

THE *LANCET*'S TWO DAYS TO BURY BAD NEWS

In the third part of a special *BMJ* series, **Brian Deer** reveals what happened when he reported misconduct in Andrew Wakefield's MMR research to the medical journal that published it

Preparing to give evidence in London to a UK General Medical Council fitness to practise panel, Richard Horton, editor of the *Lancet*, nodded in turn to three accused doctors, seated among their lawyers to his left. First, Simon Murch, almost close enough to touch. Next, John Walker-Smith, more distant. Finally, Andrew Wakefield, at the far end of the hearing room. Each smiled thinly and nodded back.

The four had last met together three and a half years before, at the *Lancet*'s offices, nearly two miles north. There they had begun the journey that now brought their reunion in this, the longest medical disciplinary inquiry ever. Running for 217 days, between July 2007 and May 2010, it would probe the research and a paper that launched the MMR vaccine scare, and would lead to Wakefield and Walker-Smith being struck off.^{1 2}

Their previous encounter was in 2004, on the afternoon of Wednesday 18 February. They had gathered in Horton's office to deal with an approach from me concerning a four month *Sunday Times* investigation. For five hours that morning, I had briefed the *Lancet*'s senior staff about a now notorious 1998 paper in their journal.³ It reported on 12 children seen at the Royal Free hospital, north London, and claimed to have discovered a possible "new syndrome" involving regressive autism, inflammatory bowel disease, and MMR.

Mostly I had stood, occasionally pulling documents, as Horton, with five editors, took notes. I told them that the

paper's first author, Wakefield, was retained by a lawyer and was funded to help sue vaccine manufacturers. Admissions criteria for the study had been manipulated and ethical safeguards flouted. A group of developmentally challenged children of parents who blamed MMR had been brought to the hospital to create a case against the vaccine. I said I thought that the study was "rigged."

At one point, I drew a diagram of a cluster of complaints, which had been used to link autism with the vaccine.⁴ "In the paper, the parents of eight of 12 children apparently said words to the effect of 'It was the MMR, doctor,'" I told the meeting, convened around the journal's boardroom table. "But when the series was extended to 30 children, only the parents of three more made that claim. So, why would the allegations bunch together at the start?"

I had assumed that when I finished Horton would say that an investigation was needed to untangle these complex matters. There were at least three strands: possible research fraud, unethical treatment of vulnerable children, and Wakefield's conflict of interest through the lawyer. But within 48 hours, and working with the paper's three senior authors, the journal was to publish a 5000 word avalanche of denials, in statements, unretracted to this day.⁵⁻⁹

Years later, in the witness chair at the GMC hearing, Horton recalled that morning. "These were three sets of allegations which went to the heart of the credibility of the paper,

and were clear allegations of research misconduct," he told Sally Smith, Queen's Counsel for the doctors' regulator, on 7 August 2007. "We contacted Dr Wakefield, Professor Walker-Smith and Dr Murch, and asked the three of them to come to the *Lancet*'s offices so that we could discuss these allegations."

Observing the GMC proceedings, I too remembered that day. Wakefield had arrived at the *Lancet* before I left the building. All three authors were former Royal Free staff, as was Horton—a fellow in the late 1980s. A decade before Wakefield's publication, he had researched in hepatology, on the same corridor as Wakefield in gastroenterology.

During the 2004 meetings—first with me, and then with the authors—Horton was caught in a bind. Facing public alarm over MMR and professional scepticism towards the research, for years he had championed his former colleague. "I do not regret publishing the original Wakefield paper," he said in a 2003 book, at the height of the UK scare. "Progress in medicine depends on the free expression of new ideas. In science, it was only this commitment to free expression that shook free the tight grip of religion on the way human beings understood their world."¹⁰

Raising Galileo's ghost, he could not have then known how much of Wakefield's research was free expression. As I revealed in the *BMJ* two weeks ago, in not one case in the series of 12 children could the now retracted¹¹ paper be reconciled with National Health Service records.¹² And last week, I reported on Wakefield's secret business scheme, intended to harvest millions from the scare.¹³

Horton, moreover, was a crusader for integrity and had pressed for tough action against research fraud. As a force behind both the



International Committee of Medical Journal Editors and the Committee on Publication Ethics, he had campaigned with Richard Smith, then the *BMJ*'s editor, for a statutory watchdog on research misconduct. Despite their efforts, however, nothing had come of this, and Horton would now adopt a different approach.

Impropriety denied

"In this particular case," he told the GMC tribunal of three doctors and two lay members, seated to his right at the hearing, "we went to the vice-dean of the Royal Free, laid out the nature of the problem, and asked him to investigate and come back to us, as best he could, with his own judgment of the veracity or not of the allegations. In addition to that, we would look at the documentation as best we could and try and form our view as to whether those allegations were true."

It was a position he would develop in March 2010, after the panel's findings¹⁴ fully endorsed what I had told him. "We asked the institution

where the work was conducted—the Royal Free hospital—to complete an investigation," he submitted in a written statement to the journalists' magazine *Press Gazette*. "They did, and they cleared Wakefield of wrongdoing."¹⁵

But documents, emails, and replies obtained under the Freedom of Information Act reveal no formal investigation. What emerges is merely a scramble to discredit my claims during the 48 hours after I disclosed the information. They show the journal's editor, the paper's senior authors, and the Royal Free medical school, frantically mobilising against me. Were it not for the GMC case, which cost a rumoured £6m (£7m; \$9m), the fraud by which Wakefield concocted fear of MMR would forever have been denied and covered up.

The denial began as soon as I left the *Lancet* on that Wednesday in February 2004. Seated around a circular table in Horton's private office, the four doctors shared their thoughts and devised a strategy. Wakefield admitted only being retained for a lawsuit and denied receiving money himself. His legal role, he said, was to perform "quite separate" viral research, not



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the clinical study that appeared in the journal.

His claims were false. He was personally paid more than £435 000 through the lawyer, according to accounts I later obtained.¹⁶ And a corresponding "clinical and scientific study,"¹⁷ with the same protocol and principal authors as the paper, had been submitted to the UK Legal Aid Board for funding before the first of the 12 children was admitted. He had hired himself out explicitly to make a case against the vaccine, as a secret grant application revealed.

"The objective," he and his retaining solicitor had written in the application to the legal board, "is to seek evidence which will be acceptable in a court of law of the causative connection between either the mumps, measles and rubella vaccine or the measles/rubella vaccine and certain conditions which have been reported with considerable frequency by families of children who are seeking compensation."¹⁸

At their meeting with Horton, the paediatric gastroenterologists Walker-Smith and Murch also denied impropriety. I had claimed that some children were solicited, rather than

spontaneously referred. This was denied. I said there was no ethical approval. Denied. In short, there was nothing wrong, apart from Wakefield's conflict of interest. They agreed to issue statements through the journal to make things clear.

"It was a difficult but useful meeting today," Walker-Smith wrote that evening as he minuted their discussion, in one of a flurry of emails among the doctors. "I have been asked to write something about referral for our combined statement to the *Lancet*... Simon I believe you will answer in detail the charge of deception in relation to the Ethical Committee, the most serious charge of all and indeed for us all. Andy you will deal with the legal issues."

The next morning, Thursday, Wakefield responded with a draft of his contribution. It was addressed to Walker-Smith, Murch, and Horton—plus Wakefield's personal MMR campaign publicist, Abel Hadden of Bell Pottinger Communications in Mayfair. "Abel,"

this said in an addendum. "I have not got to your changes yet."

Meanwhile, elsewhere other events were unfolding that would shortly shine light on Horton's mindset. The day before our meeting, I had visited Evan Harris, at the time member of parliament for Oxford West and Abingdon. He was a doctor and member of the British Medical Association's ethics committee, and had an interest in the MMR controversy. He then turned up to observe my presentation to the *Lancet*, and afterwards requested copies of my documents.

At 13.16 Thursday, I emailed my agreement, and Harris bounced this forward to the journal. "Please see below for authorisation to send me Brian's papers on the research ethics," he wrote to Horton, 13 minutes later, planning to rely on the same material as the editor. "He wants me to give him an opinion and I explained I needed the papers. Hope they can be faxed forthwith under authority of one of your colleagues as you are out."

Horton, at the time, was at the Royal Free with Walker-Smith, Murch, and Humphrey

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- ▶ Rapid response: John Took's comment on the MMR series (*BMJ* 2011;342:c7452)
- ▶ Podcast: Brian Deer discusses his investigation (podcasts.bmj.com)
- ▶ *Student BMJ*: The Wakefield saga retold in a comic strip (student.bmj.com)

Hodgson, the vice-dean. In Hodgson's base-ment office they "reviewed the allegations," Horton told the GMC panel, and "decided on a course of action." Then "we all went up to the department of paediatric gastroenterology," where the doctors "investigated" the children's records. He explained that Walker-Smith went to look at a biopsy book "to establish questions about referral patterns." Then "a view was formed about the evidence in support of, or not, the allegations."

In short, the accused were investigating themselves—an investigation that Horton would say "cleared Wakefield."¹⁵

"I think you said Professor Walker-Smith looked back at the biopsy book," Sally Smith asked him.

"He looked back at the biopsy book, as I recall," replied Horton, editor of the journal since 1995. "Dr Murch and Professor Walker-Smith together looked at the case notes. I will be honest and say I cannot remember whether Dr Wakefield did or did not look at the case notes himself."

In fact, Wakefield was not invited on to the Royal Free's campus, having been constructively dismissed from the school

two years previously. But only he knew all the names of the paper's 12 anonymised children, and from home he faxed a list for the others to use.

That Thursday afternoon, Horton returned to his office, where he then dealt with the MP's request. Photocopying my email to Harris and Harris's to him, at 16.27 he faxed them to the medical school, with a handwritten pledge to the vice-dean. "Humphrey," this said, referring to the documents I had agreed to be shared, "this sequence of emails demonstrates the apparent collusion between Harris and Deer. Needless to say, I have not, and will not, pass on these documents to him."

No doctor interviewed

The Harris correspondence was not read to the panel, but members received Horton's evidence with interest. "Is it customary," asked Parimala Moodley, a member of the council of the Royal

College of Psychiatrists, "for an investigation of possible serious research misconduct to be carried out by the people who have been so accused of the misconduct?"

Horton paused to gather his thoughts. "It is customary for the institution to lead an investigation and to gather the data which will inevitably involve those who took part in the investigation," he replied. "It is then the responsibility of the institution to make sure that there is some kind of separation between its interpretation of those findings and those who are involved in the investigation who are being in some sense accused of a set of allegations, and once that interpretation by the institution has taken place and has been conveyed to whoever has brought the allegations to them then we can go forward. So there certainly

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should be some separation, which is why in the first instance I wanted to get the reaction from Dr Wakefield, Professor Walker-Smith, and Dr Murch, but after that my duty was to go to the head of the institution, the vice-dean, in this case Professor Hodgson."

But there had been no separation and no independent inquiry—as both the hospital and medical school later confirmed.

No doctor was interviewed, and no documents were generated. There was only the "informal process" just described. This, I was told, involved "discussion with clinicians," their "review of the relevant clinical papers," and study of an ethics committee file. "The written outcome of this process was the statements made by clinicians concerned and the Medical School published in the *Lancet*."¹⁹

The shallowness of this process was exposed at the GMC hearing, where the panel read the children's hospital records. The pages were thick with evidence of orchestrated referrals and indications that the prime purpose was research. One child's notes contained a legal aid letter, and the ethics committee file was a scorcher.

Even the patients' referral circumstances might have alerted a dispassionate investigator to the need to dig deeper into the cases. The panel would notice that child 2 and child

9 in the paper were solicited by Walker-Smith, at Wakefield's behest. Children 1, 5, 9, and 10, meanwhile, were referred to the Royal Free gastroenterologists without mention of any history of bowel problems. And child 4 and child 8 were referred directly to Wakefield, whose contract forbade clinical work.

"Thank you for asking to see this young boy," child 3's referral letter began.

"This 7¾ year autistic child's parents have been in contact with Dr Wakefield and have asked me to refer him," said child 5's.

"[Child 8's] mother has been to see me and said you need a referral letter from me in order to accept [child 8] into your investigation programme."

Meanwhile, ethics documents, reviewed by Hodgson, did not square with what was published in the journal. The hospital's file referred to a study of 25 children with disintegrative disorder, an exceptionally rare and serious degenerative brain condition.²⁰ This affects school age children, and Walker-Smith had told the ethics committee that the prognosis for such patients was "hopeless."²¹

But none of the 12 children was diagnosed with this disorder: they were a heterogeneous group, mostly reported with autism. And one patient—child 7—was referred to the hospital with no developmental diagnosis.

The ethics file, which I was shown, also included correspondence generated after the *Lancet* publication. David Hull, a former president of the British Paediatric Association, had noted the extraordinary battery of tests endured by the children. This included ileocolonoscopy, magnetic resonance imaging brain scans, electroencephalography and evoked potentials, lumbar punctures, and barium meal and follow throughs. The paper said that these "investigations were approved" by the ethics committee, which he thought might clash with codes requiring tests on children to be clinically indicated.²²

In order to respond to Hull, the committee chair, Michael Pegg, had been consulted. He advised that the paper was wrong. "In his letter Professor Hull states: 'I see that the investigations were approved by the Ethical Practices Committee,'" wrote Pegg in a memo on the file studied by Hodgson. "This is, of course, incorrect. We did not approve the investigations. We approved data collection from clinically indicated investigations. It is not, at present, the role of an ethics committee to question clinicians' judgment as



The Royal Free Hospital, north London



Andrew Wakefield and his wife Carmel



Evan Harris (left) and Brian Deer outside the GMC



The General Medical Council, London

to what are and what are not clinically indicated investigations.”

Nevertheless, to deal with me, the doctors—now five—pressed on with preparing their statements. Wakefield, Walker-Smith, and Murch would cover their allocated topics, while Hodgson would respond solely on the ethics. Horton would collate and form judgments on the material and publish their explanations through his journal. They would be issued to the media on that Friday afternoon.

They were to deny what the GMC would later prove.

“Before I go on to the statements by the doctors, which were published in the *Lancet*, and by the Royal Free,” Sally Smith said to Horton at the hearing, “can I ask you, have there been other occasions when you have had to investigate allegations made about a research paper and its propriety, in general terms?”

“Frequently.”

“Is it customary to discuss and take the word of those against whom the allegations are made?”

“It is.”

Back in February 2004, the email traffic documented how that custom panned out. At 10.27 on the Friday morning, Wakefield issued “an updated version of my response.” He circulated this to his publicist Hadden, plus Walker-Smith, Murch, Hodgson, and Richard Horton. “Richard, you have an earlier version,” he commented in the text. “This cuts out repetition to the last allegation and puts the argument more succinctly.”

At 12.24, Horton faxed Hodgson six pages of “draft statement docs.” And at 14.12 he sent the vice-dean another fax, with 13 pages of statements. All would be read aloud to the GMC panel, with many key paragraphs repeated.

“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, were brought to the attention of senior editorial staff,” Horton’s said. “The . . . allegations of alleged research misconduct have been answered by clarifications provided by the senior authors of this work . . . 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.”

Hodgson’s said: “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.”

Media firestorm

Listening to these statements, years after they were issued, brought back my memories of those days. I had approached the *Lancet* on the instructions of John Witherow, editor of the *Sunday Times*. He had told his executives that I should speak to “god” on the subject matter, to be sure we were getting it right. My first attempt was with Richard Smith, the former *BMJ* editor. But he was on holiday. So I telephoned Horton.

I had discussed my findings at the Wednesday meeting in confidence. I expected guidance and at least a quote. I thought Horton would say that an investigation was required, and I assumed this might take some time. My inquiries at that stage had consumed four months of research, accumulated key documents in five lever arch files, and had taken from 9 am to 2 pm to present.

But Horton would say nothing. He left the room

to meet the authors and released the statements without speaking to me again. He released them, moreover, first to everyone but me. Even the vice-dean formed a view of why this was.

“The *Lancet* editor’s actions have been to regard the allegations . . . as allegations of research misconduct, and following the medical editorial code has carried out an investigation according to agreed guidelines, and intends to publish the result of the investigation pre-emptively,” Hodgson told his UCL superiors in a memo that Friday. “No doubt one—but I believe only one—motive is to safeguard the *Lancet*’s reputation by getting the riposte in first, and ‘spoiling’ the story.”

But if this was Horton’s aim, it proved a mistake. His actions sparked a media firestorm. Although denying all of the most serious of my findings (now proved), he conceded that Wakefield had a conflict of interest—and that weekend was what journalists call “slow.”

The BBC was on the story within half an hour of the statements’ release. Independent Television

News called Harris. And all of Fleet Street knew the thrust of an impending splash in the *Sunday Times*, the UK’s market leading Sunday broadsheet.

The furore blazed from Friday until Wednesday. The triple vaccine was on the agenda once again. This time, however, it was not Wakefield’s campaign, which for years had exploited parents’ fears. “Misconduct inquiry for doctor in MMR scare,” shouted the *Independent on Sunday*’s front page. “GMC to investigate ‘conflict of interest.’”

My paper’s contribution was a front page and inside spread,



“Revealed: MMR research scandal.”²³ And, with the *Daily Mail* backing Wakefield, public uproar raged as the implications of that scandal were debated. The secretary of state for health and the chief medical officer issued statements. Tony Blair, the prime minister, told breakfast television: “I hope— now that people see that the situation is somewhat different from what they were led to believe— they will have the triple jab because it is important to do it.”²⁴

Wakefield attempted to brazen it out, issuing a further statement to media. “It has been proposed that my role in this matter should be investigated by the General Medical Council,” he said on the Monday. “I not only welcome this, I insist on it, and I will be making contact with the GMC personally in the forthcoming week.”

The same day, a caseworker for the regulator called me from Manchester. Did I have any further information? And two days later, at 12.16 Wednesday, I emailed him the conclusions of my research. I summarised what I had said to the *Lancet*’s senior staff and pledged my cooperation, in the public interest.

Over the following weeks and months, email traffic trickled on, especially at the Royal Free’s campus. The former dean, Arie Zuckerman, who had known about the lawyer, said he was being advised by the Medical Defence Union. Walker-Smith, whom the GMC was to clear of dishonesty, said he had learnt of Wakefield’s “financial details” from me. A press officer who in 1997 had proposed a press conference for the paper, issued statements for the hospital and school, brushing me off.

“I suppose we could say if you have any concerns about Brian Deer’s conduct you could consult the Press Complaints Commission,” she suggested to managers fielding grievances from Wakefield supporters about my access to the ethics committee file.

There was also a stream of internal documents, aimed at dealing with me, not the doctors. “Briefing note re Brian Deer’s e-mail 12th March 2004—limited to issues of substance,” one report was headed. “Line 8... Line 16-19... Line 20... Line 22... Line 28... Line 30-35... Lines 30-36... With respect to the specific questions that Brian Deer now asks, the issues are (a)... (b)... (c)... (d)... (e)...”

But there was no change of stance over the substance of the scandal, either at the institution or at the journal. Although it would be another eight months before the GMC approached the accused, three years before

a formal “notice of inquiry” was issued, and newspapers dismissed the prospect of any charges,^{25 26} the key players remained frozen in the positions they had agreed in February 2004.

In the end, the mammoth hearing got to the bottom of the matters that I had raised six years before. In a 143 page raft of findings against the three authors, the panel, chaired by general practitioner Surendra Kumar, ruled the research to have been unethical and falsely reported in the paper, which was retracted by the *Lancet* four days later. Murch, who during the hearing repudiated his 2004 statement, was found to have shown “insight” and was not struck off. But Wakefield was found guilty on four counts of dishonesty, and Walker-Smith was found to have ordered invasive procedures on children without clinical grounds or ethical approval.

In his later statement to *Press Gazette*, Horton (who did not respond to our request for comment) said he welcomed the outcome. “We are very happy with the result,” he said. “Despite much past debate, this is the first time an official, independent investigation by a recognised regulatory body has proven these allegations. They are welcome because they gave us full authority to retract Dr Wakefield’s paper.”¹⁵

But this was not the editor’s mood before the hearing began. Electronic chatter, once again, tells the tale. “The role of Brian Deer mystifies me,” he sent from his Blackberry to the mother of two children in the paper, two and a half years before he took the witness chair. “My own view is that the GMC is no place to continue this debate. But the process has started and it will be impossible to stop.”

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