

[Reprint - Secrets of the MMR scare]

Timeline

BMJ, the British Medical Journal

by

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<http://briandeer.com/solved/bmj-wakefield-timeline.htm>

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Introduction

In the wake of an investigation for The Sunday Times, Brian Deer was invited by BMJ, the British Medical Journal, to deepen the story of the MMR vaccine scare.

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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

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

March 1995: Andrew Wakefield, a researcher at the Royal Free medical school, files for a patent claiming that Crohn's disease and ulcerative colitis may be diagnosed by detecting measles virus in bowel tissue and body fluids

September 1995: Paediatric gastroenterologist John Walker-Smith moves with most of his team from Bart's hospital, London, to set up a service at the Royal Free

February 1996: JABS solicitor, Richard Barr, retains Wakefield, at £150 an hour, plus expenses, to support a speculative legal attack on MMR manufacturers. This contract is not publicly disclosed

July 1996: The first child is admitted to the Royal Free for research to try to show a link with MMR. The research is commissioned by, and supported with a £55,000 grant from, the UK Legal Aid Board, but this is not publicly disclosed

September 1996: Wakefield and his mentor Roy Pounder meet medical school managers to discuss market projections for a new business based on purportedly diagnosing Crohn's disease from the presence of measles virus

June 1997: Claiming that the measles virus in MMR causes problems, Wakefield files for a patent on a "safer" single measles vaccine and for products to treat both autism and inflammatory bowel disease. This, too, is not publicly disclosed

February 1998: The Lancet publishes a 12 patient case series by Wakefield and 12 others, proposing a link between MMR and a "new syndrome" of autism and bowel disease. At a press conference, he urges the use of single vaccines instead of MMR

February 1998: Just days after the press conference, Wakefield and business partners meet Royal Free medical school managers to discuss a joint company to develop products based on his MMR claims, including "a replacement for attenuated viral vaccines"

February 1999: Unigenetics is incorporated, with Wakefield and a Dublin pathologist, John O'Leary, as directors. The company is awarded £800,000 by the Legal Aid Board to perform tests on samples from children seen at Walker-Smith's Royal Free unit

December 1999: Mark Pepys, new head of medicine at the medical school, challenges Wakefield about his business scheme and puts him on notice that he must replicate his research

January 2001: The Daily Mail and other newspapers launch campaigns backing Wakefield, working with JABS, after he publishes a purported review of his evidence and repeats his calls for single vaccines

October 2001: Wakefield is asked to leave the Royal Free after failing to mount a large scale controlled study to confirm or refute his claims about MMR

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

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 2003: Vaccination among 2 year olds falls to 78.9%: below the 92% the Department of Health says is needed to maintain herd immunity. Figures in parts of inner London are half the national rates

September 2003: The Legal Services Commission stops funding for Barr's lawsuit after barristers for the claimants report to the commission that, on the evidence, they cannot make a case that MMR causes autism

February 2004: The Sunday Times reveals that the Legal Aid Board funded the Lancet research and that many of the children were litigants. Richard Horton, the journal's editor, rejects more serious charges against the authors, later proved by the GMC

March 2004: Ten of the 1998 paper's 13 authors, excluding Wakefield, retract its "interpretation" section, which claimed an association in time between MMR, enterocolitis, and regressive developmental disorders

November 2004: Channel 4's Dispatches reveals Wakefield's single vaccine patent and that, despite Wakefield's claims that the culprit for the disorders is measles in MMR, molecular tests in his laboratory found no trace of the virus

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"

April 2006: As measles outbreaks are reported across Britain, the first death in the UK from the disease in 14 years is reported—a 13 year old boy from the traveller community

December 2006: The Sunday Times reveals Wakefield's personal funding from Barr to support the lawsuit over MMR: £435,643 plus expenses, from the legal aid fund. Some other Royal Free doctors were also paid

January 2007: Two days after the payments from Barr are revealed, the Medical Protection Society stops funding for Wakefield's libel actions and through him agrees to pay the defendants' costs of about £800,000 on top of its own legal bills

July 2007: At a fitness to practise hearing in London, the General Medical Council opens its case alleging serious professional misconduct by the Lancet paper's three senior authors, Wakefield, Walker-Smith, and endoscopist Simon Murch

February 2009: The Sunday Times alleges that Wakefield "fixed" the appearance of a link between MMR and autism. He denies fraud and files a complaint with the UK Press Complaints Commission, which he later abandons

February 2009: In the United States, three test case judgments for 5000 claims based on Wakefield's theories are handed down in federal court, rejecting the allegation that MMR can cause autism. They are upheld on appeal in August 2010

January 2010: A panel comprising three doctors and two lay members gives findings of fact on the GMC's case, upholding dozens of charges against Wakefield, Walker-Smith, and Murch and sending all three forward for sentencing

February 2010: Six years after the matters were raised with the Lancet, the journal fully retracts the 1998 paper. Horton describes aspects of it as "utterly false" and says he "felt deceived"

May 2010: After a 217 day inquiry, the GMC panel orders Wakefield and Walker-Smith to be erased from the medical register, but notes that Murch had shown "insight" and finds him not guilty of serious professional misconduct

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Appendix

Exposed: Andrew Wakefield

and the MMR-autism fraud

Brian Deer's award-winning investigation

<http://briandeer.com/mmr/lancet-summary.htm>

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With revelations spread over more than seven years, between late 2003 and early 2011 Brian Deer pursued a landmark public interest investigation for The Sunday Times of London, the United Kingdom's Channel 4 Television network and BMJ, the British Medical Journal, into allegations linking the three-in-one measles, mumps and rubella vaccine (MMR) with claims of a terrifying new syndrome of bowel and brain damage in children. These allegations led to a decade-long health crisis in the UK, and sparked epidemics of fear, guilt and infectious disease, which would be exported to the United States and other developed countries, spawning every kind of concern over vaccinations.

Almost incredibly, the trigger for what became a worldwide controversy over vaccine safety was a single scientific research paper published in a medical journal - the Lancet - in February 1998. Written by a then-41-year-old academic researcher, Andrew Wakefield, and co-authored by a dozen associates, it reported on the cases of 12 anonymous children with brain disorders who had been admitted to a paediatric bowel unit at the Royal Free hospital in Hampstead, north London, between July 1996 and February 1997.

Backed by an extraordinary video news-release and press conference, the five-page paper's claims provoked substantial media interest, and were followed by a sustained onslaught against the vaccine. This included further publications by Wakefield criticising MMR, and led to an unprecedented collapse in public confidence in the shot, which, since the late 1980s in the UK and the early 1970s in the US, for examples, has been routinely given to children soon after they are one year old, almost eradicating measles and rubella from developed countries.

The prime cause of the alarm was findings in the paper claiming that the parents of two thirds of the 12 children blamed MMR for the sudden onset of what was described as a combination of both an inflammatory bowel disease and what Wakefield called "regressive autism", in which language and basic skills were said to have been lost. Most disturbingly, the first behavioural symptoms were reported to have appeared within only 14 days of the shot.

Although the research involved only a dozen children, and its results have never been replicated, many medical breakthroughs have begun with small-scale observations, and, if true, Wakefield's findings might have been the first snapshot of a hidden epidemic of devastating injuries. "It's a moral issue for me," he announced at the 1998 press conference, where he called for a boycott of the triple MMR in favour of breaking it up into single measles, mumps and rubella shots, to be given at yearly intervals. "I can't support the continued use of these three vaccines, given in combination," he said, "until this issue has been resolved."

As the doctor campaigned, UK vaccination rates slumped: below the level needed to keep measles at bay. Even Tony Blair became embroiled in the controversy when Wakefield supporters suggested - the Blairs say wrongly - that the prime minister's youngest son was not vaccinated with MMR. Meanwhile in America, a ferocious anti-vaccine movement took off after Wakefield toured US autism conferences and, in November 2000, appeared on the CBS network's 60 Minutes programme linking MMR with what he called an "epidemic of autism". This was followed by campaigners' claims that all vaccines are suspect: either due to their content, or because of the number given to children.

"In 1983 the shot schedule was ten. That's when autism was one in 10,000. Now there's 36, and autism is one in 150," argued American actress Jenny McCarthy, who blamed MMR for her own son's autism, and gained the highest profile in the US movement. "All arrows point to one direction."

Andrew Wakefield's role unmasked

But as journalists queued to report on parents' fears, Brian Deer was assigned to investigate the crisis, and unearthed a scandal of astounding proportions. He discovered that, far from being based on any findings, the public alarm had no scientific basis whatsoever. Rather, Wakefield had been secretly payrolled to create evidence against the shot and, while planning extraordinary business schemes meant to profit from the scare, he had concealed, misreported and changed information about the children to rig the results published in the journal.

Before Deer's inquiries, Wakefield had appeared to all the world to be an independent, if controversial, researcher. Tall and square-headed, with hooded eyes and a booming voice, he was the son of doctors (a neurologist and a family practitioner), had grown up in Bath, a prosperous west-of-England spa town, and joined the Royal Free in November 1988 after training in Toronto, Canada. His demeanour was languid - he was privately educated - and, born in 1956, he was a lingering example of the presumed honour of the upper middle class.

But Deer's investigation - nominated in February 2011 for two British Press Awards - discovered that, while Wakefield held himself out to be a dispassionate scientist, two years before the Lancet paper was published - and before any of the 12 children were even referred to the hospital - he had been hired to attack MMR by a lawyer, Richard Barr: a jobbing solicitor in the small eastern English town of King's Lynn, who hoped to raise a speculative class action lawsuit against drug companies which manufactured the triple shot.

Unlike expert witnesses, who give professional advice and opinions, Wakefield had negotiated an unprecedented contract with Barr, then aged 48, to conduct clinical and scientific research. The goal was to find evidence of what the two men claimed to be a "new syndrome", intended to be the centrepiece of (later failed) litigation on behalf of an eventual 1,600 British families, recruited through media stories. This publicly undisclosed role for Wakefield created the grossest conflict of interest, and the exposure of it by Deer, in February 2004, led to public uproar in Britain, the retraction of the Lancet report's conclusions section, and, from July 2007 to May 2010, the longest-ever professional misconduct hearing by the UK's General Medical Council (GMC).

Barr [audio] paid the doctor with money from the UK legal aid fund: run by the government to give poorer people access to justice. Wakefield charged at the extraordinary rate of £150 an hour - billed through a company of his wife's - eventually totalling, for generic work alone, what the UK Legal Services Commission, pressed by Deer under the freedom of information act, said was £435,643 (then about \$750,000 US), plus expenses. These hourly fees - revealed in The Sunday Times in December 2006 - gave the doctor a direct personal, but undeclared, financial interest in his research claims: totalling more than eight times his reported annual salary and creating an incentive not only for him to launch the alarm, but to keep it going for as long as possible.

In addition to the personal payments, Wakefield was awarded an initial £55,000, which he had applied for in June 1996, but which, like the hourly fees, he never declared to the Lancet as he should have done, for the express purpose of conducting the research later submitted to the journal. This start-up funding was part of a staggering £18m of taxpayers' money eventually shared among a small group of doctors and lawyers, working under Barr's and Wakefield's direction, trying to prove that MMR caused the previously unheard-of "syndrome". Yet more surprising, Wakefield had asserted the existence of such a syndrome - which allegedly included what he would dub "autistic enterocolitis" - before he performed the research which purportedly discovered it.

This Barr-Wakefield deal was the foundation of the vaccine crisis, both in Britain and throughout the world. "I have mentioned to you before that the prime objective is to produce unassailable evidence in court so as to convince a court that these vaccines are dangerous," the lawyer reminded the doctor in a confidential letter, six months before the Lancet report.

And, if this was not enough to cast doubt on the research's objectivity, The Sunday Times investigation unearthed another shocking conflict of interest. In June 1997 - nearly nine months before the press conference at which Wakefield called for single vaccines - he had filed a patent on products, including his own supposedly "safer" single measles vaccine, which only stood any prospect of success if confidence in MMR was damaged. Although Wakefield denied any such plans, his proposed shot, and a network of companies intended to raise venture capital for purported inventions - including "a replacement for attenuated viral vaccines", commercial testing kits and what he claimed to be a possible "complete cure" for autism - were set out in confidential documents.

One Wakefield business was awarded £800,000 from the legal aid fund on the strength of (later discredited) data which he had supplied. And, even as the Lancet paper was being prepared, behind the scenes he was negotiating extraordinary plans to exploit the public alarm with secret schemes that would line his pockets. "Disgraced doctor Andrew Wakefield plotted to make £28 million a year from the MMR jab panic he triggered," was how the British tabloid newspaper The Sun, for example, reported in January 2011 on this late disclosure from Deer.

Behind the veil of confidentiality

As with the researcher, so too with his subjects. They also were not what they appeared to be. In the Lancet, the 12 children (11 boys and one girl) had been held out as merely a routine series of kids with developmental disorders and digestive symptoms, needing care from the London hospital. That so many of their parents blamed problems on one common vaccine, understandably, caused public concern. But Deer discovered that nearly all the children (aged between 2½ and 9½) had been pre-selected through MMR campaign groups, and that, at the time of their admission, most of their parents were clients and contacts of the lawyer, Barr. None of the 12 lived in London. Two were brothers. Two attended the same doctor's office, 280 miles from the Royal Free. Three were patients at another clinic. One was flown in from the United States.

The investigation revealed, moreover, that the paper's incredible purported finding - of a sudden onset of autism within days of vaccination - was a sham: laundering into medical literature, as apparent facts, the unverified, vague - and sometimes altered - memories and assertions of a group of unnamed parents who, unknown to the journal and its readers, were bound to blame MMR when they came to the hospital because that was why they had been brought there. Wakefield, a former trainee gut surgeon, denied this. But the true number of families accusing MMR wasn't eight, as the paper said: it was 11 of the 12 (later all 12) and in most cases records noted parents' compensation claims before the children were referred.

"Mum taking her to Dr Wakefield, Royal Free Hospital for CT scans/gut biopsies," wrote one family doctor in the north-east of England, for example, before referring the only little girl in the project (who did not have inflammatory bowel disease). "?Crohn's—will need ref letter—Dr W to phone me. Funded through legal aid."

In the light of such discoveries, the case was overwhelming to dig deeper into Wakefield's findings. In an exercise never before accomplished by a journalist, Deer was able to exploit the GMC hearing to go behind the face of the 1998 paper, identify the subjects, and access patient data. Penetrating veils of medical and legal confidentiality, he discovered that the hospital's clinicians and pathology service had found nothing to implicate MMR, but that Wakefield had repeatedly changed, misrepresented and misrepresented diagnoses, histories and descriptions of the children, which made it appear that the syndrome had been discovered.

As first revealed in The Sunday Times in February 2009, the effect was to give the impression of a link between MMR, bowel disease and the sudden onset of autism when otherwise none was evident. Standard, but unreported, blood tests for inflammation in the children were normal. And what the hospital's clinicians and pathology service actually found in the children's guts was severe constipation, with predominantly normal [table] biopsies and benign or normal features. When taken together with developmental histories and diagnoses, moreover, not one case was free of critical mismatches between the paper which launched the vaccine crisis and the kids' contemporaneous records. Some children were a cause for concern before vaccination. Some were deemed normal months afterwards. Some did not have autism at all.

"If my son really is Patient 11, then the Lancet article is simply an outright fabrication," said the father of the penultimate child in the series - admitted to the Royal Free, at age 5, from northern California and whose history was falsely reported in the paper.

Children's protections sidelined

In addition to finding that the study had been rigged, the investigation uncovered a raft of further issues, including irregularities in ethical supervision. Research on patients is governed by national and international standards - particularly the Helsinki declaration - and no reputable hospital review board would have endorsed the kind of fishing expedition Wakefield embarked on for Barr. Without that endorsement, moreover, no reputable medical journal would have published any resulting paper. Against that background, to satisfy the Lancet's patient-protection requirements, but without revealing to hospital authorities what was really going on, Wakefield falsely reported that a gruelling five-day battery of invasive and distressing procedures performed on the kids - including anaesthesia, ileocolonoscopies, lumbar punctures, MRI brain scans, EEGs, radioactive drinks and x-rays - proposed for the lawsuit, was approved by the Royal Free's ethics committee.

But Deer revealed that, despite the research being executed on the uniquely vulnerable, developmentally challenged children of sometimes distraught parents hoping for money, the ethics committee was not told the truth about the project, and had given no such approval. Responding to Deer in 2004, Wakefield and his key associates, paediatricians John Walker-Smith and Simon Murch, denied this explosive discovery and issued a formal statement. But, after being confronted with the proof at the GMC hearing, they changed their story and - despite clear rules - now argued they needed no approval.

The investigation also probed Wakefield's basic science. The story was much the same. He had obtained the legal money and planned his business ventures against a theory of his own that the culprit for both inflammatory bowel disease and autism was persistent infection with measles virus, which is found live as a normal part of MMR. But Deer revealed on Channel 4 that sophisticated, unreported, molecular tests carried out in Wakefield's own lab had found no trace of measles in the children's guts and blood. Those tests were among a string which found no evidence of the virus. The Sunday Times also disclosed critical flaws in one apparently positive study, which involved materials supplied by Wakefield. This had misled thousands of families affected by autism, both in the UK and the US, ensnared for years in hopeless litigation based almost entirely on his measles theory.

Deer (who in April 2006 reported the first British measles death in 14 years) took no view on whether vaccines may or may not cause autism, but never found any scientific material which repeated the Lancet findings. Although all kinds of children, including those with autism, suffer from digestive issues, he learnt of a mass of authoritative research which rebutted Wakefield's claims. "Specifically, numerous studies have refuted Andrew Wakefield's theory that MMR vaccine is linked to bowel disorders and autism," was how the American Academy of Pediatrics summarised the consensus in an August 2009 statement to NBC News for a Dateline programme [video] featuring both Wakefield and Deer. "Every aspect of Dr Wakefield's theory has been disproven."

The impact of the investigation has been felt around the world, with media coverage from New Zealand [audio] to Canada [video]. In the UK, the revelations prompted a 2004 statement by the prime minister, a collapse in the anti-MMR campaign, and a rebound in vaccination levels. In the US - where the Barr-Wakefield deal was joined by allegations marshalled by American attorneys that a mercury-based vaccine preservative, thimerosal, was also at fault - findings by Deer were presented by the Department of Justice in federal court, followed in February 2009 by scathing judgments. After hearing a test case of petitions from some 5,000 families, one presiding judge said: "Therefore, it is a noteworthy point that not only has that 'autistic enterocolitis' theory not been accepted into gastroenterology textbooks, but that theory, and Dr Wakefield's role in its development, have been strongly criticized as constituting defective or fraudulent science."

Wakefield campaign denies everything

In response to Deer, Wakefield supporters denied that he took money for research, and, amid a barrage of sometimes paid-for smears and crank abuse of the journalist, lauded the doctor as a "hero". But the father-of-four's deceptions had not only triggered the resurgence of sometimes fatal or brain-

disabling measles outbreaks, plunged countless parents into the hell of believing it was their own fault for agreeing to vaccination that a son or daughter had developed autism, and misled an ethics committee over child rights and safety, but it was discovered that he had gone as far as to betray a vaccine safety whistleblower whose identity he discovered [video] and had bought blood from children as young as four years old, attending a birthday party, and then joked about them crying, fainting and vomiting. [video]

Meanwhile, Wakefield denied any conflicts of interest and claimed he never even said that MMR caused autism. But documents - including patents - evidenced his claims, and he published a string of further falsified reports to undermine the vaccine. Even when he knew that his allegations had been proven baseless, he was found promoting them from a controversial business in Austin, Texas, called Thoughtful House, where - after being fired from the Royal Free in October 2001, following his refusal to repeat the Lancet study with a larger number of children - he held a \$280,000-a-year post, spun from his campaign.

Throughout the investigation, Wakefield refused to co-operate, filed baseless complaints and issued statements denying every aspect. He also initiated, sought to stall and then abandoned with some £1.3m (\$2m) costs, a two-year "gagging" libel lawsuit, financed by the Medical Protection Society, which defends doctors against their patients. In reply, Deer and Channel 4 pressed for a speedy trial, publicly accusing Wakefield of being "unremittingly evasive and dishonest". His conduct in the litigation was also damned by a High Court judge, who said that Wakefield "wished to extract whatever advantage he could from the existence of the proceedings while not wishing to progress them", and that the doctor was using the lawsuit as "a weapon in his attempts to close down discussion and debate over an important public issue".

Lancet paper retracted and doctor ousted

Faced with overwhelming proof of misconduct, Wakefield would concoct a preposterous conspiracy theory [video] to account for his exposure, and denied rigging his results. "The notion that any researcher can cook such data in any fashion that can be slipped past the medical community for his personal benefit is patent nonsense," he argued in a March 2009 statement. "Scientific rigor requires repeatability for verification of any research and Mr Deer's implications of fraud against me are claims that a trained physician and researcher of good standing had suddenly decided he was going to fake data for his own enrichment."

But on 28 January 2010 - after 197 days of evidence, submissions and deliberations - a panel of three doctors and two lay members hearing the GMC case handed down verdicts which wholly vindicated Deer. Branding Wakefield "dishonest", "unethical" and "callous", they found him guilty (against a criminal standard of proof) of some three dozen charges, including four of counts of dishonesty and 12 involving the abuse of developmentally-challenged children. His research was found to be dishonest and performed without ethical approval. Five days later, the Lancet fully retracted the paper from the scientific literature, prompting international media interest and further retractions.

"What is indisputable is that vaccines protect children from dangerous diseases," said The New York Times, in one of a string of editorials in leading newspapers. "We hope that The Lancet's belated retraction will finally lay this damaging myth about autism and vaccines to rest."

Three weeks later, on 17 February 2010, Wakefield was ousted by the directors of his Texas business, and on 24 May - day 217 of the GMC hearing - he was ordered to be erased from the UK doctors' register, ending his career in medicine. On 21 December 2010, that erasure was confirmed after he abandoned a court appeal against the verdicts.

Medical journal calls the fraud

Finally, in January 2011, BMJ, the British Medical Journal, concluded the investigation with a three-week package of disclosures and editorials, including three major reports by Deer: How the case against the MMR vaccine was fixed, How the vaccine crisis was meant to make money and The Lancet's two days to bury bad news. The package (which involved peer-review and separate editorial checking of key evidence and documents) also included an introduction by Deer, Pildown medicine, explaining the fraud and comparing it with Britain's most notorious scientific forgery. In editorials, the

BMJ called Wakefield's research "an elaborate fraud" and accused the Royal Free medical school and the Lancet of "institutional and editorial misconduct".

Among hundreds of media reports worldwide on the BMJ revelations - which were covered by all north American networks and reached almost half of Americans surveyed days later in a Harris poll - The New York Times said in a second editorial on the affair: "Now the British Medical Journal has taken the extraordinary step of publishing a lengthy report by Brian Deer, the British investigative journalist who first brought the paper's flaws to light - and has put its own reputation on the line by endorsing his findings."

Three months later, Deer's personal journey found closure when in April 2011 he was named specialist journalist of the year in the British newspaper industry's annual Pulitzer-style Press Awards. Judges for the Society of Editors praised what they called his "outstanding perseverance, stamina and revelation on a story of major importance". They said of his investigation: "It was a tremendous righting of a wrong".

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