimed that Dr Wakefield received Pounds 55,000 from the Legal Aid Board to conduct the pilot project and that, since there was a substantial overlap of children in both studies, this was a financial conflict of interest which should have been declared to the editors and his co-authors.

The editors said Dr Wakefield had two roles in this work.

"First, he was the lead investigator of a Royal Free study into the nature of a new syndrome with bowel and psychiatric symptoms.

"Second, he was commissioned through a lawyer to undertake virological investigations as part of a study funded by the Legal Aid Board.

"At the time of submission and eventual publication of his 1998 Lancet paper, this second study had not been disclosed to the editors of The Lancet and his co-authors."

They said "the perception of a potential conflict of interest remains", adding: "This funding source should, we judge, have been disclosed to the editors of the journal."

Prof Walker-Smith denied in a statement to the editors that there had been bias in the pattern of referral for the children in the Lancet paper.

"No children were invited to participate in the study," he said.

Dr Wakefield agreed in his statement that the children were referred according to clinical need.

"Whether parents perceived an association with MMR vaccine or not, whether parents had approached lawyers with the intent to seek legal redress, or whether children were in receipt of legal aid funding or not, had no bearing whatsoever on their selection for clinical investigation or inclusion in the Lancet report."

He said he had had no specific knowledge of the legal status of the children on whom he was undertaking the virological studies.

He added: "Funds received from the Legal Aid Board were paid into, and properly administered through, a research account with the special trustees of the Royal Free Hampstead NHS Trust."

The Royal Free and University College Medical School and the Royal Free Hampstead NHS Trust told the editors: "We are entirely satisfied that the investigations performed on the children reported in the Lancet paper had been subjected to appropriate and rigorous ethical scrutiny."

Tonight, Sunday Times reporter Deer told PA News: "Following a five hour confidential briefing to the Lancet by myself on Wednesday, Richard Horton, the editor, has chosen to attempt to defend his own inexcusable publication of the MMR paper, which has jeopardised the health and safety of millions of children around the world.

"He has attempted a classic tabloid journalistic 'spoiler' in an attempt to distract attention from the very serious allegations which will be published in The Sunday Times this week."

Liberal Democrat MP Dr Evan Harris, a member of the science and technology select committee who has seen the paperwork underlying the Sunday Times story, told PA

News: "What the Lancet has found is a serious matter of non disclosure and conflict of interest, which has an impact on the credibility and validity of the interpretation of the research findings.

"Given the importance attached to the work of the Royal Free Hospital group by the media in the MMR debate, an inquiry is needed to establish what actually happened during this study and related studies and how Legal Aid Board funding was spent.

He added: "The Lancet and Royal Free have investigated themselves, and parents worried about MMR will need a fully independent inquiry."

Conclusion of GMC Screening process

- i) inappropriate,
- ii) not in the best interests of your patients,
- iii) fell seriously below the standard of conduct to be expected of a registered medical practitioner;

12.

- a) In 2002 the Chief Medical Officer wrote to you in response to your proposal that a meeting be convened with you, Professor Walker-Smith and Mr Richard Barr,
- b) In the letter, the Chief Medical Officer posed a number of questions including whether you and your colleagues had obtained informed consent from patients used as controls within the study, for the use and retention of control tissues,
- c) The Chief Medical Officer also asked that these samples be made available for independent testing,
- d) You failed to respond substantively to the questions posed by the Chief Medical Officer,
- e) Your actions as set out in heads 12 a) to d) fell seriously below the standard of conduct to be expected of a registered medical practitioner.

In reaching that decision the screener relied on the following evidence

Charge	Supporting Information	Page
1-12	Lancet paper entitled "Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children".	29-39
	E-mail from Brian Deer to GMC dated 25 February 2004.	40-46
	E-mail from Brian Deer to GMC dated 12 March 2004, including statement to Brian Deer from Royal Free and University College Medical School dated 11 March 2004.	47-49
	E-mail from Brian Deer to GMC dated 1 July 2004.	50-63
	Document entitled "Royal Free Hampstead NHS Trust Ethical Practices Sub-Committee Protocol and Pro-Forma" relating to project 172-96, including (undated) letter from Dr. Epstein to Dr. Wakefield, and letter from Dr. Pegg to Dr. Walker-Smith dated 7 January 1997.	64-101
	Document entitled "Health Service Guidelines; NHS Management Executive; Local Research Ethics Committees".	102-128

Document entitled "Royal Free Hampstead NHS Trust Ethical Practices Sub-Committee Application for Approval of Ethical Project 172-96".	129
Letter from Professor Zuckerman to Dr. Pegg dated 27 July 1998.	130
Letter from Professor Zuckerman to Professor Sir David Hull dated 27 July 1998.	131-132
Letter from Dr. Pegg to Professor Zuckerman dated 24 July 1998.	133-134
Letter from Professor Brent Taylor to Professor Zuckerman dated 23 July 1998.	135
Letter from Dr. Pegg to Professor Zuckerman dated 20 July 1998.	136
Letter from Dr. Walker-Smith to Dr. Pegg dated 15 July 1998.	137
Letter from Professor Zuckerman to Dr. Walker-Smith dated 15 July 1998.	138
Letter from Professor Zuckerman to Dr. Pegg dated 9 July 1998.	139
Letter from Professor Zuckerman to Professor Taylor dated 9 July 1998.	140
Letter from Professor Sir David Hull to Professor Zuckerman dated 6 July 1998.	141-142
Letter from Dr. Walker-Smith to Dr. Pegg dated 9 January 1997.	143
Letter from Dr. Pegg to Dr. Walker-Smith dated 7 January 1997.	144-145
Letter from Maureen Carroll to Dr. Wakefield dated 14 November 1996.	146
Letter from Dr. Walker-Smith to Dr. Pegg dated 11 November 1996.	147-148
Memorandum from Maureen Carroll to Dr. Pegg dated 10 October 1996, enclosing a query from a committee member plus outcome.	149-152
Letter from Maureen Carroll to Dr. Wakefield dated 1 October 1996.	153
Copy of application for ethical approval for project 172-96, including approval documentation.	154-190
Document entitled "Royal Free Hospital & Medical School Local Research Ethics Committee Application for Approval of Ethical Project" relating to project 122-99.	191
Letter from Dr. Pegg to Sir Liam Donaldson dated 13 March 2002.	192
E-mail from Professor Carol Black to Dr. Pegg dated 4 March 2002.	193
Letter from Sir Liam Donaldson to Dr. Pegg dated 25	194

February 2002.	
Letter from Maureen Carroll to Dr. Wakefield dated 24 January 2001.	195
Memorandum from Maureen Carroll to Dr. Pegg dated 11 January 2001.	196
Paper from the American Journal of Gastroenterology entitled "Enterocolitis in Children With Developmental Disorders".	197-202
Letter from Dr. Wakefield to Dr. Pegg dated 15 December 2000.	203-205
Letter from Dr. Pegg to Dr. Wakefield dated 29 July 1999.	206-207
Letter from Dr. Wakefield to Dr. Pegg dated 16 July 1999.	208-209
Document entitled "A clinical and immunological study of children with autistic enterocolitis".	210-214
Letter from Dr. Pegg to Dr. Wakefield dated 21 June 1999.	215-216
Document entitled "Royal Free Hospital & Medical School" containing query regarding project 122-99 dated 8 June 1999.	217
Document entitled "Royal Free Hospital & Medical School" containing query regarding project 122-99 dated 4 June 1999	218
Letter from Maureen Carroll to Dr. Wakefield dated 3 June 1999.	219
Document entitled "Royal Free Hospital and Medical School Ethics Committee Application Form" relating to project 122-99 "Immunological and virological studies in autistic enterocolitis".	220-244
Letter from Dr. Wakefield to Dr. Pegg dated 29 May 1999.	245
Document entitled "A Statement by Dr. Andrew Wakefield".	246-249
Document entitled "A Statement by Dr. Simon Murch".	250-252
Document entitled "A Statement by Professor John Walker-Smith".	253
Correspondence from The Lancet by Dr. Wakefield entitled "MMR-responding to retraction", including Editor's reply.	254-257
Document entitled "The Lancet MMR fiasco: summary of a scandal".	258-259
Document entitled "Revealed: MMR Research Scandal".	260-262
Document entitled "Focus: MMR-The Truth Behind The Crisis".	263-268
Document entitled "Lancet editor "regrets" research paper which caused worldwide vaccine scare".	269
Document entitled "Authors retract MMR-autism finding after newspaper investigations nails research".	270
Document entitled "Tony Blair joins calls to support MMR after Lancet research is denounced".	271-272
Document entitled "Journalist hits back over "inexcusable"	273-275

	journal that "risked children's safety".	
	Document entitled "MMR scare study published in the Lancet wasn't approved by an ethics committee".	276-277
	Document entitled "Washington Post reviews Wakefield story so far, with plans for Texas business".	278-280
	Document entitled "Taxpayer case for MMR action is stopped after £15m was spent on stoking fear".	281-282
	Document entitled "The annotated Andrew Wakefield: can MMR scaremonger be relied on for the truth?".	283-286
	Document entitled "Wakefield misled top UK medical research body of the source of MMR children".	287-288

The Screener also took into account Good Medical Practice.

Screeners' comments:

This case raises serious allegations about Mr. Wakefield. If proven the charges raise issues of serious professional misconduct. I recommend consideration by the PPC.