

# STATEMENT

## A statement by the editors of *The Lancet*

On February 18, 2004, serious allegations of research misconduct concerning an article by Dr Andrew Wakefield and colleagues published in *The Lancet* in February, 1998,<sup>1</sup> were brought to the attention of senior editorial staff of the journal.

The allegations are:

- (1) That, contrary to a statement in the *Lancet* paper, ethics approval for the investigations conducted on the children reported in the study, some of them highly invasive (eg, lumbar puncture), had not been given.
- (2) That the study reported in *The Lancet* was completed under the cover of ethics approval for an entirely different study of 25 children with “A new paediatric syndrome: enteritis and disintegrative disorder following measles/rubella vaccination”.
- (3) That, contrary to the statement in the *Lancet* paper that children were “consecutively referred to the department of paediatric gastroenterology” at the Royal Free Hospital and School of Medicine, children were invited to participate in the study by Dr Andrew 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.
- (4) That the children who were reported in the *Lancet* study were also part of a Legal Aid Board funded pilot project, led by Dr Wakefield—a pilot project with the aim of investigating the grounds for pursuing a multi-party legal action on behalf of parents of allegedly vaccine-damaged children, the existence of which was not disclosed to the editors of *The Lancet*.
- (5) That the results eventually reported in the 1998 *Lancet* paper were passed to lawyers and used to justify the multi-party legal action prior to publication, a fact that was not disclosed to the editors of *The Lancet*.
- (6) That Dr Wakefield received £55 000 from the Legal Aid Board to conduct this pilot project and that, since there was a substantial overlap of children in both the Legal Aid Board funded pilot project and the *Lancet* paper, this was a financial conflict of interest that should have been declared to the editors and was not.<sup>2</sup>

The editors of *The Lancet* have seen and reviewed the documentary evidence available in support of these allegations. In acting on this information we have followed the guidelines on dealing with alleged misconduct as set out by the UK Committee on Publication Ethics, on which representatives of *The Lancet* sit.<sup>3</sup> We have presented this evidence to the senior authors of the 1998 *Lancet* paper (Dr Wakefield, Professor John Walker-Smith, Dr Peter Harvey, and Dr Simon Murch) in order to seek their responses. Dr Richard Horton, Editor of *The Lancet*, has also shared this information with Professor Humphrey Hodgson, vice-Dean and campus director of the Royal Free and University College Medical School, London, the institution at which the original work took place.

With this notice are accompanying statements from Dr Murch, Professor Walker-Smith, and Dr Wakefield, answering the allegations of research and publication misconduct, together with a statement from the Royal Free and University College Medical School.

Given these four statements, together with an evaluation of the available documents, we consider that:

### *Allegation 1*

The evidence we have seen indicates that ethics committee approval was given for data collection from clinically indicated investigations in the children with an initially undiagnosed illness and who were described in the 1998 *Lancet* paper. This illness was at first believed to be enteritis combined with a disintegrative disorder. Subsequent detailed clinical investigations eventually showed this condition to be the syndrome finally reported in *The Lancet*. This course of events was not described in full in the *Lancet* paper, although the similarity of the behavioural changes with those of a disintegrative psychosis (Heller’s disease) were commented on in the discussion section of the 1998 *Lancet* paper. In summary, the evidence does not support this allegation.

### *Allegation 2*

As described under Allegation 1, detailed clinically appropriate investigations led to a re-evaluation of the initial diagnosis of these children, as set out in protocol 172-96. The evidence we have seen indicates that there was no attempt by investigators to conduct the study of children reported in *The Lancet* in 1998 under cover of an entirely different investigation. In sum, the evidence does not support this allegation.

### *Allegation 3*

Professor Walker-Smith notes that although the referral pattern was unusual—direct contact by patients with Dr Wakefield leading to referral to the Royal Free—the children were indeed consecutively referred. He reports that to the best of his recollection he did not invite any children to participate in the study. Thus, as far as the facts can be ascertained by a review of the case notes and from memory, children reported in the 1998 *Lancet* paper were consecutively referred to the Royal Free and were not deliberately sought by the authors for inclusion in their study based on parents’ beliefs about an association between their child’s illness and the MMR vaccine.

### *Allegations 4–6*

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. We judge that it should have been so disclosed, irrespective of the number of children overlapping between the pilot project funded by the Legal Aid Board and the *Lancet* paper. Such a disclosure would have provided important information to editors and peer reviewers about the context in which this work was taking place—a context that would have been vital in making a final decision about publication. We believe that our conflict of interest guidelines at the time should have triggered such a disclosure, including the fact that a significant minority of the children described in

the *Lancet* paper were also part of the Legal Aid Board funded pilot project. These guidelines stated that: "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 difficulty of adopting a dual role as a clinical investigator and as a participant in an evaluation on behalf of the Legal Aid Board is revealed in Dr Wakefield's response to Allegation 5. Although it may be correct that "this [*Lancet*] publication . . . added nothing further to the issue of causation than that that was already well known to the lawyers", the perception of a potential conflict of interest remains. Editors and reviewers should have had an opportunity to take his dual role into consideration when assessing this paper for publication.

Finally, although the Legal Aid Board funding referred to a different aspect of Dr Wakefield's work from that reported in *The Lancet*, the perception of a conflict of interest nevertheless remains. This funding source should, we judge, have been disclosed to the editors of the journal.

### Summary

The first three allegations of alleged research misconduct have been answered by clarifications provided by the senior authors of this work. The wording in the published paper regarding Ethical Practice Committee approval and patient referral was accurate, yet at the same time summarised obviously lengthy and complex institutional and clinical review and referral procedures. In the light of the public controversy surrounding this work and the allegations made to us, one could argue that more explanation could and should have been provided in the original paper. Although, with hindsight, this seems a reasonable criticism, all research papers published by all journals are inevitably concise accounts of often complicated research protocols. We do not judge that there was any intention to conceal information or deceive editors, reviewers, or readers about the ethical justification for this work and the nature of patient referral. We are pleased to have had the opportunity to clarify the scientific record over the matters raised by these serious allegations.

We regret that aspects of funding for parallel and related work and the existence of ongoing litigation that had been known during clinical evaluation of the children reported in the 1998 *Lancet* paper were not disclosed to editors. We also regret that the overlap between children in the *Lancet* paper and in the Legal Aid Board funded pilot project was not revealed to us. We judge that all this information would have been material to our decision-making about the paper's suitability, credibility, and validity for publication.

In considering what sanctions *The Lancet* should apply, the COPE guidelines<sup>3</sup> give eight options in a ranked order of severity. Given the public-health importance of MMR vaccination, together with the public interest in this issue, we have decided to pursue a course of full disclosure and transparency concerning these allegations, the authors' responses, the institution's judgment, and our evaluation.

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- 1 Wakefield AJ, Murch SH, Anthony A, et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet* 1998; 351: 637-41.
- 2 In 1998, *The Lancet* required that: "The Editor needs to be informed [of any conflicts of interest] and will discuss with you [the authors] whether or not disclosure in the journal is necessary. All sources of funding must be disclosed, as an acknowledgment in the text."
- 3 See <http://www.publicationethics.org.uk/cope1999/gpp/dealing.phtml>.

## 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.

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. 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. Specifically, for several years previously we had looked after an autistic child with severe ulcerative colitis who eventually required colectomy (not included in the study), and the second child colonoscoped (on September 2, 1996) had ileitis of sufficient extent that a diagnosis of probable Crohn's disease was made. 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. 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. News of this improvement was rapidly disseminated among parents of autistic children, which I believe led to many further referrals. This child was included in the study, with additional investigations performed after ethics approval was obtained.

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). 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. Our working title for these cases had, however, remained disintegrative disorder, while some parents referred to their child as autistic, and others did not. The whole area of nomenclature in autistic spectrum disorders was notably difficult at that stage. As we saw more patients, we moved towards a more inclusive label of autism, which was used in subsequent correspondence after February, 1998, to the Ethical Practices Committee. 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 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. 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. All patients reported met these criteria. The consultant paediatricians responsible for the children's care decided on the investigations, although advice was taken from colleagues at

other centres. We determined that these investigations were required clinically, not only to characterise gut inflammation but also to exclude primary neurological diseases. We had in particular taken advice for the neurological investigations, since some of the referrals appeared to have suffered an encephalitic illness, 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. Several of these cases had not been investigated to exclude a primary cause of their regression, and we thought it important to ensure that we were not missing underlying metabolic or genetic abnormality. 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), 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 protocol was referred back at first submission in November, 1996, with clarifications and amendments suggested, and was approved in December, 1996. This protocol formed the basis for all children investigated in the 1998 *Lancet* paper, and all were investigated. 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.

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

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”. 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. 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, which had been conducted entirely according to the 1996 approval. Thus, there was no change in the name of the ethical approval requested for the 1998 paper, as mistakenly alleged.

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.

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. 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.

Thus, I can confirm that the patients presented in the *Lancet* study were investigated in accordance with the ethics committee approval of December, 1996, and that no attempt was made to seek retrospective approval.

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## A statement by Professor John Walker-Smith

I deny the allegation that there was systematic bias in the pattern of referral for the children in the 1998 *Lancet* paper. No children were invited to participate in the study.

Upon review of the Centre for Paediatric Gastroenterology, Royal Free Hospital, work book entitled “Biopsies VI 4/9/95 to 21/7/97”, we confirm that the children who were reported in the *Lancet* paper of 1998 were the first 12 children consecutively referred to the university department of paediatric gastroenterology with autism and related disorders, who had gastrointestinal symptoms requiring ileocolonoscopy to exclude chronic bowel inflammation. These children were referred to me at the university department of paediatric gastroenterology at the Royal Free Hospital from July 25, 1996, to February 24, 1997—one being referred from the island of Jersey and one from the USA. By the time the paper was accepted for publication, as mentioned in an appendix to the *Lancet* paper, up to January 28, 1998, a further 40 children had been so investigated, 39 with the syndrome reported in the paper. The children were all investigated specifically and exclusively by clinical need to determine whether bowel inflammation was present that could then be appropriately treated.

These children were referred to the Royal Free by their general practitioner (ten cases) or consultant paediatrician (two cases). Some parents had heard of Dr Wakefield’s previous work on inflammatory bowel disease and specifically requested referral, but the channel of referral was always as described above. However, the pattern of referral was often that the parents of the children approached Dr Wakefield directly knowing of his work, frequently by telephone. In the case of one patient, in whom it has been alleged that I contacted a consultant in order for a referral to be made, he had been asked by the parents of this child to contact me to explain what investigations were available at the Royal Free for children with autism and bowel problems. To the best of my recollection, I did not invite any children to participate in our study.

None of the children at the time of the referral was known by the team of paediatric gastroenterologists who cared for and investigated these children to be involved in a pilot project commissioned by the Legal Aid Board. At the time of consultation, I was aware that some parents were engaged in legal proceedings. Review of the clinical notes of the 12 children in the 1998 *Lancet* paper indicate that we had become aware at the time of publication that one child was involved in litigation proceedings against the vaccine manufacturers.

John Walker-Smith

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## A statement by Dr Andrew Wakefield

Allegation 4 completely misrepresents the facts. These were two quite distinct issues; the first a clinical report of 12 cases and the second, a hypothesis-testing laboratory study to examine for the presence or absence of measles virus in autistic children when compared with appropriate controls.

A minority of the children described in the 1998 *Lancet* report were part of the second study that was funded in part by the Legal Aid Board (later to become the Legal Services Commission). The relationship of these two distinct studies to the legal status of the relevant children is set out below. Professor Walker-Smith has already described the basis for the referral of these children according to clinical need.

At the time that the children reported in the 1998 *Lancet* paper were referred to Professor Walker-Smith for investigation of their gastrointestinal symptoms—the time material to their sequential investigation and subsequent inclusion in the report—none of the 12 reported children was in fact legally aided, ie, in receipt of legal aid certificates and therefore legal aid funding.

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. Since these allegations were made I have returned to parents (and where appropriate their current lawyers) to determine these facts. At the time the children underwent ileo-colonoscopy (ie, the time at which their pathology, as reported in *The Lancet* in 1998, was detected and reported by endoscopists and histopathologists), one child had been granted a legal aid certificate. The authors had no knowledge of this fact until now.

In support of this and in view of these allegations, parents of children in the 1998 *Lancet* report have provided a written signed statement that (i) they contacted me for help given their child's gastrointestinal symptoms, (ii) their referral to the department of paediatric gastroenterology at the Royal Free was through their child's doctor, (iii) that at no time did I encourage them to seek legal redress through the courts in the MMR class action, and (iv) that their child formed part of the initial study of 12 children reported in *The Lancet* in 1998.

Independently, I was commissioned through a solicitor, Richard Barr, to undertake quite separate virological studies on ten children. This is entirely in line with other university-based studies that have been similarly funded by the Legal Services Commission, and reported, for example, in the *BMJ*.<sup>1</sup> The list of children provided to me by Richard Barr was based on his knowledge of an overlap between patients referred to the Royal Free and those whose parents had made contact with Richard Barr. I could not have constructed such

a list since I had no knowledge of the litigation cohort or the legal status of children within this cohort. I was specifically concerned with addressing the scientific question in relation to measles virus—a perfectly legitimate question in view of the nature of the intestinal disease and the sequence of events in the children. Measles virus infection of the intestine is a specific interest of mine.

Once again, it is important to emphasise that I had no specific knowledge of the legal status of the ten children on the list other than as described above. Investigations, in light of the current allegations, indicate that four of these children (exact number to be confirmed by Richard Barr) were among those reported in the 1998 *Lancet* paper. The virological studies on these children have been submitted for publication. If and when these studies are finally published, due acknowledgment will be made of all sources of funding, including that from the Legal Services Commission.

Allegation 5 is an inaccurate misrepresentation of the facts. The results eventually reported in the 1998 *Lancet* paper were in the public domain long before their publication in February, 1998, having been presented at several national and international scientific meetings. They were readily available for interested parties to scrutinise and interpret as they saw fit. The findings were not actively made available to the media until after publication but, other than this, there was no attempt to conceal these data.

Such was the level of concern from the clinical and scientific team at the findings in this group of children with a similar history and an apparently novel bowel pathology, that I and Professor Walker-Smith reported them to a meeting in October, 1997, convened by the Hon Tessa Jowell MP, then Minister of Health, attended by the Chief Medical Officer Sir Kenneth Calman and other officials from the Department of Health in the presence of Richard Barr of Dawbarns solicitors, and representatives of interested parent groups. Barr, for his part, was in attendance as a lawyer, responsibly concerned by the sheer numbers of parents reporting, to him, developmental regression and gastrointestinal symptoms in their children following MMR vaccination.

It is important to emphasise that the only aspect of the 1998 *Lancet* paper that could have been used to justify a multi-party action, as in the foregoing accusation, is the parents' perception of a temporal relationship between MMR vaccine exposure and onset of symptoms. This perception was well known to the lawyers long before we were even aware of the role of the lawyers, or the proposed multi-party action, and certainly long before our publication in *The Lancet* in 1998. This publication alone added nothing further to the issue of causation than that which was already well known to the lawyers. The accusation is therefore specious. My own report to the Legal Services Commission on this matter was served in 1999.

With respect to allegation 6, as has been indicated above, these were two separate matters. One, a report of clinical investigations, and the other, a study commissioned quite independently through Richard Barr. The latter study was designed in order to explore the issue of possible causation. These studies were concerned with viral detection in the diseased intestinal tissues of ten potentially affected children. This approach is entirely in line with other university-based studies that have been similarly funded by the Legal Services Commission, and reported in the *BMJ*.<sup>1</sup> 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.

I have stated above that the origin of the list of children was provided to me by Richard Barr. My involvement was limited to the legitimate concern: was measles virus present in the intestinal tissue of these children?

As outlined above, I can confirm that publication of the relevant virological studies is still awaited. An interim submission of a report of this study (rejected) contained an explicit acknowledgment of the Legal Aid funding; this will be made available as necessary.

If and when the relevant virological studies are finally published, due acknowledgment will be made of all sources of funding, including that from the Legal Services Commission.

For none of these or any subsequent children has legal status influenced the need for investigation or the interpretation of the findings. Where it is known that children are in receipt of legal aid certificates or where studies receive funding from the Legal Services Commission, this will be included in any relevant publication.

The clinical and pathological findings in these children stand as reported. They have now been confirmed independently by reputable physicians and pathologists. On the basis of the molecular detection of measles virus in the diseased intestine of these children this issue, too, merits further study.

I regret the difficulties that this issue has caused my colleagues over the last week and I am grateful to them for their advice and support. I am enormously grateful for the timely manner in which Richard Horton has dealt with this issue and for his clarification of the issues surrounding perception and reality where conflict of interest may be concerned.

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

*Andrew Wakefield*  
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- 1 Altmann P, Cunningham J, Dhanesha U, Ballard M, Thompson J, Marsh F. Disturbance of cerebral function in people exposed to drinking water contaminated with aluminium sulphate: retrospective study of the Camelford water incident. *BMJ* 1999; **319**: 807–11.

## **A statement by The Royal Free and University College Medical School and The Royal Free Hampstead NHS Trust**

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. Because the nature of the condition affecting child behaviour and gastroenterological symptoms was unknown and required elucidation, the investigation of these children was properly submitted to and fully discussed by the Ethical Practices Committee at the Royal Free Hampstead in 1996. Specifically, that committee was a sub-committee of the then Camden and Islington Health Authority Research Ethics Committee (subsequently incorporated into the new Central Office for Research Ethics Committee arrangements) whose decisions were independent of the university and hospital. The committee, after clarifying a number of issues including that the children's investigations were defined by the clinical symptomatology and diagnostic requirements, and having taken expert advice, approved the protocol submitted.

The clinical management and investigation of these children was performed at the Free by a dedicated team of consultant paediatric gastroenterologists, in full consultation with and agreement of the parents of the affected children. The investigations were those thought appropriate in the light of the severity of the children's symptoms according to the clinician's judgment at the time.

Had the advice of the Institutions been sought at the time concerning conflict of interest, they would undoubtedly have advised that any potential conflict should be declared, so that others could judge whether such conflicts were real.

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