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Feature

Secrets of the MMR scare

How the vaccine crisis was meant to make money

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*In the second part of a special BMJ series, **Brian Deer** reveals a secret scheme to raise huge sums from a campaign, launched at a London medical school, that claimed links between MMR, autism, and bowel disease*

John Walker-Smith, professor of paediatric gastroenterology, hurried to Malcolm ward on the sixth floor of the Royal Free Hospital, London, with what any doctor would think was bad news. An 8 year old boy, admitted for five days of investigations, had been provisionally diagnosed with Crohn's disease. But when the child's mother—here anonymised as "Mrs 2"—years afterwards recounted what happened, she seemed pleased to have received information she expected and made it sound as if Walker Smith was glad too.

"He skipped into that room like a 2 year old," she told me. She remembered he said: "[Mrs 2], you were right."

Brightly painted with murals, Malcolm ward was Walker-Smith's. It came with his employment contract. Exactly one year previously, in September 1995, he had been lured to the Royal Free with many perks, of which this was one. Previously the hospital had no children's bowel service, but with him it had a chance of the best.

The initiative to recruit him, however, had not come from management. It came from an academic researcher in the gastroenterology department: a former trainee surgeon, Andrew Wakefield.¹ He wanted Walker-Smith, who would bring access to children's gastrointestinal tracts, to help him prove a personal theory. This was that Crohn's disease was caused by persisting measles virus infections²—most notably, he came to suggest, from vaccines.³

"You used to hear Wakefield's people talking about how they would win the Nobel Prize for this," remembers Brent Taylor, the Royal Free's head of community child health, who frequently clashed with the pair. "The atmosphere here was extraordinary."

But instead of honours, the two men reaped disgrace. In January and May 2010, the UK's General Medical Council found them guilty of a raft of charges over a project involving child 2.⁴ Wakefield, now 54, was judged by a five member panel to be guilty of some 30 charges, including four counts of dishonesty and 12 of causing children to be subjected to invasive procedures that were clinically unjustified; Walker-Smith, 74, was deemed irresponsible and unethical.⁴ Both were struck off the medical register^{5 6} and have since filed High Court appeals.



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Working on a lawsuit

Their misconduct arose out of a fishing expedition, in which Malcolm ward was the pond for the measles theory. Since February 1996, seven months before child 2's admission, Wakefield had been engaged by a lawyer named Richard Barr, who hoped to bring a lawsuit against vaccine manufacturers.^{7 8} Barr was a high street solicitor, and an expert in home conveyancing,⁹ but also acted for an anti-vaccine group, JABS. And, through this connection, the man nowadays popularly dubbed the "MMR doctor" had found a supply of research patients for Walker-Smith.

"The following are signs to look for," Barr wrote in a newsletter to his vaccine claim clients, mostly media enlisted parents of children with brain disorders, giving a list of common Crohn's disease symptoms. "If your child has suffered from all or any of these symptoms could you please contact us, and it may be appropriate to put you in touch with Dr Wakefield."

The first to be admitted—in July 1996—was a 3 year old boy with autism. But, according to his records, reviewed by the GMC panel, he was so constipated that, despite two attempts, the endoscopist could not reach his small intestine. So child 2, who had diarrhoea (found to be constipation overflow) was the first to have his ileum intubated.

Child 2 also had autism, the first signs of which came on "a few months" after MMR vaccination.¹⁰ His mother was referred to Wakefield by the JABS organiser,¹¹ and the boy would not only be the lead test case in Barr's eventual, failed, lawsuit but would feature with 11 other children in a now notorious, retracted, *Lancet* paper linking the vaccine with bowel and brain problems.¹²

He was admitted on Sunday 1 September 1996 and endured a gruelling battery of investigations.¹³ These included magnetic resonance imaging of his brain, electroencephalography and evoked potentials, radioactive Schilling test, blood and urine tests, and lumbar puncture—all specified in an agreement with Barr.¹⁴

A viral diagnostic

The following day, Monday, child 2 had an ileocolonoscopy, which, in common with seven other children reported in the paper, the GMC panel would find was not clinically warranted. Tuesday was Wakefield's 40th birthday. And on Wednesday, with the news that the boy—still on the ward—might have Crohn's disease, the doctor produced a remarkable document. It was an 11 page draft of a scheme behind the vaccine scare, now revealed for the first time in full.

The document was headed "Inventor/school/investor meeting 1."¹⁵ Based on a patent Wakefield had filed in March 1995 claiming that "Crohn's disease or ulcerative colitis may be diagnosed by detecting measles virus in bowel tissue, bowel products or body fluids,"¹⁶ it proposed starting a company that could reap huge returns from molecular viral diagnostic tests. It predicted a turnover from Britain and America of up to £72.5m a year.

"In view of the unique services offered by the Company and its technology, particularly for the molecular diagnostic," the document noted, "the assays can command premium prices."

To help finance the scheme, Wakefield looked to the government's legal aid fund—meant to give poorer people access to justice. For the previous seven months, child 2 had been enrolled with Barr's firm,¹⁷ which since February 1996—two years before the paper's publication—had been paying the researcher undisclosed fees of £150 an hour, plus expenses.⁸

"The ability of the Company to commercialise its candidate products," the draft plan continued, "depends upon the extent to which reimbursement for the cost of such products will be available from government health administration authorities, private health providers and, in the context of the molecular diagnostic, the Legal Aid Board."

As it turned out later, child 2 did not have Crohn's disease, but three weeks after drafting the plan, Wakefield met three others to discuss it. One was his mentor, Roy Pounder, the Royal Free's professor of gastroenterology and later vice president of the Royal College of Physicians. The others were Bryan Blatch, the medical school's secretary, and Cengiz Tarhan, its finance officer.

Money from the lawyer

Discussions about the business continued over the following years, but Wakefield's involvement with Barr was quickly noted. In October 1996, the medical school's dean, Arie Zuckerman, a virologist, was told that the lawyer had offered to pay the school for a "clinical and scientific study,"^{18 19} and had sent a first instalment of £25 000.^{20 21} This was held in suspense while Zuckerman sought confidential ethical advice from the British Medical Association, although Wakefield had already started spending it.

"Arising from recent widespread publicity given to this research," Zuckerman (who told me he does not want to discuss these matters) wrote of Wakefield's already televised claims about Crohn's disease, "the Legal Aid Board has provided funding through a firm of solicitors representing Crohn's disease sufferers and we have been asked to make an appointment to the staff of the Medical School, specifically to undertake a pilot study of selected patients."²⁰

The BMA answered fully the following March, after its ethics committee had considered the issue. It said that money could be accepted provided there was proper research oversight and transparency over funding and patient sources.

But the dean remained concerned and so made an arrangement with the hospital's chief executive, Martin Else, who managed a charity called the Special Trustees. Else, now chief executive of the Royal College of Physicians (who told me that he was "not aware of any significant issue being raised"), agreed that the charity could take Barr's payment and hold it as a grant for Wakefield.²² So the legal money (which eventually totalled £50 000 and seed funded the business scheme) was moved from the medical school into a numbered hospital charity account and then paid out for Wakefield's research on the MMR vaccine—back in the medical school.²³

"Further to our conversation regarding the establishment of a fund with the Special Trustees for your income and expenditure associated with the MMR research," Else wrote to Wakefield, "I can confirm that a grant will be established for the purpose, given your written confirmation that there is no conflict of interest involved."²⁴

Wakefield obliged, but the arrangement raised issues about the two institutions' involvement in the vaccine crisis.²⁵ For when the *Lancet* paper was published, in February 1998, and the scare was launched at a televised press conference, nobody was aware that Wakefield was receiving substantial personal payments from Barr.¹ But both the medical school's dean and the hospital's chief executive knew that his research was part funded through a lawyer.²⁶

The paper itself, meanwhile, included a funding statement, which Else later told me he did not notice. "This study was supported by the Special Trustees," it said, with no mention of legal aid or Barr.

The lawyer, however, was forthright when later asked. He said he paid for the *Lancet* research. "I remember noting at the time that the funding acknowledgment wasn't there," he told me. "But it didn't seem to be a big deal, because it just wasn't a big deal in those days."²⁷

Behind the press conference

Neither school nor hospital stood on the sidelines. They threw their weight behind Wakefield. In the build-up to the press conference, they installed extra phone lines and answering machines to field the expected panic, and distributed to broadcasters a 23 minute video news release showcasing Wakefield's claims. "There is sufficient anxiety in my own mind for the long term safety of the polyvalent vaccine—that is, the MMR vaccination in combination—that I think it should be suspended in favour of the single vaccines," he said, in one of four similar formulations on the videotape.²⁸



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Single vaccine patent filed by Wakefield

The press conference and video boosted the commercial plans, which were moving forward behind the scenes. The following week, Wakefield brought two associates to the school for an already scheduled meeting with the finance officer Tarhan. One was the father of child 10 in the paper. The other was a venture capitalist. And two days after the meeting, they submitted a 13 page proposal to launch a joint business with the school. It would be focused on a new company, Immunospecifics Biotechnologies Ltd, aiming not only to produce a diagnostic test, as proposed 18 months earlier, but also "immunotherapeutics and vaccines."²⁹

Given the previous week's publicity drive, the vaccine plans were sensitive. But the school had long known of this ambition. First surfacing in Wakefield's 1995 patent for a diagnostic test for Crohn's disease, it had been fleshed out in 1997, eight months before the press conference, in a patent for a "safer" single measles shot.³⁰

The revised business plan was ambitious and detailed, aiming to raise £2.1m from investors. It spanned the detection of Crohn's disease, the treatment of autism, and "a replacement for attenuated viral vaccines."

The methods for the molecular test for Crohn's disease were newish. But those for the treatment and vaccines were dated. They relied on transfer factor, a largely abandoned fringe technology to move immune cells from person to person.³¹

Nevertheless, the school remained interested, and a two year courtship ensued. Even as the vaccine scare escalated, triggering a deluge of referrals to Walker-Smith, staff at Freemedic, the commercial arm of what was now the merged Royal Free and University College Medical School, poured over contracts and plans.

Trading was to be fronted by Carmel Healthcare Ltd—named after Wakefield's wife. Firmly rooted in Barr's lawsuit, which eventually paid Wakefield £435 643, plus expenses,³² the business was to be launched off the back of the vaccine scare, diagnosing a purported—and still unsubstantiated³³—"new syndrome." This, Wakefield claimed, comprised both brain and bowel diseases, which, after Crohn's disease was not found in any of the *Lancet* children, he dubbed "autistic enterocolitis."³⁴

"It is estimated that the initial market for the diagnostic will be litigation driven testing of patients with AE [autistic enterocolitis] from both the UK and the USA," said a 35 page "private and confidential" prospectus, which was passed to me by a recipient. It aimed at raising an initial £700 000 from investors and forecast extraordinary revenues. "It is estimated that by year 3, income from this testing could be about £3 300 000 rising to about £28 000 000 as diagnostic testing in support of therapeutic regimes come on stream."³⁵

Carmel was registered in the Irish Republic, where Wakefield would also become a director of another business. This was Unigenetics Ltd, incorporated in February 1999 with a Dublin pathologist, John O'Leary. After Wakefield submitted a confidential report to the Legal Aid Board,³⁶ Unigenetics was awarded—without checks—£800 000 of taxpayers' money²⁸ to perform polymerase chain reaction tests on bowel tissue and blood samples from children passing through Malcolm ward.

The key players in Carmel were the same as in the first company, Immunospecifics, with their planned equity now set out. Wakefield would get 37%, and the father of child 10 22.2%. The venture capitalist would get 18%, Pounder 11.7%, and O'Leary 11.1%.

Some would also be awarded extra money in advance, in proposed "executive and non-executive staff costs." Wakefield was set to get £40 000 a year,³⁷ in addition to his legal earnings and medical school salary, with an annual travel budget of £50 000 for the business.

Here was another striking conflict of interest, but Wakefield had long made clear his expectations. "The Company will endeavour to ensure that the principal members of its management and scientific team are suitably incentivised by the allocation of Equity and stock options," he had written in September 1996, when child 2 was still on the ward.

Carmel was to be based at the Coombe Women's Hospital, Dublin, where legal aid money paid for a laboratory. A prospectus described a public relations effort aimed at two "target" audiences: "parent groups and lawyers representing affected individuals" and "major pharmaceutical companies."

"Once the work of Professor O'Leary and Dr Wakefield is published, either late in 1999 or early in 2000, which will provide unequivocal evidence for the presence of the vaccine derived measles virus in biopsy samples," the prospectus said, "the public and political pressure for a thorough, wide ranging investigation into the aetiology of the bowel conditions will be overwhelming.

"As a consequence of the public, political and legal pressures brought to bear, the demand for a diagnostic able to discriminate between wild type and vaccine derived measles strains will be enormous."

Keeping it secret

To facilitate negotiations, letters and draft contracts went back and forth to the Royal Free. A principal document was finished in the autumn of 1999, naming Wakefield, Pounder, Carmel, Immunospecifics Biotechnologies (IB Ltd), the medical school, Freemedic, an American foundation called Neuro Immuno Therapeutics, and its head, Hugh Fudenberg, an immunologist.³⁸

"Royal Free and Immuno entered into the Letter Agreement (as defined in this Agreement)," began a typically meaty clause. "Under its terms Royal Free was to assign to Immuno the intellectual property rights subsisting in the Inventions. In consideration of this assignment Immuno was to pay £10 000 to Royal Free, and was to grant Freemedic an option, over shares representing 10% of Immuno's issued share capital."³⁹

All of this went forward between the parties in secret. Another document aimed to gag the school. "RFUCMS and Freemedic agree to maintain all information about IB Ltd, its business plan, fund raising proposals etc provided by IB Ltd . . . as confidential and will not disclose the same to any third party and will restrict access thereto to the Directors and senior personnel."

This latter document was never signed, and strictly therefore of no effect. But University College London (UCL) honoured its spirit, ensuring that the scheme went unreported. And when I was tipped off about Wakefield's business arrangements, the college fought me for three years under the freedom of information act to keep its involvement hidden.

"UCL is coming to the conclusion," the college told the hospital in a February 2005 email, "that many of our docs on file fall into the exemption under section 36 of the Act whereby to disclose information 'would or would be likely to prejudice the free and frank provision of advice; the free and frank exchange of views for the purposes of deliberation or the effective conduct of public affairs.'"

Refusals were authorised by UCL's provost, Malcolm Grant, a professor of environmental law. Only when Richard Thomas, at the time the UK's information commissioner, travelled to the college's offices and later served a formal notice, did they release the documents into my hands.

Among the more striking were those through which the school could deny any involvement in the scheme. "That is to say if Freemedic choose not to be associated with the company in the first instance they may not wish to exercise their options until they are ready to be associated at some time in the future," Tarhan wrote to child 10's father in July 1999, as they divided the notional spoils. "We have discussed the reasons for this before."⁴⁰

Another letter—to Wakefield—in November 1999 said: "Therefore neither Freemedic nor the School are in any way involved with Carmel until such options are formally exercised and shares are taken up."³⁷

Why investors might have paused

But for all the preparations, ready for presentation to investors, one critical issue for the apparent inventions was not broached—that the company's ambitious products might not work.

Investment analysts told me that the late 1990s was a prime time to raise cash from optimists. "Money flowing into the City post-deregulation had driven the start-up of a load of inexperienced investment schemes in biotech," one pointed out. "Very few venture capitalists have the technical knowledge."

Investors might have been encouraged by the mounting vaccine scare and by the *Lancet's* backing for Wakefield.⁴¹ But there were curious fundamentals in the secret scheme which the best informed investors might have noticed.

Firstly, transfer factor, for the proposed treatments and vaccines, had long been abandoned by industry. Proposed in the 1940s as a bespoke blood product remedy, it was all but killed by impractical cost, risk of infection, and lack of evidence or standards. Later reformulated as a treated milk pill, as in proposals such as Wakefield's—which relied on the colostrum of pregnant goats—experts suggest that it is therapeutically inert.⁴² Today, it is promoted on the internet as a cure all.

Secondly, there was Hugh Fudenberg, the American immunologist with his Neuro Immuno Therapeutics foundation. He was under sanction at the time from his local medical board over his prescription and use of controlled drugs.⁴³ When I interviewed him in August 2004 for a Channel 4 documentary,²⁸ he claimed to cure autism with transfer factor, which he said he rolled out like pizza "three molecules deep" on his North Carolina kitchen table.

"And where does that come from?" I asked.

"From my bone marrow."

"From your own personal bone marrow?"

"Yeah."

Another hidden flaw, which would emerge only later, was the Dublin measles tests—over which vaccine lawsuits in Britain and America would founder.⁴⁴ These tests were promoted as detecting persistent virus from past MMR vaccinations. But blood from Walker-Smith's patients, analysed by O'Leary, failed to give consistent results.

For instance, child 2 had all the elements for Wakefield's theory: regressive autism, bowel problems (actually diagnosed as a food intolerance⁴⁵), and a mother who blamed MMR. He was vaccinated at 15 months of age in November 1989. A blood test for the virus 11 years later was negative. Then, two years after that, another result from the boy was positive. Then, two months after that, one was negative.

Preparing for the launch

In advance of such results, Wakefield relied on what he called a series of "impending" papers. "A variety of topics were discussed in the meeting with reference to the forthcoming publication of the paper in *Nature* (date to be confirmed)," said a confidential Carmel "communications programme," for example, passed to me by someone present.⁴⁶

The launch was scheduled for March 2000, with an attention grabbing stunt three months earlier. No *Nature* paper appeared, and Wakefield's platform was to be a London meeting of the Pathological Society of Great Britain and Ireland.⁴⁷ There, with O'Leary and Pounder (who both declined to comment on my findings), he planned to present research claiming a breakthrough. Based on alleged gut biopsy samples from Walker-Smith's patients—10 with autism and three with Crohn's disease—tested at the Dublin laboratory, it claimed a "possible causal link" and, given a Wakefield presentation, promised a storm like the press conference two years before.



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Wakefield (centre) at the press conference to launch the *Lancet* research

Meanwhile, he nurtured relationships, with drug industry support, including front of the plane overseas travel. "Please find enclosed a cheque for £2876.70 from Axcan Pharma Inc, a refund of my airfare with regard to my Canadian trip,"⁴⁸ he told the special trustees, for example, as he put final touches to the scheme. He was also then negotiating a Johnson & Johnson consultancy⁴⁹ and had longstanding connections with Merck and SmithKline Beecham.

The scheme unravels

But as the Carmel plans were finalised, Wakefield's fortunes reversed. On the brink of his business launch, it foundered.

The unravelling began after the arrival in the school of a new head of medicine: Mark Pepys. A fellow of the Royal Society and a specialist in amyloid diseases, he brought huge grants and was now the school's biggest name. He was astounded to find Wakefield being feted. "I said I wouldn't transfer my unit if he was there," Pepys told me. "And you know what they did? They promoted him."

With Chris Llewellyn-Smith, a theoretical physicist and at that time UCL's provost, Pepys struck in December 1999, barely two months after starting at the Royal Free. Wakefield was summoned from the hospital's Hampstead campus to the college's central London headquarters. He was challenged over the scheme, then on the verge of fruition, and was given a two page letter.

"We remain concerned about a possible serious conflict of interest between your academic employment by UCL, and your involvement with Carmel," it said, in part. "This concern arose originally because the company's business plan appears to depend on premature, scientifically unjustified publication of results, which do not conform to the rigorous academic and scientific standards that are generally expected."⁵⁰



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Wakefield and his wife Carmel, after whom the doctor named one of his health businesses

This marked the end of any commercial deals with Wakefield, and the beginning of his end at the Royal Free. When eventually ousted from his job, he said, "I have been asked to go because my research results are unpopular."⁵¹ And in response to my investigation, he would allege sinister conspiracies to stop him revealing what he claimed were vaccine secrets.^{52 53}

But the paperwork does not show this. Despite all that had happened, UCL volunteered to support his work. It offered him continuation on the staff, or a year's paid absence, to test his MMR theories. He was promised help for a study of 150 children (to try to replicate his *Lancet* claims from just 12) and, in return for withdrawing from the January London conference, he would be given the intellectual property free.

"Good scientific practice," the provost's letter stressed, "now demands that you and others seek to confirm or refute robustly, reliably, and above all reproducibly, the possible causal relationships between MMR vaccination and autism/autistic enterocolitis/inflammatory bowel disease that you have postulated."

At the time, Wakefield agreed. Then his employer waited. It prompted, waited longer, and prompted again. "Three months have elapsed," Llewellyn-Smith wrote to him in March 2000, asking for "a progress report on the study proposed" and "not to make any public statements" in the meantime.⁵⁴

But the study did not happen. The 1998 *Lancet* research had been a sham.¹⁰ Trying to replicate it with greater numbers would have been hopeless.

Wakefield, however, shrugged off his non-compliance as arising from some fault of the school's. "It is clear that academic freedom is essential, and cannot be traded," he eventually responded in September 2000. "It is the unanimous decision of my collaborators and co-workers that it is only appropriate that we define our research objectives, we enact the studies as appropriately reviewed and approved, and we decide as and when we deem the work suitable for submission for peer review."⁵⁵

This was a step too far, and in October 2001 Wakefield was shown the door. As I understand it, he got two years' money, a statement clearing him of misconduct, the intellectual property for £10, uncollected, and a gag on Royal Free comment. "We paid him to go away," Pepys told me. "And, of course, one of the conditions of him going away was that I wasn't supposed to say anything critical of him to anybody, for ever after."

Wakefield would never perform the research anywhere, or prove his measles theory. His vaccine plans—predictably—went nowhere. And when I put these matters to him, he and his lawyers acknowledged receipt but offered no further response.

Public fears over the vaccine had yet to reach their peak. My investigation would not begin for two years. But Wakefield would never again hold an academic post, and the secret scheme behind the scare was no more.

October 1988:

The three in one measles, mumps, and rubella vaccine is introduced to the UK after successful use in the US since 1971. Previously, single measles and rubella vaccines were used, and there was no licensed mumps vaccine



Virginia Bottomley, the then Conservative health secretary, in 1994 launching the multi-million pound MMR vaccination campaign with Professor Sir Kenneth Calman, chief medical officer for England at the time

September 1992:

The UK Departments of Health withdraw two brands of MMR vaccine after research shows them to be associated with a raised incidence of transient mumps meningitis, although much lower than with natural disease

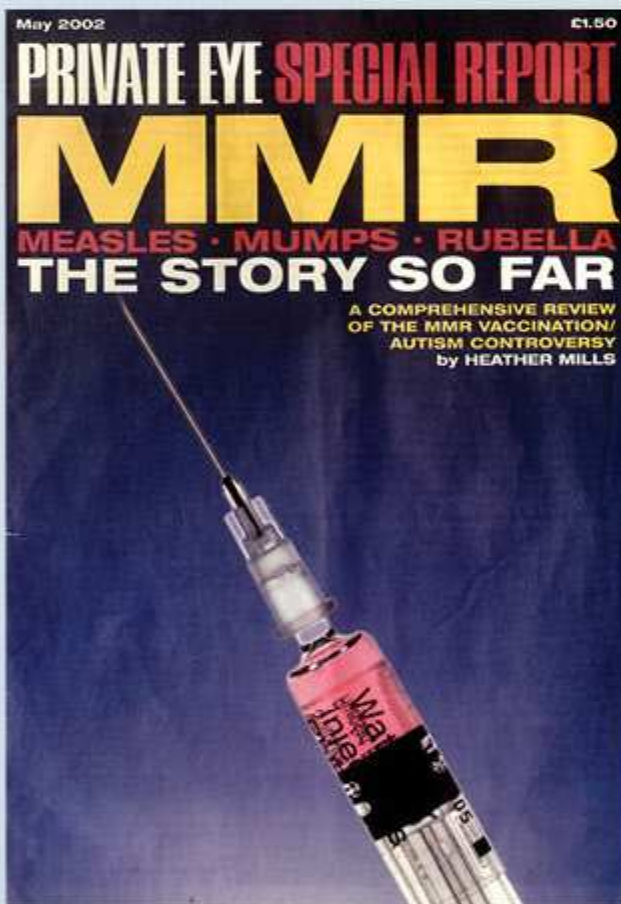
January 1994:

A campaign group, JABS, is launched in Wigan, Lancashire, alleging that MMR causes brain damage and other problems in children. Autism and inflammatory bowel disease are not initially claimed



May 2002:

Amid continuing media campaigns over MMR, particularly by the Mail and Telegraph groups, the magazine *Private Eye* issues a special edition, written in collaboration with families that are suing vaccine manufacturers

**January 2001:**

The *Daily Mail* and other news campaigns backing Wakefield JABS, after he publishes a pur of his evidence and repeats hi vaccines

October 2001:

Wakefield is asked to leave th failing to mount a large scale c confirm or refute his claims ab

December 2001:

Prime Minister Tony Blair is ambushed by Wakefield supporters, who claim that his youngest son, Leo, did not have MMR. The Blairs initially decline to comment but much later deny the claim



Brian Deer questions Wakefield as part of the Channel 4 *Dispatches* programme

January 2005:

Wakefield initiates libel lawsuits, funded by the Medical Protection Society, against the *Sunday Times*, Channel 4, and Brian Deer over Deer's website, claiming that all allegations are false and defamatory

March 2005:

Among much research rejecting any link with developmental disorders and bowel disease, research is published showing that, after MMR was discontinued in Japan, the incidence of autism diagnoses continued to rise

October 2005:

In the London High Court, Mr Justice Eady refuses an application from Wakefield to freeze his libel actions and orders him to proceed to trial of Deer's allegations against his "honesty and professional integrity"

Scho

A 13-YEAR-OLD boy has become the first per Britain for 14 years to measles in a sign th disease, once a commo is resurfacing.
The boy's death is th since the scare over th bined measles, mump

April 2006

As measles reported a first death the disease is reported old boy fro communit

December

The *Sunday* Wakefield funding fr support th MMR: £43 expenses aid fund. Free docto

January 20

Two days payments revealed, Protection funding fo

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Notes

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Footnotes

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Provenance and peer review: Commissioned; not externally peer reviewed.

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