Cause No. D-1-GN-12-000003

Dr Andrew J. Wakefield, MB., BS., FRCS,	**§**	**IN THE DISTRICT COURT OF**
	§	
Plaintiff,	**§**	
	§	
v.	**§**	**TRAVIS COUNTY, TEXAS**
	§	
The British Medical Journal, a d/b/a of BMJ Publishing Group Ltd., also d/b/a BMJ Group, and BMJ, Brian Deer, Individually, and Dr Fiona Godlee, Individually,	**§**	
	§	
Defendants.		**250th JUDICIAL DISTRICT**

AMENDED DECLARATION OF BRIAN DEER IN SUPPORT OF DEFENDANTS' ANTI-SLAPP MOTION TO DISMISS

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I. Personal Background and Introduction

1. My name is Brian Deer. [*Personal information has been redacted from this paragraph*].

2. I am a graduate of the University of Warwick, England, with a Bachelor of Arts in Philosophy, and I have been a professional journalist ever since. I have worked for the *Sunday Times* of London in various capacities, staff, contract, and freelance, since 1981, with a strong emphasis on public interest and investigative journalism. In addition to the *Sunday Times*, my work has appeared in the *Mail on Sunday*, the *Guardian*, the *Observer* and numerous other publications. I have also reported for the UK's Channel 4, a national network. Examples of my reporting are also published on my website, briandeer.com. Approximately one quarter of my work has concerned medical and healthcare issues.

3. I have won two British Press Awards, which are the highest distinction for a newspaper writer in the United Kingdom, the equivalent of the Pulitzer Prize in the United States. The citation for the first award, in 1999, stated that I was "probably the only journalist in Britain that polices the drugs companies." For the second award, in 2011, the judges described my investigation of the controversy over the measles, mumps and rubella ("MMR") vaccine – the reporting at issue in this lawsuit – as "a tremendous righting of a wrong."

4. I make this declaration, which amends my 9 March 2012 declaration, based on personal knowledge of the facts stated herein. Even where styled as a present-tense response to Wakefield's allegations in this case, (unless otherwise indicated) the following represents my thought process and subjective state of mind at the time of publication – why I reported what I did and why I believed it to be true.[1]

[1] All of the documents attached to this declaration are authentic, true and correct copies of the same. As to the documents for which I am not personally able to authenticate (*e.g.*, hospital records), the copies attached to this declaration are true and correct copies of the documents as I received them and have maintained them in my possession.

II. A History of My Reporting on Wakefield and the MMR Vaccine Controversy

A. Following the Controversy as it Developed

5. I first heard of Andrew Wakefield in February 1998, when I read in the *Guardian* newspaper about his MMR vaccine research, which was to be published that weekend in the *Lancet*, a British medical journal. By that time, a fair amount of my journalism had been in the field of medicine, and at the time of Wakefield's *Lancet* article,[2] I was intensively researching a report on the three-in-one vaccine against diphtheria, tetanus and pertussis, that had caused international controversy in the 1970s and 1980s. This was an investigation for the *Sunday Times Magazine*, and I spent about six months on interviews and newsgathering. This material was on my mind as I read the *Guardian's* article in which Wakefield and 12 co-authors, at the Royal Free hospital and medical school, north London, were reported to have found a possible link between the three-in-one MMR vaccine and a new syndrome of brain and bowel damage in children.

6. Perhaps a few months later, I pulled Wakefield's five-page paper from the British Library and made a photocopy. I did not study it carefully at that time, but I certainly read the "abstract" or "summary" section, which typically appears at the beginning of papers in the *Lancet*. The abstract, which is written by the authors, includes the following sections: "Background," "Methods," "Findings" and "Interpretation." It is the portion freely available online, and is often the only passage that many people actually read.

7. The abstract of Wakefield's *Lancet* paper, attached as Exhibit 1, states:

> SUMMARY
>
> **Background** We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder.
>
> **Methods** 12 children (mean age 6 years [range 3-10], 11 boys) were referred to a paediatric gastroenterology unit with a history of normal development followed by loss of acquired skills, including language, together with diarrhoea and abdominal pain. Children underwent

[2] Wakefield AJ, Murch SH, Anthony A, *et al*. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet* 1998: 28 January.

> gastroenterological, neurological, and developmental assessment and review of developmental records. . . .
>
> **Findings** Onset of behavioural symptoms was associated, by the parents, with measles, mumps, and rubella vaccination in eight of the 12 children, with measles infection in one child, and otitis media in another. . . .
>
> **Interpretation** We identified associated gastrointestinal disease and developmental regression in a group of previously normal children, which was generally associated in time with possible environmental triggers.

8. The first finding jumped off the page: In two thirds of the cases reported, the cited "environmental trigger" (described elsewhere in the paper as the "apparent precipitating event") was the MMR vaccine shot.

9. I also looked at the paper's tables (which are reproduced separately in Exhibit 1), which tabulated the 12 cases in detail. Table 1 listed the children, anonymised by number, referring to apparent bowel disease, and Table 2 set out various details of the apparent precipitating event for their developmental disorders. The time between the apparent precipitating event and the onset of problems was given. This information corresponded with information in the text, indicating that in *eight* of the *12* cases the apparent precipitating event was the MMR shot, and also with the startling additional claim that what was described in Table 2 as the "first behavioural symptom" occurred within just *14 days*. Table 1, meanwhile, listed what were described as "histological findings" – meaning findings under a microscope – of "non-specific colitis" in the intestines of 11 of the 12 children.

10. In my mind, this was an extraordinary finding. That a single London hospital – much less the Royal Free[3] – could report a dozen families, described as "consecutive", with two out of three of them making such a striking association that doctors would present it in the *Lancet*, was major news. The paper also spoke of the discovery of a putative "unique disease process", and a hitherto unheard-of "syndrome". Predictably, such claims provoked considerable public interest.

[3] At the time, the Royal Free hospital had no department or reputation for evaluating developmental disorders such as autism and would not have been a likely place for the *Lancet* children's parents to seek clinical help for their kids.

11. I found it particularly curious that the "results" section of the paper stated that the first signs of autism ("behavioural symptoms" of a "behavioural diagnosis" of "autism") followed within 14 days. From my previous reporting, I was aware that, in both the United Kingdom and the United States, the governments had established compensation schemes, largely in response to the controversy over DTP, intended to help "vaccine victims." Both schemes required a time-frame – a so-called "temporal link" – for the possibility of causality to be entertained. For DTP, that time-frame was 14 days in the UK. This 14-day figure, in fact, had first surfaced in a research paper about DTP, also from a London hospital, and also published in a British journal. It was known as the *Kulenkampff* paper[4].

12. With that knowledge, I recognized that Wakefield's *Lancet* paper invoked the same window. The children in his paper were said to have shown problems within a maximum of 14 days of receiving the MMR shot, with an average time given as just 6.3 days.

13. The importance of this time frame to both the paper and to the vaccine controversy which it triggered cannot be overestimated. Remarkably, the *only* information in the 4,000-word paper – which would become the evidential foundation for what evolved into a worldwide health scare – was the claim that eight of 12 parents made the association of regressive developmental disorders with MMR, and the additional claim of a 14 day maximum/6.3 day average temporal link. Apart from assurances in the text that Wakefield had checked the children's records (and thus the information was not merely derived from unsubstantiated allegations or potentially unreliable recollections), *no* other findings or results in the paper evidenced any connection between MMR and autism.

14. But why, I wondered, would the reported maximum temporal link be the same for two different vaccines? I knew the suspect component of DTP, at the time, was a whole-cell formalin-killed pertussis (whooping cough) bacterium, while MMR contained three

[4] Kulenkampff M, Schwartzman JS, Wilson J. Neurological complications of pertussis inoculation. *Arch Dis Child*; 1974.

small, attenuated live viruses. Why, I wondered, would two vaccines with such different technologies be associated with exactly the same, neat, 14-day figure?

15. At that time, however, I was busy with other projects, and I put Wakefield's paper away. After one lengthy inquiry into vaccines, I was not seeking another. Vaccines are a hugely multi-disciplinary area of medicine, with numerous technical complexities. During my DTP inquiries, I had forced myself to come to learn the fundamental science and medicine relating to the controversies, rather than merely recycle opinions. I also did not want to become type-cast as a "medical journalist." That was 1998, and for the next several years, from the sidelines, I watched the story unfold.

B. My First *Sunday Times* Reports in 2004

16. In September 2003, I was encouraged by my editor to think of investigations suitable for the "Focus" section of the *Sunday Times*, which generally contains longer, more in-depth reporting. One of several topics suggested to me was MMR, which was back in the news as a result of an impending TV documentary-drama on Wakefield. A typical *Sunday Times* "Focus" piece might then have taken up to four days to research and write, but I hoped I might spend perhaps three weeks on MMR.

17. My first action was to attend a screening of the drama. At the time, a major class action product liability trial of MMR's safety was pending in the High Court, London. After seeing the film, my first phone call was to a litigation campaign group called "JABS" (Justice Awareness and Basic Support),[5] focused on this lawsuit, whose organiser told me, in a manner suggesting that she did not really understand the import of her words, that JABS members had taken part in Wakefield's *Lancet* research.

18. I had not seen this fact reported anywhere in the vast media coverage of the controversy. Wakefield and his co-authors had not disclosed that the purported "consecutive

[5] In the United Kingdom, "shots" are called "jabs."

series of children" who had presented at the hospital included individuals whose families were members of an anti-vaccine litigation campaign group. Evidently, the paper was not, as it had appeared to all the world, a report of patients merely turning up routinely and telling an alarmingly similar story.

19. My reporting also involved interviewing Rosemary Kessick, who was not only the lead test case plaintiff in the product liability litigation, but was the mother of one of the children in Wakefield's research. During the interview, she told me a story about the apparent onset of her son's problems that could not be reconciled with any of the 12 anonymised cases in the paper. Specifically, she said that her son's first behavioural symptoms began up to *six months* after his MMR shot, and hence well outside the 14-day maximum. Although she confirmed that her son was included in the paper, the account she gave did not match any of those reported.

20. Soon after beginning my inquiries, I also learnt that the government – through its Legal Aid Fund – had paid £55,000 for Wakefield to perform precisely the research described in the *Lancet* (plus additional tests which I later found were included in a second Wakefield paper, submitted at the same time, but rejected by the journal). In the first weeks of my inquiries, I interviewed officials of the Legal Services Commission (previously known as the Legal Aid Board). They told me that the paper was what they called "open" publication of information supplied to them in confidence to advance the product liability lawsuit – which was against drug companies that manufactured MMR. At the time of the *Lancet* research, the case had not yet been filed, but these Legal Service Commission officials confirmed that, at the time of the research, the case was actively being prepared with funding provided by their agency to carry out tests on clients.

21. In researching this story, I attempted to interview Wakefield, but, as I will explain later, he refused. I therefore continued with my inquiries and obtained interviews

with other key figures. For example, I interviewed an attorney named Richard Barr, who was the principal plaintiff lawyer driving the product liability litigation, which by then had enrolled some 1,600 clients. After a formal interview, we talked on the phone. He squarely told me that he had arranged for the research in the *Lancet* to be paid for from Legal Aid funds and said he remembered noting at the time that the appropriate funding acknowledgement had not been made. (A true and correct recording of Mr Barr's statement appears on my website, at http://briandeer.com/audio/richard-barr.mp3). To my knowledge, Mr Barr has never sought to retract this statement. In my mind, this was an important admission, revealing that he had paid for Wakefield's research on behalf of litigation clients.

22. On Saturday 14 February 2004, my MMR article was made ready for publication. However, I had already told my editors the previous week that, in my judgment, the material was so detailed that we needed to give Wakefield more time to respond. As it was, the allegations had been put to him (I believe) on Wednesday or Thursday, for Sunday publication, and I felt this was potentially unfair. *Sunday Times*' executives disagreed, observing that allegations were routinely, and fairly, put to subjects for response on a Friday night. However, on Saturday morning, the *Sunday Times* Editor, John Witherow, overruled his executives and ordered the story held till the following week, as I had advised.

23. After having previously refused, Wakefield now agreed to an interview, but imposed the extraordinary condition (which I have never encountered before or since during three decades in journalism) that the reporter working on the story – myself – would not be present. He was then interviewed, on 18 February 2004, by three other journalists, none of whom had been sufficiently involved to master the factual background necessary to deal with his answers.

24. Mr Witherow also ordered that I speak to the most authoritative source on the matter. I first tried to contact the *BMJ*'s then-editor, Dr Richard Smith. He was on holiday,

so I arranged to meet with Dr Richard Horton, editor of the *Lancet*. Our meeting took place at the *Lancet*'s offices, simultaneously with the other reporters' interview with Wakefield at his publicist's offices in Mayfair. My presentation lasted several hours, and was attended by Dr Horton, several of his senior staff, and a member of parliament, Dr Evan Harris.

25. When I finished my presentation, Dr Horton's attitude became uncooperative. He refused make any comment, or even to admit that an investigation was required. Instead, he told me that Wakefield was on his way to the *Lancet*'s offices. These events are accurately recounted in the *BMJ* report "*The* Lancet*'s Two Days to Bury Bad News,"* published in January 2011 as the third in the series "Secrets of the MMR scare." Dr Horton did, however, later concede that Wakefield had a conflict of interest over the funding from Mr Barr.

26. On Sunday, 24 February 2004, two reports by me were published in the *Sunday Times*. On Page 1, the article was headlined *"Revealed: MMR Research Scandal."* A two-page Focus centre-spread was headlined: *"MMR: The Truth Behind the Crisis."* True and correct copies of these articles are attached as Exhibit 2.

C. Reaction to the 2004 *Sunday Times* Reports

27. In the wake of these reports, the government's health secretary said he believed that the General Medical Council ("GMC"), which licenses all UK doctors, should investigate the matter. In response to this, Wakefield issued a statement, a copy of which is attached as Exhibit 3, in which he said he would "welcome" a GMC investigation and would "insist" on one. Among other things, he denied any conflict of interest and claimed that the money – reported as £55,000 – was not paid to him personally.

28. Evidently, the GMC was listening. I was contacted by a GMC official who asked if I had anything to add to my published reporting. In response, I sent him an email

setting out a summary of my findings as of that time, a copy of which is attached as Exhibit 4.

D. The *Lancet*'s First Retraction

29. Less than two weeks after my first reports, ten of the *Lancet* paper's authors – but not Wakefield – retracted their claim to have found "an association in time" between administration of MMR and developmental regression. The *Lancet* contemporaneously published a three-paragraph retraction statement, headed: "Retraction of an interpretation." I attach this "partial" retraction as Exhibit. 5. I regarded the retraction as vindicating my reporting.

30. Even though I did not know the full extent of Wakefield's connection with the MMR litigation and the *Lancet* paper's litigation underpinnings, I was impressed by the disingenuous quality of his response. For example, he published a letter (which I have attached as Exhibit 6) in the 17 April 2004 edition of the *Lancet*, titled *"MMR – Responding to Retraction,"* in which he made highly misleading statements:

> Almost six years have passed since AJW disclosed in a letter published in *The Lancet* that he was undertaking a pilot study on behalf of the Legal Aid Board (later to become the Legal Services Commission)… He wrote on May 2, 1998, 3 months after the original paper: "Only one author (AJW) has agreed to help evaluate a small number of these children on behalf of the Legal Aid Board."

31. But the letter to which Wakefield referred made no reference to any "pilot study" at all. As background, a doctor had written to the journal, following publication of the paper, enclosing a factsheet issued by Mr Barr's law firm, and suggesting that Wakefield was somehow involved in litigation that might have affected his findings. Wakefield responded by asserting:

> Only one author (AJW) has agreed to help evaluate a small number of these children on behalf of the Legal Aid Board.

32. But this response provided no clue that Wakefield had been running any "pilot study," and anybody reading it would naturally assume that the "help" he referred to arose as

a result of his research, not that it was the basis of the research itself. Wakefield had also stated in his May 1998 letter that "No conflict of interest exists," which was plainly false.

33. In fact, although I did know it at the time, even one of Wakefield's co-authors, Professor John Walker-Smith (who did not know the full extent of Wakefield's involvement in the litigation) had been concerned about the conflict of interest inherent in the fact that participants in the research were seeking compensation. In a 20 February 1997 letter from Walker-Smith to Wakefield, which I would later receive through Freedom of Information disclosures, Walker-Smith stated (Ex. 7)[6]:

> It is clear that the legal involvement by nearly all the parents will have an effect on the study as they have a vested interest. . . .
>
> I think this makes our work difficult, especially publication and presentation.

E. The Channel 4 Documentary, *MMR: What They Didn't Tell You*

34. In the wake of my first *Sunday Times* reports, I agreed to produce a documentary on Wakefield and the MMR controversy for Channel 4's current affairs series *Dispatches*. I and the programme's associate producer conducted numerous interviews and obtained numerous documents and videotapes. Our first revelation shocked me. When the *Lancet* paper was published, Wakefield had taken part in a Royal Free press conference and video news release in which he claimed that, instead of MMR, single shot vaccine products were potentially safer. But we discovered that almost eight months *before* this call, he had filed for a patent on his own single-shot measles vaccine, as well as other products which only stood any chance of success if confidence in MMR was damaged.

35. We invited Wakefield to participate in the programme or to respond to questions. When we got no response, I travelled to Indianapolis, where he was speaking at a conference. When I introduced myself, he put his hand over the camera lens and fled, making no verbal response of any kind. This incident is accurately depicted in an excerpt

[6] Exhibit 7 is a true and correct copy of my *Sunday Times* article, which accurately reports the contents of the letter.

from a *Dateline NBC* broadcast on 30 August 2009, which appears on my website at www.briandeer.com/video.htm.

F. Wakefield's Libel Litigation in 2005-06

36. After the Channel 4 programme, in November 2004, I wanted to move on to other areas of journalism. But on 31 January 2005, Wakefield's lawyers served on Channel 4 a letter (which I have attached as Exhibit 8) claiming that we had libeled him. At the same time, he filed a second libel suit against the *Sunday Times* and a third against me personally over my website, briandeer.com. I was surprised by aspects of his claims in these cases, not least because some of the complaints regarded matters that were obviously true, such as:

> That the 12 children who were the subject of his *Lancet* article were not a random sample or ordinary patients referred by GPs, but his research had first been commissioned by solicitors suing the manufacturers of the MMR vaccine.
>
> That a substantial proportion of the Claimant's sample of autistic children had parents who had an interest in seeing a scientific link between the MMR vaccine and autism established.
>
> That he was being funded up to the sum of £55,000 by the Legal Aid Board on behalf of solicitors seeking evidence of a link between the MMR vaccine and autism to use in litigation against manufacturers of the vaccine.

37. I believed his action was vexatious, and I could not imagine how he would have any interest in actually seeing the merits of his claims tested. Indeed, in all three cases, he asked us to agree that his litigation be stayed, pending the outcome of his GMC hearing. Had we agreed, it would have allowed him to spend the next five years telling people that he was suing us, casting doubt on our reputations, without having to incur any legal costs or risk of an adverse judgment.

38. Although, on economic grounds, the *Sunday Times* agreed to such a stay, Channel 4 and I opposed Wakefield's manouever. After a two day hearing, in November 2005, a High Court judge, Mr Justice Eady, denied the stay, awarded us an immediate £35,000 advance on our costs, and lambasted Wakefield for using litigation for what the judge called "public relations purposes". Following Eady's ruling, Wakefield's lawsuit went

forward against Channel 4 and me for more than a year. In connection with our defense, we obtained, following a second court hearing, the confidential, unredacted Royal Free medical records of 11 of the 12 children. For the first time, I was allowed to review them, but only in the office of my attorney, where the documents were required to remain. I spent an entire day reading them, and I was stunned by their contents, which in many respects could not be reconciled with the paper.

39. What I did not expect, however, was that, even as I turned the pages, a taxi sped across London to the Royal Courts of Justice bearing Wakefield's notice of discontinuance against Channel 4 and myself. Shortly after, he also discontinued his claims against my website and the *Sunday Times*. After two years of immensely heavy litigation, which took me away from journalism for long periods and incurred costs and attorneys' fees which I believe exceeded half a million pounds on our side, he had thrown in the towel, blocking further access to the children's records.

G. Freedom of Information Disclosures

40. In 2000 – two years after the *Lancet* paper was published – the British government had passed a Freedom of Information Act (FOIA), which came into force in 2004. Under the act, I was able to obtain confidential institutional review board records, describing Wakefield's research and permissions and, later, all kinds of material.

41. One critical FOIA disclosure came from the Legal Services Commission, which I reported in the *Sunday Times* just days before Wakefield discontinued his lawsuit. Under the heading *"MMR Doctor Given Legal Aid thousands,"* on 31 December 2006 I authored an article revealing that the £55,000 which I had reported in 2004 was nothing compared with direct, undisclosed, personal payments he received in his deal with Mr Barr. They totalled £435,643 in fees, plus £3,910 expenses.

42. I learnt, moreover, that he had billed, through a company of his wife's, at the hourly rate of £150, which I understood meant that he was contractually incentivised not only to launch the MMR scare, but to keep it going for as long as possible. (I attach as Exhibit 8 a letter by which Wakefield agreed to this deal.) The contract, moreover, had begun in February 1996 – two years before the paper was published, and before any of the children had been seen at the Royal Free.

43. Under this arrangement, by the time he published and promoted the paper, in February 1998, he had already been retained as an expert in contemplated litigation. Thus, if he had failed to suggest that the vaccine was defective, he would have jeopardised his lucrative position with Mr Barr. On the other hand, by setting off a storm over MMR, he was essentially writing himself cheques of potentially life-transforming value. He was, moreover, much more than a traditional expert witness; he was the scientific architect behind the lawsuit, carrying out and leading novel research intended to create the plaintiffs' evidence.

44. No less striking were FOIA disclosures I received from University College London, which had taken over management of the Royal Free medical school. These documents, which contained information reported in the second article of my *BMJ* "Secrets" series, titled "*How the vaccine crisis was meant to make money*", revealed that Wakefield had established a network of companies that would provide litigation-driven diagnostic and consulting services, thereby exploiting the public alarm he had himself created. For example, one business plan I obtained (which is attached as Exhibit 9) included the following:

> 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. 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.

H. The GMC Fitness to Practice Hearing

45. On 16 July 2007, a five-member Fitness to Practise panel of the GMC convened in London to consider charges of serious professional misconduct against Wakefield and two

others, including Walker-Smith. With a view to a possible second *Dispatches* programme, I attended every day of the prosecution case, which ran until 19 October 2007, and I attended on most days after that. I regarded the hearing to be an extraordinary investigative tool, penetrating layers of medical confidentiality and legal privilege so as to lay bare what went on around the *Lancet* paper. Records were read aloud by QCs, and followed with great forensic care. Thus, what was being read into the public record would have great accuracy, equivalent for journalistic purposes to the documents themselves.

46. Hundreds of documents were exhibited during the proceedings, and among the most important were those that set out Wakefield's relationship with Mr Barr and gave details of a secret deal between them to try to manufacture a case against MMR. For example, the GMC panel inspected a document (which I attach as Exhibit 10) submitted by Mr Barr and Wakefield to the Legal Aid Board on 6 June 1996, before any of the children were admitted to the Royal Free, and nearly 20 months before the paper was published. This was a grant application – to which was attached the protocol for a "Proposed clinical and scientific study" – seeking funding to prove the existence what the two men called "a new syndrome." Along with detailed costings, the application said (my emphasis):

> In contrast with the IBD cases, which have a prima face [sic] gastrointestinal pathology, children with enteritis/disintegrative disorder ***form part of a new syndrome***. Nonetheless ***the evidence is undeniably in favour of a specific vaccine induced pathology***.

And:

> The objective 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***.

47. Before the GMC hearing, I had also obtained a sheaf of correspondence between Wakefield and Royal Free managers, which proved that, by his own clear, contemporaneous assertion, the *Lancet* research was sponsored by the Legal Aid Board. It also proved that Wakefield was active in the procurement of children for the project. The letters spoke of the

award of a grant of £50,000 from the board, and said that the money was to conduct work described in a protocol for a "clinical and scientific study." I attach these letters as Exhibit 11.

48. Confronted by overwhelming documentary proof at the GMC hearing, Wakefield admitted under cross-examination that children enrolled for the *Lancet* project were not routine hospital patients, but had been selected. The basis of the selection was that (1) they had bowel symptoms; (2) they had developmental disorders; and, he now acknowledged, (3) the parents associated the child's problems with vaccination. I attach as Exhibit 12 the following extract from the transcript (emphasis is mine):

> **SMITH** (counsel for the GMC): What I am suggesting to you and what I now want to ask you is where you make it clear that the children had come to the Royal Free in the first place, at least in the majority of cases, in the letters that we have looked at, because their parents, or in some cases their doctor through their parents, thought that MMR might have caused the damage?
>
> **WAKEFIELD**: That is implicit to anyone reading this paper. . . . To anyone reading this, we would have considered that to be self-evident. ***Self-referral on the basis of one or more of the symptoms of gastrointestinal problems, developmental regression and an association with environmental exposure...***

49. This selection of subjects made a mockery of the paper, which, as its very first "finding," purported to *find* an autism-vaccine association, when this association was actually built into the very fabric of the project, making the "finding" pre-ordained. Previously, Wakefield had denied this, and sued me for saying it. But now there was nowhere for him to hide.

50. The evidence laid out in front of the panel, moreover, was dominated by case-by-case reviews of the individual children's medical records, including those held at the Royal Free and to which Wakefield had access. And these showed countless discrepancies with the patient histories and diagnoses reported in the *Lancet*. His reporting of Child 1, Child 8, and Child 9 illustrate different aspects of his activities:

Child 1

51. In the case of Child 1, aged 3½ on admission to the hospital, Wakefield had tabulated in the paper's Table 2 that the "interval from exposure to first behavioural symptom" was just "1 week." This was a critical component of the sudden onset temporal link reported in the paper's Results section, and the general "association in time" in its Interpretation section. But Walker-Smith had taken a history from the child's mother in which she is only reported to have positively recalled that 7-10 days after vaccination her son was "*pale.*"

52. In addition, Walker-Smith, added to his notes, which I attach as Exhibit 13, *"? fever, ? delirious."* This meant, as he explained in letters, that the mother said, (or more likely agreed) that the boy *possibly* had had a fever and *may* have been delirious (as if the mother would remember paleness, but forget delirium). But she only positively remembered for Walker-Smith that her son was *pale* after MMR. Thus, in June 1996, Walker-Smith wrote to Wakefield (Ex. 14) (my emphasis):

> I saw this interesting child with autism, which began ***some weeks*** following MMR, although there were 7-10 days after the MMR, at the age of 1, a brief illness, ***during which he was pale, possibly had fever***, and ***his mother said*** he ***may have been delirious***.

On the same day, Walker-Smith wrote to the boy's GP:

> Many thanks for referring [Child 1] with autism. It's difficult to associate a clear historical link with the MMR and the answer to autism, although ***Mrs [1] does believe*** that [Child 1] had an illness 7-10 days after MMR when he was pale, ? fever, ? delirious, but wasn't actually seen by a doctor.

53. Where Walker-Smith told Wakefield that the boy's autism began "some weeks" after the MMR, and noted paleness, and a possible febrile episode 7-10 days after the shot, Wakefield reported in Table 2 that the "interval from exposure to first behavioural symptom" was "1 week." (*See* Ex. 1.) And this was notwithstanding Walker-Smith only repeating the positive assertion that the boy was "pale", and placing question marks against other possible

features which, in any event, could not credibly be regarded as the first "behavioural symptom" of autism.[7]

54. Moreover, as Royal Free records showed, doctors there believed that, in fact, the first signs of autism revealed themselves in this child *months* after vaccination. A selection of records (to which Wakefield had access when he wrote the paper, and which were presented at the GMC hearing) documented Child 1 as having normal development until up to *six months* after his vaccination. Although Wakefield represented this child in the *Lancet* as suffering from a *sudden onset* of regressive autism *one week* after MMR (which Child 1 received at the age of *12 months* and five days), a Royal Free record, read into the GMC transcript (Ex. 15**)**, documented the child's development as normal until he was *18 months* old – when he was recorded to have shown what a Royal Free report, to be considered later in detail, called his "initial behavioural abnormality." And this time-frame was reiterated in another Royal Free record, which was entered into the GMC transcript, and I attach as Exhibit 16, written by a consultant neurologist, and co-author of the *Lancet* paper, Dr Peter Harvey:

> after normal milestones a deterioration from 18 months or so.

55. Further, in a document served by *Wakefield himself, and affirmed by him with a signed statement of truth,* in his lawsuit against Channel 4 (Ex. 17), he stated of this child, vaccinated at 12 months:

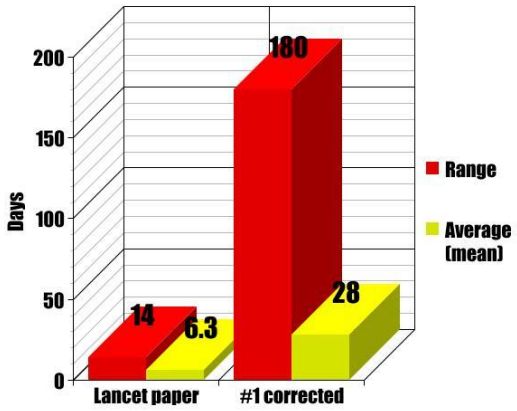
> Normal development to approximately 18 months followed by regression with loss of words and stasis of speech, comprehension and social interaction leading to a diagnosis of autism.

[7] A GP record was also read at the GMC proceedings indicating that, before MMR, the mother had been concerned about her son's hearing, and the doctor had found discharge from one ear. As I indicated in the first "Secrets" report (including in the online data supplement where the discharge is noted), concerns by parents that their child cannot hear properly are widely-recognised by specialists as a classic first symptom of the insidious appearance of autism. And, Wakefield himself reported in the *Lancet* – specifically in the case of Child 9 – an ear infection (reported by him in the paper as otitis media) was also regarded as a possible "precipitating event" for a developmental disorder. Thus, when Child 1's history was reviewed retrospectively after a diagnosis of autism, there was a record raising a possibly relevant concern *before* he had MMR.

He nevertheless wrote the case into the *Lancet*, to create the 14-day temporal link, recording a plainly false connection of "1 week".

56. Moreover, although he would claim that this boy had a "regressive" phenotype of autism (where acquired skills, including language, appear to be lost after apparent normality), and elsewhere claimed that all the children suffered from "severe developmental regression," both Child 1's hospital admission record and his discharge summary describe him as suffering from *"classical autism."* (*See* Ex. 15.)

57. Observing the GMC hearing, it was clear to me that Wakefield knew what he was doing. With his claimed 14-day maximum/6.3 day average temporal link resting on just eight children, the impact of his misreporting of even this first child was extraordinary. Leaving everything else the same, and correcting just the case of Child 1 to the 18 month maximum figure reported in Royal Free records (and adopted by Wakefield in the *Channel 4* case) 14 days becomes 180 days, and 6.3 days becomes 28 days, as illustrated in this graph:



Child 8

58. In some cases I heard presented at the GMC hearing, doctors had explicitly warned Wakefield of developmental concerns *before* a child was vaccinated. One example is the case of Child 8, the only girl in the paper who, like Child 1, was aged 3½ on admission. In Table 2, he reported her as experiencing "Post-vaccinial encephalitis?," described MMR as

the "exposure identified by parent or doctor" and gave the "interval from exposure to first developmental symptom" as "2 weeks." (*See* Ex. 1.)

59. But, as accurately reported in my first "Secrets" report, based on GMC transcript material such as the extract I attach as Exhibit 18 (emphasis is mine), her GP had taken the trouble to write:

> Dear Dr Wakefield
>
> [Child 8's] mother has been into see me and said that you need a referral letter from me in order to accept Child 8 into your investigation programme… I enclose photocopies of some recent correspondence which gives a fair idea of [Child 8's] current state***. I would simply reiterate Dr Houlsby's recent comment that both the hospital and members of the Primary Care Team involved with [Child 8] had significant concerns about her development some months before she had her MMR Vaccination.*** I take Mum's point that she has video evidence of [Child 8] saying a few words prior to this vaccination being given and her vocal abilities are now nil but I do not think we can be entirely convinced as yet that the vaccine is the central cause of her current difficulties.

60. Wakefield had received this letter, which was backed by enclosures written by specialists. But, manufacturing a link which launched the vaccine crisis, he still reported MMR in the paper as the "apparent precipitating event" for her disorder.

Child 9

61. A further anomaly surfaced in the GMC evidence: over the number of children whose parents blamed the vaccine. As I have explained, the proposition put before the medical and scientific communities, as well as the general public, was that the parents of eight of 12 children with regressive developmental disorders, who turned up consecutively at a bowel clinic at one unexceptional London hospital, said words to the effect of: "It was the MMR, doctor, and it came on within days."

62. But, as the cases were laid out in the GMC committee room, it became clear that even the eight of 12 figure was not true. In fact, the parents of *three more* children made the same allegation to Royal Free doctors, but their assertions were omitted from the paper. The complaint of the parents of Child 9 was one such example. The paper attributed the

"apparent precipitating event" for Child 9's "autistic spectrum disorder" to "recurrent otitis media," an ear infection, one week previously.

63. However, a statement was read from a local doctor who had received from the Royal Free correspondence that was described as in the "form of a discharge summary". The relevant passage of the statement, the transcript of which I attach as Exhibit 19, said:

> The letter also informed me that [Child 9]'s mother linked his mental regression at age 18-20 months to MMR which he was given at 16 months of age.

64. Although the paper acknowledged that the child had MMR two months previously, the parental disclosure (also documented in the discharge summary itself, presented at the GMC hearing) was omitted. The result, with two further such omissions, which I noted in the *BMJ*, was to: (a) greatly sharpen the temporal link reported in the paper; and (b) conceal the appearance (of what was indeed the case) that the parents were a pre-screened group of complainants against the MMR vaccine.

Wakefield's Pre-Referral Approaches to GPs and Parents

65. Wakefield was not a clinician. He was a former trainee gut surgeon, with no authority to perform any kind of medical procedure, make diagnoses or provide care to patients. Yet, during the GMC case, evidence rolled out of his repeated approaches to both general practitioners and to the parents of each child he enrolled, before the patients ever dealt with the hospital's clinicians.

66. In the case of Child 12, for example, the mother gave evidence for the GMC, supplying documents revealing Wakefield's pre-referral involvement. This, for instance, is how the GMC transcript recorded his response (Ex. 20) when she approached him (emphasis is mine):

> Thank you for your letter regarding your son. We have recently taken a profound interest in this subject, particularly in view of the link between bowel problems and Asperger's Syndrome. I would greatly appreciate if you would mind calling me at the Royal Free before 3rd August and in addition I would like you to seek a referral from your GP to Professor John Walker-Smith, Professor of Paediatric Gastroenterology at the Royal Free Hospital, for investigation. It will be necessary for me to discuss the nature of the referral with your GP

> and I would be very grateful if you could let me have his/her name and telephone number. ***Also could you please let me have your telephone number so that I can speak to you directly on the subject***.

67. But what, I wanted to know, did he have to say? I believed that he must have been briefing, or at the *very minimum*, suggestively questioning parents in a manner that could only contaminate subsequent history-taking by clinicians – particularly when there was the prospect of compensation both for the parents and for Wakefield. And although such contacts were logged in GP records, I recalled no real explanation during Wakefield's 21 days being questioned at the hearing as to why they were needed at all. I also heard GMC experts testify that it was virtually unheard of for a hospital consultant to phone patients in their homes.

68. One particularly striking record related to Child 8, the only girl. She did not have inflammatory bowel disease, but her mother was led to believe that she might, adding no doubt to her grief. The GP record, which is attached as Exhibit 21, stated:

> Mum taking her to Dr Wakefield, Royal Free Hospital for CT scans/gut biopsies ?Crohn's – will need ref letter – Dr W to phone me. Funded through legal aid.

Yet another instance appears in the GP notes of Child 5 (Ex. 22):

> Re [Child 5], Dr Wakefield, consultant gastroenterologist Royal Free rang and gave a v. lengthy and convincing case for [Child 5] to be referred to Professor John Walker Smith

69. Another striking example was a note found by GMC investigators in the records of Child 6, which, again from the transcript, I attach as Exhibit 23. The note was dated 25 March 1996 - more than four months before Child 6 was referred to the Royal Free, and the month after Wakefield signed up to his £150-an-hour deal with Mr Barr:

> Dr Wakefield – Royal Free. To discuss association measles + Autism + inflammatory bowel disease. Discussed general concerns re family. If we feel relevant can refer for treatment to Professor Walker at the Royal Free for investigation.

Wakefield's Co-authors Say They Did Not Know

70. According to professional rules for biomedical publishing[8], all authors of the paper should have been in a position to speak to its accuracy. However, one of the most disturbing features of the *Lancet* paper was that, where they commented at all, Wakefield's co-authors uniformly denied knowing what had gone on. Based on my reading of reports on the controversy, letters I obtained under FOIA, and testimony at the GMC hearing, I knew that all who commented said they did not know about the money Wakefield was receiving from Mr Barr. Pathologists said they did not write the pathology sections of the paper. The project's child psychiatrist, Dr Mark Berelowitz, did not see all of the patients. And children were anonymised in the tables, making it impossible for authors who might remember aspects of individual histories and diagnoses to know which child was which.

71. Under cross-examination on day 97 of the GMC hearing, Walker-Smith said that, before publication, Wakefield had brought him the paper's "clinical and laboratory details" already completed in a "sort of master chart". The 72-year-old retired professor also offered – on this 24th day of giving evidence – a summary of his general position:

> Q: Firstly, the whole refereeing process also relies on trust, does it not?
>
> A: We all rely on trust. I trusted Dr Wakefield.
>
> Q: I am sorry?
>
> A: We all rely on trust, yes, and I trusted Dr Wakefield.

Exhibit 24.

I. The 2009 *Sunday Times* Reports

72. The GMC hearing continued from July 2007, with many adjournments, until a final determination, after 217 days of evidence, submissions and deliberation, in May 2010. I had never envisaged anything of such duration, and my editors at the *Sunday Times*

[8] International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals (1997 edition).

concluded in February 2009 that, such was the public interest, we should publish reports. At that time, there were major outbreaks of measles in the UK.

73. On 8 February 2009, two reports by me were published: one on the front page and the other as a centrespread "Focus" feature. The front page report was headlined: *"MMR Doctor Fixed Data on Autism."* The centrespread was headlined: *"Hidden Records Show MMR Truth."* These reports, which I attach as Exhibit 25, contained virtually the same reporting that would later appear in the peer-reviewed first "Secrets" report.

J. *Cedillo* and Wakefield's Failed Vaccine Litigation in the United States

74. In the same week as my 2009 *Sunday Times* reports, three special masters in the United States Court of Federal Claims handed down orders in three test cases of Wakefield's theories, rejecting them in scathing terms. Wakefield was listed to appear for the lead test case: a severely-challenged Arizona girl, Michelle Cedillo. But the doctor was never called (which I viewed as a sign that he was seen by his own side as a liability), leaving others to advance his claims.

75. Later (but long before I wrote the "Secrets" articles) I read transcripts of the three completed test cases – *Cedillo, Hazlehurst* and *Snyder* – and noted strong criticism of Wakefield's research and integrity. For example, in October 2007, Dr Robert Rust, a pediatric neurologist, gave evidence in the *Hazlehurst* case. The transcript (relevant excerpts of which are attached as Exhibit 26) reports Rust commenting (emphasis is mine):

> The most striking observations have I can say with confidence been thoroughly discredited in the medical literature and in medical communities on the basis of the ways in which we usually thoroughly discredit things . . .
>
> The gathering of information from nonsequential patients, demonstrating those patients in the medical literature in ways that misrepresent the manner in which those patients were gathered, failure to misrepresent economic advantage related to publication, a wide variety of things. The medical community is relatively forgiving about some things in its community, but ***scientific fraud is not one of those things that we forgive.***
>
> We'd be very careful before we assign that sort of thing, but ***there is abundant evidence that that was the case here***, and for us, it's something that we don't like because we try to very hard to do what we can for patients.

76. Similarly in *Hazlehurst*, Professor Thomas T MacDonald, an eminent gastrointestinal immunologist and Dean of Research at Barts and the London School of Medicine, gave evidence with regard to Wakefield's theory about how MMR was supposed to cause autism. In February 2009, Special Master George Hastings, who presided over the *Cedillo* case, held in his judgment, a portion of which I attach as Exhibit 27 (emphasis mine):

> Dr MacDonald, indeed, went so far as to opine that Dr Wakefield's "autistic enterocolitis" theory was merely an "invention" created for litigation purposes. Similarly, Dr Rust summarized Wakefield's process of developing and disseminating his general theory, and described it as "***scientific fraud***." . . . 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***.

77. As an example of one editorial on the three decisions and their criticisms of Dr Wakefield, I attach a 17 February 2009 editorial by the *Austin-American Statesman* as Exhibit 28.

K. Wakefield's Press Complaints Commission Action

78. In the UK, newspapers and many other publications voluntarily submit themselves to a supervisory body, the Press Complaints Commission ("PCC"), which handles complaints and holds itself out to the public as offering a free alternative to litigation.

79. In a 58-page letter dated on or about 13 March 2009, Wakefield filed a complaint with the PCC regarding my February 2009 reports in the *Sunday Times*. The complaint itemised almost every aspect of the reports and denied what appeared to me to be virtually every statement within them. I reviewed Wakefield's PCC complaint in its entirety, and I judged it to be meritless. My newspaper, the *Sunday Times*, took the same view. I would have regarded some purported grievances as frankly laughable had they not made a considerable call on my time and had not plainly been contrived to harass, overwhelm the editorial systems of the *Sunday Times* and discourage further inquiry into his conduct.

80. At the outset, Wakefield sought to press his complaint, asking for immediate, unconsidered relief. After the *Sunday Times* requested time to respond in detail to his lengthy,

tendentious points, he asked that the PCC deny the *Sunday Times* its right to respond and instead rule solely based on his allegations. The PCC ultimately determined that it would stay its consideration of his complaint until it had received the determination of the GMC panel, which of course would later rule against him.[9]

L. The GMC Panel's Findings Against Wakefield

81. A GMC panel gives its conclusions in two stages. In the Wakefield case, findings of fact were handed down on 28 January 2010, a year before the "Secrets" series. Some three dozen charges were found proven against him, on a criminal standard of "sureness," which the panel, of three doctors and two lay members, made clear in its findings. One proven charge that attracted considerable public attention concerned an incident at a parents' conference in California in May 1999 at which he had joked about how he had purchased blood samples for his research from children as young as 4 years old, attending his son's birthday party, and how he said children had cried, fainted and vomited. Many other proven charges concerned further ethical misconduct: essentially of causing children with developmental disorders to be abused and exploited in a hunt for measles virus in their bowels, which he theorised came from MMR. However, I felt that the proven charges most relevant to my investigation were four concerning his dishonesty over the research.

The First Count of Dishonesty Proven to the Criminal Standard

82. The first proven count of dishonesty directly concerned the paper's content. I believe, based on many years of experience in public interest and medical journalism, that this proven count can correctly be described as one of "research fraud." In Wakefield's case, it involved an intent to mislead the medical and scientific communities and the general public on a grave issue of concern, impacting on the safety of children.

[9] A true and correct copy of the GMC findings and sanctions are attached as Exhibit 14 to the Declaration of Marc Fuller in Support of Defendants' Special Appearances.

83. Among other things, this charge said that Wakefield "knew or ought to have known the importance of describing the patient population" enrolled in the project and that he "had a duty to ensure that the factual information in the paper and provided by [him] in response to queries about it was true and accurate."

The panel ruled:

> You failed to state in the *Lancet* paper that the children whose referral and histories you described were part of a research study *project*, the purpose of which was to investigate a postulated new syndrome comprising gastrointestinal symptoms and disintegrative disorder following vaccination.

It found that Wakefield's conduct in this regard was:

> i. dishonest,
>
> ii. irresponsible,
>
> iii. resulted in a misleading description of the patient population in the *Lancet* paper;

The panel explained its reasoning:

> In reaching its decision, the Panel notes that the project reported in the *Lancet* paper was established with the purpose to investigate a postulated new syndrome and yet the *Lancet* paper did not describe this fact at all. Because you drafted and wrote the final version of the paper, and omitted correct information about the purpose of the study or the patient population, the Panel is satisfied that your conduct was irresponsible and dishonest.
>
> The Panel is satisfied that your conduct at paragraph 32.a would be considered by ordinary standards of reasonable and honest people to be dishonest.

84. The next charge also directly related to the *Lancet* paper's content. The panel noted that the paper stated that the children who were the subject of the paper were "*consecutively referred to the department of paediatric gastroenterology with a history of a pervasive developmental disorder with loss of acquired skills and intestinal symptoms (diarrhoea, abdominal pain, bloating and food intolerance)* and subsequently described them as a '*self referred*' group."

> The panel ruled that Wakefield knew or ought to have known that such a description implied:
>
> i. a routine referral to the gastroenterology department in relation to symptoms which included gastrointestinal symptoms,
>
> ii. a routine process in which the investigators had played no active part;

85. Against the criminal standard of sureness, the panel found that the referrals of Child 1, Child 9, Child 5 and Child 10 "did not constitute routine referrals to the gastroenterology department in relation to intestinal symptoms as the referring doctors referred the children for investigation of the role played by the measles vaccination or the MMR vaccination into their developmental disorders and did not report any history of gastrointestinal symptoms."

86. The panel further found that Child 2, Child 9, Child 5 and Child 12 included "active involvement in the referral process" by Wakefield. It ruled that "the description of the referral process in the *Lancet* paper" was therefore:

> i. irresponsible,
>
> ii. misleading,
>
> iii. contrary to your duty to ensure that the information in the paper was accurate;

The Second Count of Dishonesty Proven to the Criminal Standard

87. In closing arguments, on day 133 of the hearing, Kieran Coonan QC, *counsel for Wakefield*, made a formal submission to the panel. I was present. With regard to charges concerning Wakefield's use of money from the government's Legal Aid Fund, he said (emphasis is mine):

> We come to the last few points in relation to the subject of legal aid. I invite the Panel to step back and consider the reality. We say that the reality of the position is that heads of charge 3 and 4 ***amount to an allegation of fraud*** against the Legal Aid Board whether or not the prosecution is prepared to characterise it as such.

88. But that is exactly what the GMC found. Charge 4 included two counts of dishonesty, one of which was found proven. The matter concerned the grant application by Wakefield and Mr Barr to the Legal Aid Fund in June 1996. Although they had supplied detailed costings for the "clinical and scientific study," and received funding, the clinical work was in fact paid for by the National Health Service.

The Third Count of Dishonesty Proven to the Criminal Standard

89. I have previously referred to a letter submitted by Wakefield to the *Lancet* in May 1998 replying to a reader suggesting that there was some involvement of lawyers in the research. This is the letter in which he had said, "Only one author (AJW) has agreed to help evaluate a small number of these children on behalf of the Legal Aid Board", and that "no conflict of interest exists." This letter was the subject of a dishonesty charge, which I interpreted to be an example of Wakefield's after-the-fact lying. Among other things, the panel said:

> In a letter to the *Lancet* volume 351 dated 2 May 1998, in response to the suggestion of previous correspondents that there was biased selection of patients in the *Lancet* article, you stated that the children had all been referred through the normal channels (e.g. from general practitioner, child psychiatrist or community paediatrician) on the merits of their symptoms,
>
> b. In the circumstances set out in paragraphs 32.a., 34.a. and 34.b. this statement was,
>
> i. dishonest,
>
> ii. irresponsible,
>
> iii. contrary to your duty to ensure that the information provided by you was accurate;

Again, as I understood it, Wakefield had been found guilty by the panel of dishonestly describing the patient population.

The Fourth Count of Dishonesty Proven to the Criminal Standard

90. I regarded this proven charge, too, to be an example of after-the-fact lying, by which Wakefield threw sand in the face of those who tried to understand the basis of his paper. His claims had provoked so much public anxiety that, in the month after publication, a blue ribbon panel of experts was convened for a day-long conference involving some 60 senior doctors and scientists. During this event, one participant, a professor of gastroenterology, sought to understand how Wakefield had obtained the children. Among other things, the GMC panel said on this:

> a. On 23 March 1998 at a scientific meeting at the Medical Research Council convened to examine the evidence relating to measles or measles vaccine and chronic intestinal inflammation, you were asked about the issue of bias in generating the series of cases

> including the twelve children in the *Lancet* paper and you stated that all patients reviewed so far had come through General Practitioners or paediatricians by "the standard route,"
>
> b. In the circumstances set out in paragraphs 32.a., 34.a. and 34.b. this statement was,
>
> i. dishonest,
>
> ii. irresponsible,
>
> iii. contrary to your duty to ensure that the information provided by you was accurate;
>
> The Panel has taken into account that this was an important scientific meeting to consider the implications of your published research and the major public health implications arising from it.

The panel found:

> The statement you made would be considered by ordinary standards of reasonable and honest people to be dishonest.

M. The GMC Panel's Sanctions Against Wakefield

91. In May 2010, the panel reconvened in public to issue sentencing statements. Among other things, it said (my emphasis):

> ***The Panel made findings of transgressions in many aspects of Dr Wakefield's research.*** It made findings of dishonesty in regard to his writing of a scientific paper that had major implications for public health, and with regard to his subsequent representations to a scientific body and to colleagues. He was dishonest in respect of the LAB [Legal Aid Board] funds secured for research as well as being misleading … In causing blood samples to be taken from children at a birthday party, he callously disregarded the pain and distress young children might suffer and behaved in a way which brought the profession into disrepute.

And:

> The Panel concluded that Dr Wakefield's shortcomings and the aggravating factors in this case including in broad terms the wide-ranging transgressions ***relating to every aspect of his research***; his disregard for the clinical interests of vulnerable patients; his failure to heed the warnings he received in relation to the potential conflicts of interest associated with his Legal Aid Board funding; ***his failure to disclose the patent; his dishonesty and the compounding of that dishonesty in relation to the drafting of the*** **Lancet** ***paper***; and his subsequent representations about it, all played out against a background of research ***involving such major public health implications***, could not be addressed by any conditions on his registration. In addition, the Panel considered that his actions relating to the taking of blood at the party exemplifies a ***fundamental failure in the ethical standards expected of a medical practitioner***.

92. Wakefield was ordered to be erased from the medical register, with the erasure stayed pending any appeal to the High Court. He filed an appeal, but through contact with the court, I established that he abandoned this in December 2010. That month – the month

before the "Secrets" series – he was formally erased from the medical register, and the following month he was expelled from the Royal College of Pathologists.

N. My *BMJ* Reporting: "Secrets of the MMR Scare"

93. As explained at the beginning of this declaration, my initial curiosity over the 1998 *Lancet* paper was the "temporal link" by which an apparent association between MMR and autism had been generated. But, during the course of the GMC proceedings, I came to look more carefully at the other side of the project, which was a claim by Wakefield to have discovered a new inflammatory bowel disease, which he later called "autistic enterocolitis." This was a major feature of the plaintiffs' case in MMR vaccine litigation, both in the UK and the US, but I had not adequately researched this to write about it authoritatively.

94. During the GMC proceedings, this changed when I noticed yet another extraordinary feature of his research. In addition to the temporal link, the paper reported that 11 of 12 children had what was described in its Table 1 as a "histological finding" (meaning a finding under a microscope) of "non-specific colitis," (inflammation of the large bowel) and elsewhere the paper referred to a purported new inflammatory bowel disease. But, reports of the Royal Free hospital's pathology service, repeatedly read to the panel, indicated that children's colons were *healthy*.

95. The consultant pathologist responsible, Dr Susan Davies, a co-author of the paper, told the panel that, for nearly all the children, she and her colleagues had made no histological diagnosis of colitis. However, she concurred with Wakefield and others who claimed that there had been a "research review" in the medical school which had subsequently found colitis, where the pathology service had not. The panel heard that the bases of these revisions were not recorded in children's records.

96. In April 2010, after the GMC findings of fact, but before the sentencing phase, the *BMJ* published a report by me which explored this curiosity. I spoke to experts, including

Professor David Candy, a paediatric gastroenterologist who had peer reviewed the paper and recommended it for publication. He expressed surprise at the new information and told me that he believed it was wrong for the authors to have withheld the pathology service findings. My article generally suggested that, in these previously undisclosed circumstances, there was another question-mark over the paper as published.

97. My report was titled *"Autistic Enterocolitis under the Microscope,"* and led to discussions with BMJ editors over whether there was anything more that could be said, for a medical readership, about what was commonly described in Britain as the "MMR Scare." In a telephone conference, which I believe took place in June 2010, I raised various topics, and the editor in chief, Dr Fiona Godlee, commissioned three as a series.

98. In three decades in journalism, I have never spent so much time in editorial processes on one print-media project, and I have never known of articles to be subjected to such scrutiny and care, as was the case with this series. From commissioning to publication took approximately six months, and much of my basic reporting had been completed months and years before that. Although we were not all working solely on the articles for all of this period, the back-and-forth was such as I had not previously experienced.

99. At all times, based on my prior experience with Wakefield, I was mindful that the chances were high that he might initiate frivolous litigation in the High Court, or possibly lodge another time-consuming, vexatious complaint with the PCC. Apart from an admission that he was indeed the person shown in a videotape talking about buying blood from children at a birthday party, he had conceded nothing whatsoever (even where the overwhelming evidence left no room for any credible denial). It seemed possible that I would find myself back in a London court or before the PCC as a result of publishing information that I knew to be both in the public interest and true.

100. Thus, I took even greater care in my reporting than I normally would, and I observed that the *BMJ* did the same. For example, I suggested that an editor independently fact check the articles. Dr Godlee agreed, and, after repeatedly reviewing the material herself, assigned Jane Smith, a deputy editor, to perform this additional level of scrutiny. This was not because I doubted the accuracy of my reporting. On the contrary: I was eager to make myself and the extraordinary documents and other information I had obtained available for the fullest examination.

101. I also became aware that other senior editors at the *BMJ* reviewed my articles. These included deputy editor Tony Delamothe, features editor Deb Cohen, and magazine editor Trevor Jackson. The first article was additionally put out to peer review, and I learnt that this was done by a paediatrician, Dr Harvey Marcovitch. I know of no other print article to have been so extensively and carefully examined before publication.

102. During the editorial process, I attended multiple meetings at the *BMJ* offices. The first was with Dr Godlee, and we discussed the drafts of the articles, along with the most significant materials. During another meeting with her, I answered specific questions regarding various statements, and documents were reviewed. I also met for several hours with Jane Smith. She had obtained the GMC transcript (which I already had), checked my text against it in advance of the meeting, and now asked me questions and checked further material.

103. These are but fragments of an arduous process, which also involved the generation and checking of a mass of footnotes. Medical journals routinely include references to published articles and books, but I wanted something more. I wanted footnotes which would allow readers to check my factual statements, and, where appropriate, Wakefield's denials, for themselves. In my view, on a matter as controversial and filled with suspicion among some vulnerable parents as the vaccine scare, I wanted to go beyond the

expectation that I would simply be believed, or that the *BMJ*'s prestige would carry the day. Although all the supporting information could not practicably be fitted in to the printed edition of the journal, I wanted the online edition to carry factual footnotes in addition to traditional references.

104. Accordingly, the first "Secrets" report was followed by 124 online footnotes and references (compared with 39 references in the printed edition). The second report online was followed by 55 footnotes and references. The third report online was followed by 27. By this time, the GMC transcript was online, and readers could follow my footnotes to extracts of the original documents. I published further documents at my website, including, for example, material I obtained under the Freedom of Information Act.

105. In addition to the footnotes, references, and online documents, I submitted a 12-page data supplement, published online with the first report, containing two tabulations and a further 93 footnotes, making a total for that report, which is the only one of the three which Wakefield has cited in his petition, of *217* publicly checkable footnotes.

III. A Summary of the Fraud that Pervades Wakefield's *Lancet* Paper

106. I did not allege in any of the "Secrets" articles that Wakefield had engaged in "fraud." Rather, that statement of opinion was made in the first *BMJ* editorial in the series. That said, I did believe (and believed at the time of publication) that Wakefield engaged in fraud, and from about late January 2010, I squarely stated this on my website. Indeed, I believe it is beyond any serious debate that his project was a fraudulent enterprise, determined to obtain pre-agreed results. In addition, I believe (and believed at the time of publication) that Wakefield misrepresented, falsified, concealed and otherwise dishonestly manipulated the terms upon which the research had been carried out, as well as individual patient histories and diagnoses, in order to serve the aims of the speculative litigation he was supporting and his own financial interests and convictions.

A. Wakefield Needed to Show a Temporal Link Between MMR and Autism.

107. By the time I came to write the "Secrets" series, in my mind I had long since solved the riddle which had confronted me when the Wakefield paper was published in 1998. I was aware that trying to prove vaccine damage includes the essential need to demonstrate a proximate relationship between the proposed cause and the putative effect. This is invariably described in vaccine litigation literature as *"the temporal link."* I was also aware that MMR is routinely given to children at about the age at which the first behavioural symptoms of autistic spectrum disorders are generally first noticed by parents. This not only makes those parents vulnerable to suggestions that one thing caused the other, but inevitably tends to confound any possible temporal evidence.

108. During my investigation, I came upon many references in the Barr-Wakefield relationship to the fundamental need to establish a clear-cut temporal link. For example, on 22 November 1996, as the first children were being admitted for Wakefield's research, Mr Barr told the Legal Aid Board (my emphases):

> I would like to try to establish that there is ***a fairly consistent time link*** between the administration of the vaccine (MMR) and the onset of autistic features. To achieve this we have prepared a survey questionnaire (enclosed). This has been approved by Dr Wakefield… ***Dr Wakefield feels that if we can show a clear time link between the vaccination and the onset of symptoms we should be able to dispose of the suggestion that it is simply a chance encounter***.

(*See* Exhibit 12.)

109. One week later, on 29 November 1996, Mr Barr wrote to Dr Bernard Rimland, director of the Autism Research Institute in San Diego, explaining (Ex. 30):

> ***Our objective is to find out if we can establish a clear time link with the vaccine*** and to try to find out if there are any other connections.

110. At that time, this objective was at the heart of Wakefield's duties to Mr Barr. At the GMC hearing, a Legal Aid Board memo was entered into the record, minuting a meeting held on 9 April 1997 between a board official and Wakefield, Mr Barr and Barr's assistant. (*See* Exhibit 31.) Among other observations, this said:

> ***They feel confident that they can now show a temporal association at work at least*.** They now need to show biological mechanism.

111. Wakefield explicitly relied on the *Lancet* project to evidence this purported link. For example, he stressed it in a patent application, from which he hoped to gain pecuniary advantage from venture capital investors, dated 6 June 1997, claiming, among other purported inventions, his own single-shot measles vaccine. As I wrote in the *BMJ* (Ex. 32):

> "In these children the mean interval from exposure to the MMR vaccine to the development of the first behavioural symptom was six days, ***indicating a strong temporal association***," he emphasised in a patent for, among other things, his own prophylactic measles vaccine, eight months before the *Lancet* paper.

112. Indeed, a temporal link was emphasized in a Royal Free press release, approved by Wakefield, embargoed for the Saturday following the *Lancet* paper's publication. This identified both the kind of behavioural symptoms claimed to have been documented and an association in time with vaccination (Ex. 33):

> Parents reported the onset of behavioural symptoms in their children following either MMR vaccination (8 cases) or a likely measles infection (1 child previously vaccinated with MMR). ***Behavioural changes included repetitive behaviour, disinterest in play or head banging. This same temporal association with MMR has been observed by workers in the United States.***

113. Later, Wakefield invoked the same association, calibrated in just *days*, in another patent document, published in December 1998. (Ex. 34) (my emphasis):

> Before vaccination the infants were shown to have a normal developmental pattern but ***often within days of receiving the vaccination some infants can begin to noticeably regress*** over time leading to ***a clinical diagnosis of autism***.

114. The following month, in a January 1999 confidential report to the Legal Aid Board, which I obtained from a disenchanted former Wakefield supporter (Ex. 35), he told his funders:

> There is a consistent temporal relationship between exposure to MMR and the onset of behavioural symptoms, whether the parents made a contemporaneous link between these two events or not.

115. Although resting on just eight children, so central was this temporal link that he was questioned about it at the GMC hearing:

SMITH (Reading to Wakefield a letter written by Mr Barr): "Dr Wakefield feels that if we can show a clear time link between the vaccination and the onset of symptoms we should be able to dispose of the suggestion that it is simply a chance encounter. The reason for this is that there is quite a wide range of ages between which the vaccination is administered. If we can show that the onset of the autism is related in time to the vaccine we should be able to establish the point that it is no coincidence that children become autistic after the vaccination."

(To Wakefield) So that would appear to be Mr Barr saying that you were of the view that that temporal link between vaccination and onset of symptoms was important to the litigation.

WAKEFIELD: Yes, I think the attempt here was to conduct what would have been a very large study, a survey of all the clients reported, to determine if a pattern could be observed, again in relation to single exposures, re-exposure, but to see if that temporal association was there in a large group.

SMITH: Because you were of the view that it was important to the litigation to show a clear time link between vaccination and the onset of symptoms?

WAKEFIELD: It would have assisted in the analysis, yes.

SMITH: Would you go now to FTP3, please, page 1079. This is a further costing proposal but without any costs on it – a costing proposal to the legal aid board. We have looked at this before. Do you have the page?

WAKEFIELD: I do.

SMITH: We see just over half-way down:

"The evidence so far includes: – A striking temporal relationship between MMR exposure and onset of symptoms in many children."

So again an acknowledgement of the importance of that temporal relationship in the litigation.

WAKEFIELD: Again I am not a lawyer and I cannot speak to the merits of a temporal association alone in determining causation, but it is weak evidence on its own.

SMITH: Would you go to the medical records of Child 12, please, Dr Wakefield – the Royal Free records, page 9. Again, we have been to this document. This is the vaccine damage questionnaire document. If we turn to page 11, we see your signature and the date which was January 1998. On page 9, at question 1(d) the question is asked:

"In your view what is the cause of this child's diagnosis?"

You say:

"MMR at 15 months: Loss of speech development and deterioration in language skills at 16 months. Temporal relationship makes MMR likely cause."

This is one of the *Lancet* children, as we have discussed, is it not?

WAKEFIELD: Yes.

Exhibit 12.

B. The Fraud at the Heart of Wakefield's *Lancet* Research and Paper.

116. At face value, the *Lancet* paper appeared to be a description by independent researchers of a routine series of child patients attending a hospital bowel clinic in London. But even in the light of my 2004 reporting, which led to the retraction of the Interpretation, I believed it was obviously a concoction. It was a contrived exercise, executed in cahoots with a lawyer and MMR campaign groups. From the outset, the project was meant to create apparently scientific grounds for a product liability lawsuit, but without revealing this, as such a revelation would defeat the object. It was based on children *selected*, and, the GMC found, sometimes *targeted*, from families (*none* of whom lived in London) individually *coached* by Wakefield, who he knew he could rely on to criticise the vaccine when they got to the hospital.

117. The paper's first *"finding"* – that the "onset of behavioural symptoms was associated, by the parents, with measles, mumps, and rubella vaccination" – was thus a manufactured artifact of Wakefield's concealed recruitment strategy, and was no kind of "finding" at all. An honest researcher would have declared what he knew, and which, *finally*, under cross examination on day 66 of the GMC hearing, Wakefield admitted he knew: that the association between bowel issues, developmental disorders and concern over MMR had not been *found* but was part of the project's *"methods"*. It was the essential qualification for admission (Ex. 12) (my emphasis):

> SMITH: What I am suggesting to you and what I now want to ask you is where you make it clear that the children had come to the Royal Free in the first place, at least in the majority of cases, in the letters that we have looked at, because their parents, or in some cases their doctor through their parents, thought that MMR might have caused the damage?
>
> WAKEFIELD: That is implicit to anyone reading this paper. When we talk in the discussion about a possibility of a referral, selection bias, in a self-referred group, the group is self-referred because of the symptoms manifest by the children, including the history of a possible exposure to a vaccine or an infection that has led to the problem, and then seeking help from a specific unit. That is explicitly what self-referral means. Inherent in that is, to the reader, those elements of the history of the patient that have caused them to come to that unit. To anyone reading this, we would have considered that to be self-evident. ***Self-referral on the***

basis of one or more of the symptoms of gastrointestinal problems, developmental regression and an association with environmental exposure...

118. During the GMC hearing, he also admitted that he had contacted the parents of each of the children, generally by telephone, prior to their attendance at the hospital. I have previously given examples of how local doctors were also approached and briefed. This undisclosed pre-referral activity created a severe, unwarranted and secret selection bias in the study, and was bound to taint later history-taking by clinicians. Not least because, having spoken to Wakefield (who records show often suggested that the children, who he had never seen, might have Crohn's disease), the parents were understandably anxious to get their child admitted to a hospital suggesting it might be able to help.

119. The concealment of this activity could only have been expected to mislead the *Lancet*'s peer-reviewers, editors and readers into thinking that the 12 children were purely routine referrals, and that a striking accumulation of parental criticism of MMR was a cause for concern. The truth, however, was that the children were the first admissions for a project which, over a period of years, turned the hospital's children's bowel clinic into a covert litigation factory, generating clients for Mr Barr, and High Court claims of alleged vaccine damage, which did nothing to help the children but were immensely lucrative for Wakefield.

120. However, as illustrated by the cases of Child 1, Child 8 and Child 9 I reviewed above, even in the face of all this activity, the hospital's clinicians and pathologists did not generate the data Wakefield needed to fulfill his contract with Mr Barr.. To accomplish this, his fraudulent enterprise went into deeper territory: misreporting precisely what he needed to misreport to obtain the results he wanted.

C. Wakefield's Gross Misreporting: The Discrepancies Between the Versions

121. In my first report in the "Secrets" series, I briefly referred to an earlier, unpublished, version of the *Lancet* paper. I attach a copy of this earlier version, which I obtained in late 2005 or early 2006, as Exhibit 37. When I obtained this version, it was

already dated in handwriting "Aug 1997", which was about six months *after* the last of the 12 children was investigated, and about six months *before* the paper purporting to describe them was published in February 1998.

122. To my knowledge, the authenticity of this draft is uncontested. Assisting verification, I obtained under FOIA a letter dated 4 August 1997 from Walker-Smith, supplying the pre-publication version to another senior doctor at the hospital, Professor Brent Taylor (Ex. 38). I have spoken to Professor Taylor, who confirmed to me that Exhibit 37, attached hereto, is a copy of the document supplied to him. I also obtained a letter from Wakefield to Taylor, dated 14 January 1998 (Ex. 39), attempting to trace individuals in possession of what Wakefield called this "early version of our paper" and asking Taylor about who else may have it.

123. In my judgment, at least as of February 2006 and at all times thereafter, this version of the paper (which Walker-Smith says in his letter was submitted to the *Lancet*) contains data which, if compared with the published version, arouses serious concern. Side-by-side comparison demonstrates that (long after the child patients had left the hospital) evidence which purportedly linked their disorders with vaccination was progressively *altered*. Moreover, it was altered at a time when Wakefield working with Mr Barr to try to prove the existence of the "new syndrome" linked in time with, and purportedly caused by, MMR.

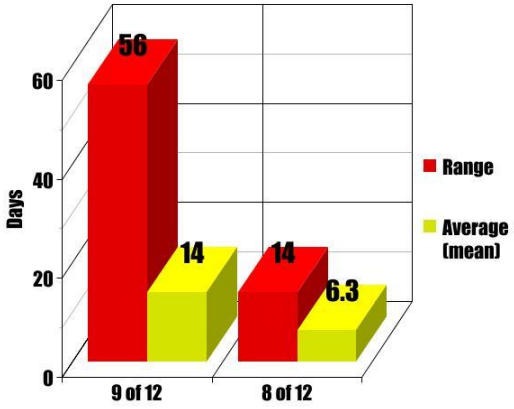
124. Both the August 1997 and February 1998 versions of the paper contain a 14-day temporal link. But in 2006 I noticed that, while the published paper invokes 14 days as the *maximum* time (with an *average* of just *6.3 days*) between MMR administration and what Wakefield called the "first behavioural symptom" of a "behavioural diagnosis" of "autism", the pre-publication version is *different*. This version reports 14 days as the *average* time (with a *maximum* of *56 days*): a substantially longer interval. Thus, in the second half of

1997, long after the children had gone, the purported temporal link associating vaccination with autism was dramatically *tightened*, and yet curiously retained 14 days.

125. A second difference between the versions, which I noted in 2006, is that one of the patients' histories was reinterpreted so as to *remove* a critical parental allegation of a link between the vaccine and autism. In the August version, the parents of *nine* of 12 children (three-quarters) are reported to have made this association. But in the published version, six months later, the parents of only *eight* (two-thirds) are said to have done so.

126. In fact, as I have said, Royal Free records clearly show that the parents of *11* children actually made the critical allegation at the hospital. With regard to the two versions, however, it is clear that *nine* of 12 was *changed* to *eight* of 12. Nothing I have seen explains this, and I cannot think of any convincing explanation.

127. The following graph demonstrates the effect of this change:



128. The bars on the left represent data in the draft, while those on the right reflect those in the published paper. As the graph shows, by the simple act of removing *just one* parental complaint against the vaccine, the temporal link tightened from an *average* of 14 days to a *maximum* of 14 days.

129. In addition to tightening the temporal link between the shot and onset of symptoms, Wakefield's manipulation of the data had the effect of simultaneously making it more believable. Based on many years of medical journalism, discussion with scientists and

knowledge of the *Lancet* editor's disposition, I thought in 2006, and at all times subsequently, that if Wakefield had revealed the true position, which was that 11 of 12 families had associated MMR with their child's problems when they came to the hospital, it would have unmasked the covert nature of the patient group and fatally damaged his mission for Mr Barr.

Further Alterations Between Versions of the Paper

130. The temporal link and the number of parents said to be complaining about MMR were by no means the only changes that Wakefield effected between versions. And, as a comparison I prepared in 2006 tabulates (Ex. 40), all changes capable of doing so pointed in the same direction. This was either to *increase* the apparent pathology, or to *obscure* the methods by which that pathology was supposed to have been found.

131. In addition to the changes tightening the temporal link, the reporting of gastroenterology was also altered. *Firstly,* the number of children whose colons were reported to be *"endoscopically normal"* (meaning that they looked normal to an endoscopist viewing the bowel on a TV monitor) *fell with the passage of time*. Notwithstanding the last endoscopy having been performed about six months before the August version, between August and the following February the number of children whose guts were reported to be endoscopically normal *went down*: from *6 of 12* (one half) to *4 of 12* (one third). Given that endoscopists report their observations at the time of the procedure, I could think of no proper explanation in what was held out to be a clinical case series of reports.

132. *Secondly,* the number of children reported in the paper as having a "red halo" around lymphoid follicles in the gut (also determined by observation and suggesting inflammation) *doubled* over time: from *2 of 12,* in August, to *4 of 12* in February.

133. *Thirdly,* the number of children reported as having "patchy" inflammation in their colons – possible disease as determined by "histology" (meaning pathologists looking at tissue samples under a microscope) – *rose* between versions: from *eight of 12,* in August, to

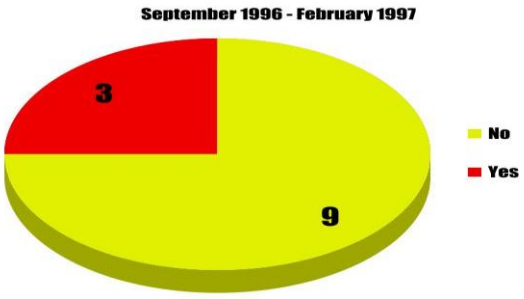
11 of 12 the following February. This change alone reclassified the findings in the colons of *one quarter* of the children: from *healthy* to *diseased.*

134. *Fourthly*, (although Tables 1 and 2 are missing) details were given in the pre-publication version with regard to the only female patient (Child 8). In the August version, her gastroenterological tract was said to be *"normal"*, both endoscopically *and* histologically. But in the published paper, six months later (following no fresh investigation of the child, who lived 280 miles away), her small bowel was said to have endoscopically "prominent ileal lymph nodes" and she was reported to have histologically "acute and chronic non-specific colitis; reactive lymphoid nodular hyperplasia". Again, *health* was changed to *disease*.

135. Even in 2006, I was concerned about these changes, and discussed them with various doctors and scientists. My concerns increased as I followed the GMC case, where it was revealed that the hospital's pathology service had reported largely *normal*, *healthy*, histological findings from the children's guts. These findings were then reported to, and approved at, weekly sessions with clinicians. Yet Wakefield's paper reported that 11 of the 12 children's guts were *diseased* with what he called *"histological findings"* of colitis.

136. So, the pathology service data (1), plus the August version (2) and the final published paper (3) gave *three different stories* with regard to the inflammatory health or otherwise of the children's bowels. The following three pie charts illustrate the effect of these alterations:

The first reflects results from the hospital pathology service, as the children were admitted between July 1996 and February 1997. "Yes" means, broadly, colitis:



Then in the pre-publication version:

Finally, in the published paper:

137. As I have said, during the GMC hearing, Dr Susan Davies, a *Lancet* co-author and the consultant histopathologist supervising the pathology service involvement in the project, testified that hospital pathologists had generally not found what she would call "colitis". She went on to explain her understanding that Dr Amar Dhillon, another consultant histopathologist, had performed a subsequent "research review" in the medical school attached to the hospital. However, with data available from three stages of the project, it becomes clear that results must have been changed at least *twice*. Again, I can conceive of no legitimate, good-faith explanation for these additional, unreported, changes to a clinical case series.

Yet More Alterations

138. Still further anomalies emerged as I compared the August 1997 version with the text published the following February. One fringe aspect of the research was to test the 12 children, and a number of alleged controls, for methylmalonic acid (a measure of vitamin B12 status). The changes here were bizarre. Most striking was that the number of patients

reported to have been tested in this regard *went down with the passage of time.* In August, the number tested was *11* children. But by the next February it was only 8.

139. In another instance of alteration, the August version of the paper gave information on the number of ileo-colonic (small and large bowel) biopsy series (tissue samples) taken from allegedly "matched" controls. The control samples were said to be from histologically *normal* mucosa taken during procedures on *other children* (for purported comparison with the *Lancet* children). The pre-publication version said there were *ten controls*. However, six months later the number fell to only *five controls*.

140. I knew from my previous journalism that the manipulation of controls (comparator patient or materials data) is a well-known means of exaggerating research findings. I found it difficult to understand how, over time, and after a manuscript has been submitted to a journal, the number of controls can *go down* without some form of *post-hoc* manipulation.

141. According to the published paper (at page 638, col 1, and in the acknowledgments at 641), five *age-* and *site-matched* control specimens (meaning that the *age* of the subjects and the *place in the gut* from which the tissues were taken were the same as those reported from the 12 subject children) were supplied to Wakefield by Professor Paola Domizio of the London Hospital. Speaking to me in 2011, she confirmed a statement in an expert report she supplied in 2003 for the product liability litigation (and which I first read in 2005). In this report, she declared that she had supplied *ten* control specimens for the Royal Free project. Moreover, she said they were *not* labeled for age or site. If she is correct, therefore (and I believe her to be an experienced histopathologist of considerable professional standing), the controls *could not have been matched*, as Wakefield claimed in the *Lancet*. I attach a copy of the relevant page from her report as Exhibit 41.

142. I do not know who selected the five from Professor Domizio's ten, but precisely which samples were chosen could have had a substantial impact on any comparisons with the *Lancet* children. For example, *normal, healthy* inflammatory responses may commonly be greater on the right side of the colon than on the left, and also whoever picked the samples could have selected those with the *least* inflammatory changes. Such changes would have been slight (if any) variations in the numbers and types of particular cells viewed on slides. "Inflammation" in this context is not what a lay person would likely assume. Selection of what might be called the five "cleanest" controls from the ten would, by comparison, have made biopsy samples from the *Lancet* patients appear to pathologists to be *more* inflamed than they otherwise might. In any event, the claims of age- and site-matching (which would have helped to reassure editors, peer reviewers and readers about the rigor of Wakefield's research techniques and the robustness of his claim to have discovered a putative new "syndrome") were, on Professor Domizio's account, false.

D. Wakefield's Gross Misreporting: The Pro Forma Records

143. In one of Wakefield's prior lawsuits against me in the UK (*Wakefield v Channel 4 & Ors.*), his lawyers in 2006 disclosed to me a series of Royal Free pro forma reports, aggregating histories and other data from the children. These were documents from *his* research, supplied by *him*. Indeed, he relied on pro formas from this series in his book, perversely titled *Callous Disregard*, the relevant chapter from which I have attached as Exhibit 42.

144. Wakefield abandoned his lawsuit before trial so, in accordance with UK civil procedure rules, I did not report the contents of these documents in my articles. They were, however, in my mind at the time I wrote the "Secrets" series, and they informed my evaluation of his research and integrity. The forms were powerful confirmation that there was something seriously wrong with the *Lancet* paper and with his conduct in writing it.

145. I attach as Exhibits 43-47 copies of five of these forms: specifically those for Child 1, Child 6, Child 12, Child 11 and Child 5, respectively. These are half (four) of the eight children whose parents were reported in the paper to have blamed MMR, plus one of three further children whose parents' made the same critical disclosure when they came to the hospital, but which was withheld from the journal so as to generate the published *eight of 12* figure. The reports are headed:

> Report on the investigation into the possible link between viral exposures and developmental disorders in children

146. When passed from Wakefield's London lawyers to my London lawyers in 2006, these reports (and others from the *Lancet* series) were redacted on their first pages for the children's names and other identifying information. The reports came to me bundled together with some three dozen further such reports on children who were not included in the *Lancet* series. Thus, effective redaction of the identifying information would render the documents useless to me for any substantial evidential purpose. I would be in a similar position to Wakefield's co-authors when they reviewed the paper before publication. I would not know which child was which and, therefore, would be unable to cross-check data.

147. However, perhaps following oversight by Wakefield's lawyers, I found that each child's name and hospital patient number had survived, unredacted, in a histology section inside each report. Thus, vital information about what he knew of these patients was revealed to me.[10]

Child 1 – Exhibit 43

148. According to Table 2 of the paper, in the case of Child 1, the *"interval from exposure to first behavioural symptom"* of what was tabulated as a subsequent *"behavioural*

[10] Some of the reports were missing from the disclosure, including those for Child 2 and Child 7. In Exhibits 43-47, I have redacted the information identifying the children. Also, some years ago, for my own reference, I made a few handwritten notes on the documents, and on the first page I pasted a portion of text taken from a table contained in a bespoke document served on me by Wakefield during the previous lawsuit. These should generally be disregarded.

diagnosis" of autism was given as *"1 week"*. As I have previously shown, this brief interval – even for just this first of the eight children – was critical to generate the paper's 14-day maximum/6.3 day average temporal link. This link was the paper's only evidence incriminating MMR as a possible cause of autism. Moreover, it was not left as a mere parental allegation, but was adopted *as fact* and tabulated *as fact* – purportedly supported by a review of children's records.

149. However, the Royal Free report at Exhibit 43 disposes of any such claim, and confirms hospital records presented at the GMC hearing. At page 3, a box asks whether the child's initial development was normal, and, if answered *"Yes"*, asks *"If Yes, until when?"* It then gives *"Age"*, and provides a box to be completed. The box was completed:

> 18 months

150. At page 5 of the report, the age of the child at the date of MMR vaccination is given as: *"12 months"* (with the date). Thus, according to confidential records from the project, disclosed in litigation, the child is reported to have experienced normal behavioural development (which obviously must preclude symptoms of autism) for *six months* after MMR, and not *one week* as claimed in the paper.

151. But exactly what was the first *"behavioral symptom"* (precursor to a purported *"behavioural diagnosis"* of autism), according to his own project's pro forma record-keeping? Returning to page 3, the report contains a box headed: *"Initial behavioural abnormality (specify):"*

152. The box is completed in terms *entirely incompatible* with the *Lancet* paper, and *entirely compatible* with the case presented at the GMC and in the *BMJ*:

> At 18 months noted to have lost words and no longer progressing in speech, comprehension and social interaction.

153. Moreover, despite Wakefield's claims in the *Lancet* and throughout his campaign against MMR (including a core distinction he made between "regressive" and

"classical" autism) that this child had *regressive autism*, a box on page 3 is headed *"Initial diagnosis:"*. There are no other diagnosis boxes completed on the form. This box is completed:

> Classical Autism

154. Finally with regard to Child 1, page 5 contains a box with the heading: *"Adverse reactions, related vaccine and interval from first symptom:"* This is answered (my emphasis):

> 7-10 days after MMR vaccination [Child 1] had a brief illness – pale, ***possibly*** pyrexial and delirious.

155. Thus – as evidenced at the GMC hearing and accurately explained in the first "Secrets" article – the *only* symptom reported to have been positively asserted by the mother as associated in time with MMR was that, 7-10 days later, her son was *pale*. And yet, deleting question-marks, Wakefield adopted *as fact* that this (*possibly* feverish) episode was the first *"behavioural symptom"* of regressive autism*"1 week"* after MMR, and used it to generate the bogus 14-day maximum/6.3 day average temporal link.

Child 6 – Exhibit 44

156. On page 1 of Child 6's Royal Free report is a summary box headed *"Clinical diagnosis"*. It is completed:

> Lymphonodular hyperplasia, non specific colitis and Aspergers

157. On page 3, the report asks with regard to the patient *"Initial development – normal:"* so as to ask a question to be answered. It may be recalled from the *Lancet* "abstract" that the paper's Interpretation section described the patients reported within it as "a group of *previously normal* children" (my emphasis).

158. Nevertheless, in response to the pro forma question as to whether Child 6's initial development was *normal*, the report answers squarely:

> ***No.***

159. Also on page 3 is a box headed *"Initial diagnosis:"* The box is completed: *"Aspergers Syndrome"*. Wakefield, however, did not enter this information in the *Lancet*. According to the paper, this child had a "*regressive developmental disorder"* with Table 2 falsely completed *"Autism"*.

160. Asperger's syndrome is neither a regressive developmental disorder, nor is it, by definition under the nosology claimed in the paper to be relied upon by Wakefield, a "behavioural" or "developmental" diagnosis of autism. Subsequent boxes on page 3 of the report show that Child 6 was diagnosed at a specialist child development centre in Brighton (60 miles south of London) by a specialist paediatrician, and confirmed at Guy's hospital, London (a flagship UK medical centre), by a Dr Gillian Baird, who I established (and made a note of on the form) to be a "consultant developmental pediatrician" at a specialist assessment unit.

161. No developmental paediatrician saw this boy at the Royal Free, which had no centre for developmental issues and (probably unknown to the parents) almost no expertise in evaluating them. Nevertheless, a final box on page 3 is headed: *"Current diagnosis (RFH):"* (meaning Royal Free Hospital). The box is completed:

> Aspergers Syndrome (most likely).

162. In 2007, or thereabouts, I appended a handwritten note stating (from the GMC proceedings) that this tentative diagnosis was confirmed in a "Berelowitz letter to W", meaning a letter from the Royal Free child psychiatrist, Dr Mark Berelowitz, to Wakefield. Indeed, the information contained here (and elsewhere in the pro forma reports) is wholly consistent with material presented at the GMC and accurately reported in the *BMJ*.

163. Among other things, on page 4 of the report for Child 6 is a tabulation of vaccinations received by this little boy, with the dates of administration. The tabulation notes a third DTP vaccination on 1 January 1992 and an MMR vaccination, 18 months later, on 15

June 1993. Turning to page 5, we come to a box headed *"Adverse reactions, related vaccine and interval from first symptom:"* This is followed by two paragraphs, one relating to DTP and the other to MMR (My emphasis):

> After 3rd DPT vaccination [Child 6] was described by [his mother] as crying too much and having a high pitched scream 5 minutes post vaccination. This persisted for 12 hours. [Child 6] then described as having an ***episode of 'two tone colour' – near cot death – admitted to the Ipswich Hospital for 2 days*** for observation.
>
> ***Fever, constant cold and blotchy rash one week after receiving MMR vaccination.*** This lasted for 2 weeks. Behaviour became aggressive. 2 months later [Child 6] developed abdominal pain prior to defaecation, sometimes passing blood and mucous in stool.

164. We then learn from the report the surprising information that the mother did not even initially blame MMR at all. Returning to page 4, we find a box headed *"Outcome/complications (specify infection and complications):"* which is completed only with regard to MMR It says (my emphasis):

> Measles rash noted by [Mrs 6] ***1 week prior to MMR vaccination.*** Dr advised that MMR be administered regardless. (history taken by Professor Walker-Smith at OPA on 02.10.96.
>
> Reported by GP Dr Ball in a letter dated 03.04.93 that [Mrs 6] concerned that ***since measles infection*** [Child 6] had been generally unwell. Reported as developing sudden pyrexia's and listlessness.

165. In fact, other medical records presented at the GMC hearing showed that the measles infection was some *three months* before MMR and not one week as evidently misreported to Walker-Smith by the mother when she came to what is reported above as the "OPA" (outpatient appointment – before admission). It should be noted that GP Dr Ball's letter of *1993*, referring to measles, was written before the mother had heard of Wakefield.

166. In summary: Wakefield claimed in the *Lancet* that Child 6 was "*previously normal*" and showed the *"first behavioural symptom"* of *regressive autism "1 week"* following MMR. But there is nothing in this Royal Free report, or in the contemporaneous documentation reviewed by the GMC panel, to substantiate *any* of these claims.

Child 12 – Exhibit 45

167. As with Child 6, Wakefield asserts in Table 2 of his paper that Child 12 had a *"behavioural diagnosis"* of "Autism". However, the Royal Free report on this child, again, tells a different story. On page 1 is a box headed *"Clinical diagnosis:"* This box is completed:

> Aspergers Syndrome
> Ileal lymphonodular hyperplasia and mild colitis

168. As I will explain below, under the nosology explicitly stated by Wakefield to have been employed, Asperger's syndrome is a *different diagnosis* to autism, and is not regressive.

169. I believed, in 2006 and at all times since, that the reason Wakefield did not tabulate the true diagnosis was because, prior to the UK MMR litigation being filed (in October 1998), he was attempting to convince the *Lancet*'s editors, peer reviewers and readers – and also most vitally his funders at the Legal Aid Board – that he had discovered a coherent "new syndrome" of *regressive autism* and inflammatory bowel disease, putatively caused by MMR.

170. At page 3 of Child 12's report, the diagnosis is restated in terms wholly concordant with records presented at the GMC hearing. A box headed *"Initial diagnosis:"* is completed *"Aspergers 11 September 1996"* This date is one month after the boy first attended an outpatient clinic at the Royal Free. Another box, at the foot of page 3, is headed: *"Current diagnosis (RFH):"* It is completed:

> Language Delay
> Possible Attention Deficit Disorder
> Possible Features of Asperger's

171. Language delay is not an autistic spectrum disorder, and there is no reference in the report to any diagnosis of autism.

Child 11 – Exhibit 46

172. The report for Child 11 contains information suggesting that it is based at least in part on a medical report which the parents (who travelled with their son from California) had sent to Wakefield in January 1997 (Ex. 48). At page 5 of the pro forma, a *"vaccination history"* box contains information for "MMR". It gives the date he received the vaccine as:

> 7.5.92
> (15 months)

173. Returning to page 3 of the report, at the top of the page is a summary section. This asks the question: *"Initial development – normal:"* which is answered: *"Yes"*. In the following line, the question is asked *"If Yes, until when?"* The question is answered with *"Age"* and then a box for the age to be given. The box has been completed:

> 13 months

174. This date would be *before* Child 11 received MMR.

175. Also at page 3 is a box headed: *"Initial behavioural abnormality (specify):"* The first line of the response is completed thus:

> 18 months: Slowed speech patterns ?one history says symptoms from 13 months

176. At page 5 of the report, following a *"vaccination history"* table, is a box with several headings, the first of which is *"Adverse reactions, related vaccine and interval from first symptom:"* This box is completed:

> MMR: Viral infection, with cough & intermittent fever. Followed by viral pneumonia. Suggested Mycoplasmium pneumonia

177. A second heading asks: *"By whom was the reaction noted?"* The answer is given:

> Doctor visited (9.6.92 & 23.6.92)

178. On this detailed and specific information, plainly drawn from records, the doctor first visited 32 days after Child 11 (whose parents are wealthy and highly educated) received MMR. This visit was in response to an apparent *viral chest infection*. This is clearly not a

credible example of what the pro formas call an *"initial behavioural abnormality"* and the *Lancet* paper – meaning the same thing – calls a *"first behavioural symptom"*.

179. And yet, notwithstanding 32 days elapsing before the doctor arrived, and notwithstanding the diagnosis of a viral infection, Wakefield's paper tabulates the *"interval from exposure to first behavioural symptom*" for this boy as "*1 week*" – a claim unsupported in any aspect anywhere in the pro forma report, or even later in Wakefield's book. This claim was further denied by the father, in 2011 correspondence to me and Daniel Olmstead (a Wakefield cohort), as an *"outright fabrication"* (Ex. 49).

180. And, yet again, this bogus "1 week" interval – exactly the same time period as falsely reported for Child 1 – was critical to Wakefield's mission.

Child 5 – Exhibit 47

181. I have previously explained that Wakefield omitted *three* parental disclosures of an alleged MMR-autism association, so as to reduce the *11 of 12* figure logged at the hospital to *8 of 12* and thereby obtain the 14-day maximum/6.3 day average temporal link. As I state in the first "Secrets" report (with its footnote 92), Royal Free records show that the parents of Child 5 were among those who blamed MMR for the onset of their child's autism, but whose critical disclosure at the hospital was withheld from the paper. The pro forma report confirms this. A box at page 3 is headed *"Initial behavioural abnormality (specify):"* This is completed:

> Loss of language – less sociable – began making strange noises.
> Lost interest in his surroundings.
> Diagnosed as deaf at 2 years of age.

182. Under a *"Vaccination history"* table on page 5 is a box with three headings, the first of which is "*Adverse reactions, related vaccine and interval from first symptom:".* The response is completed:

> MMR – 2 months later 'growling voice' and loss of speech.

183. The second heading asks *"By whom was the reaction noted?"* This is answered:

Parents

184. Nevertheless, Table 2 of the paper records the *"Exposure identified by parents or doctor"* as *"None – MMR at 16 months"*. The child's case, with its inconvenient two-month time-frame, is also omitted from the calculation performed by Wakefield to generate the 14-day maximum/6.3 day average temporal link.

185. This child's gastroenterology status was also altered. On page 6 is a box with details of colonoscopy findings, giving the endoscopist's name (Dr Simon Murch) and the procedure date. Under *"Findings"* is a paragraph which concludes with the sentence (my emphasis):

> There were prominent follicles in the ileum, but ***not sufficient to call lymphoid hyperplasia***. The ileal mucosa appeared fully normal.

186. The title of Wakefield's paper, and his claim of a new bowel disease, included the expression "ileal lymphoid nodular hyperplasia" (LNH) – meaning swollen lymph glands in the distal small bowel. However, as can be seen here, the endoscopist explicitly *ruled out* this finding for Child 5. I attach a corresponding extract from the GMC transcript as Exhibit 50, where an identical text of the endoscopy report was evidenced.

187. Nevertheless, for the paper's Table 1, the finding was altered – from an entirely *normal* observation in the small bowel to one of purported *disease*. Under "Endoscopic findings" the paper records:

> LNH of T ileum

Once again, the data was *changed* and *misreported.*

E. Wakefield's Gross Misreporting: The *Channel 4* Admissions

188. In addition to the inadequately redacted pro formas, in his lawsuit against Channel 4 and myself Wakefield's lawyers provided me in November 2006 with verified information making a substantially different factual case regarding the times which elapsed between MMR administration and the onset of behavioural symptoms to what was reported

in the *Lancet*. (*See* Ex. 17.) In what is known in England as a "Part 18 request for information" from the defendants, Wakefield tabulated, above a signed statement of truth, what he said were the "Behavioural and other symptoms reported to the Claimant". This table set out not only what he meant by "behavioural symptoms"[11], but also children's ages and the purported times to onset of these symptoms after vaccination.

189. As with the pro formas, an effort had been made to withhold information from us which would identify the children. Specifically, the "behavioural and other symptoms" were double-anonymised, not only by withholding the children's names, but also by assigning them random numbers, so that, for examples, the first child was tabulated with reference number 9, and the second with the reference number 7. But, despite these efforts, the 12 children had been left tabulated in the same sequence as they were in the paper, meaning that once their identities were revealed in the pro formas, and other factual cross-checks performed, it was possible to read the table child-by-child.

190. In six cases from this 2006 tabulation, the temporal links were substantially different to those in Table 2 of the paper (with five of these altered cases among the vital eight where parents were reported to have made an association between MMR and autism). Three cases were capable of reconciliation, while a further three were not capable of proper comparison due to missing or internally contradictory information. Of those where the data was different, the ages and times to onset given were at sharp variance with the paper, and were *invariably* older and longer.

[11] Developmental regression; loss of words; stasis of speech, comprehension and social interaction; became clumsy, walking into things; head-banging and screaming; became destructive; dribbling; toe walking; hand flapping; aggression; complete loss of speech; stopped walking round furniture and regressed to crawling; appeared to stop learning; repetitive behaviours and could no longer hold a cup; "disappeared"; making strange noises; lost interest; socially unresponsive; aggressive behaviour; convulsion; secondary incontinence; ataxia; seizures; myoclonal jerks; lost eye contact; lost play interests.

Child 1

191. In *the Lancet*, Wakefield reported the "Age at onset of first symptom – Behaviour" for Child 1 as "12 months". In his 2006 statement in *Channel 4*, however, he claimed that the "Behavioural and other symptoms reported to the Claimant" were "Normal development to approximately 18 months, followed by developmental regression with loss of words and statis of speech, comprehension and social interaction…"

Child 2

192. In the *Lancet*, Wakefield reported the "Age at onset of first symptom - Behaviour" for Child 2 as "13 months". In his 2006 statement in litigation, however, he claimed that the "Behavioural and other symptoms reported to the Claimant" were "Normal development to approximately 15 months. Following MMR at 15 months became clumsy, walking into things, within a few days. Progressed to head-banging and screaming by 2 weeks. Became destructive, started dribbling and toe walking…"

Child 6

193. In the *Lancet*, Wakefield reported for Child 6 that the "Interval from exposure to first behavioural symptom" was "1 week". In his 2006 statement in litigation, however, he claimed that the "Behavioural and other symptoms reported to the Claimant" were "Onset of rash, fever, drowsiness, aggressive behaviour and convulsion within 2 weeks of MMR vaccination, followed by developmental regression, secondary incontinence and clumsiness."

Child 7

194. In the *Lancet*, Wakefield reported for Child 7 that the "Interval from exposure to first behavioural symptom" was "24 h". In his 2006 statement in litigation, however, he claimed that the "Behavioural and other symptoms reported to the Claimant" were "Within one month of MMR at 21 months, developed ataxia and developmental regression. Suffered

seizures and longstanding headaches. Unexplained developmental regression. Diagnosis Asperger's syndrome."

Child 10

195. In the *Lancet*, Wakefield reported the "Age at onset of first symptom – Behaviour" for Child 10 as "15 months". In his 2006 statement in litigation, however, he claimed that the "Behavioural and other symptoms reported to the Claimant" were "Normal development to 16 months. After an apparent measles infection at 16 months developed rash, fever, vomiting and reduced level of consciousness. Over following 4 months lost eye contact, verbal skills, social and play interests and developed repetitive behaviours."

Child 11

196. In the *Lancet*, Wakefield reported the "Age at onset of first symptom – Behaviour" for Child 11 as "15 months". In his 2006 statement in litigation, however, he claimed that the "Behavioural and other symptoms reported to the Claimant" were "Developmental regression starting at 18 months with loss of speech, repetitive hand movements, reduced eye contact, progressing to complete loss of speech by 2.5 years."

F. Wakefield's Gross Misreporting: The Children's "Diagnoses"

197. At some time in 2004, I was told by a senior paediatrician that paediatricians in the Brighton area of England had indicated to him that they knew of patients included in the paper who were claimed by Wakefield to have regressive autism but who the paediatricians believed did not have autism at all. However, such is medical confidentiality that my source did not know the identities of the children, and, even if he did know, he would not have disclosed them to a journalist. Subsequently, first in discovery in *Channel 4*, and then in public sessions of the GMC, it became clear that this rumour was well founded.

198. Extraordinarily, I discovered that two of these children (Child 6 and Child 7 in the Wakefield series) were brothers, and that the mother of the third child (Child 12) had

been referred to Wakefield, and simultaneously to Mr Barr, by the mother of the brothers (who must therefore also be inferred to have been involved with contemplated litigation prior to her children's admission to the hospital).

199. On the paper's first page, Wakefield described all of the 12 children as suffering from "regressive developmental disorder" and, in Table 2, assigned to 9 of them what he alleged to be a "behavioural diagnosis" of "autism." But at least these three Brighton children did not have regressive autism, or, in fact, any diagnosis of autism.

200. Under "Patients and methods – Clinical Investigations" (page 637), the paper claims that children were neurologically and psychiatrically assessed against DSM-IV criteria (actually misspelt "HMS" in the text), with footnote 1 leading to the Diagnostic and Statistical Manual (DSM-IV), 4th edition, published by the American Psychiatric Association in 1994. This definitive manual lists the pervasive developmental disorders and clearly distinguishes autism and Asperger's Disorder as *different diagnoses*. I attach the official DSM-IV classifications, taken from the DSM-IV Handbook, published in 1994, as Exhibit 51.

201. However, in the cases of Child 6, Child 7 and Child 12, Asperger's Disorder (in the latter case only even suggested at the Royal Free as involving possible features additional to a language delay) is improperly reported in the *Lancet* as a diagnosis of "Autism".

202. In addition to reliance on DSM-IV, explicitly invoked in the paper and used routinely by specialists all over the world, I sought advice from experts. These included Eric Fombonne, professor of psychiatry at McGill University, Montreal, who is a preeminent international authority on autism, and Professor Brent Taylor, head of community child health at the Royal Free. In addition, prior to publication of the first "Secrets" report, *BMJ* deputy editor Jane Smith emailed me the peer review opinion of paediatrician Dr Marcovitch.

All confirmed that I correctly understood the distinction between autism and Asperger's disorder.

203. Professor Fombonne explained to me in an email dated 5 October 2007 (Ex. 52):

> A child who has a diagnosis of Asperger by definition does not meet criteria for autism. Autism preempts a diagnosis of Asperger. If a child was diagnosed with Asperger, it means that it did not mean criteria for autism. The terminology of 'regressive autism' (which by the way is not a specific diagnosis, it is just a qualifyer attached to the diagnosis of autistic disorder for those children with autism who experience some loss of skills in the second year of life) cannot therefore used for a child with Asperger unless all these terms are used very loosely and in an interchangeable manner;

He said:

> There is no such thing like regressive Asperger. Regression, or loss of skills, occurs in about 20% of children with autistic disorder, usually between 14 to 24 months of age. Most loss of skills involve loss of language skills (typically a few word (10 or 20) that were used and disaapear) and are quite often with concomitant losses of other skills (ie social behavior is affected as well). Regression occurs with about the same proportion in children who have a diagnosis of PDDNOS. Regression is usually not described in Asperger and the terms regressive Asperger was not and is not currently in use. The reason is that by definition language development is normal in Asperger disorder and the presence of a regression of the type seen in autism would almost certainly rule out Asperger as a diagnosis in a child. The first symptoms in Asperger usually occur later than in autism (precisely because of the normal language development) and often the first concerns by carers apply to the social behavior or the unusual interests of the child.

204. I also studied various scientific papers and book chapters, for example reference 46 in the first "Secrets" report[12]. I also copied and read a chapter quoted from in a 1996 research ethics committee application by Wakefield[13].

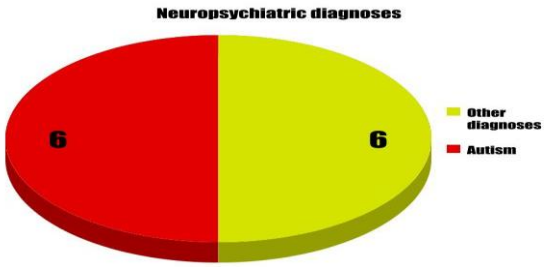
205. A plain reading of the diagnoses given for the three children from the Brighton area – including, for examples, in the pro forma reports referred to above for Child 6 and Child 12 (Exs. 44-45), and, for Child 7 in Wakefield's *Channel 4* Part 18 submission and a 1997 diagnosis letter from Dr Berelowitz (Ex. 53) – establishes that they were *not* diagnosed with autism. They had no diagnosis of *regressive autism*, nor of any "regressive

[12] Filipek PA. "Autistic Spectrum Disorders," in Swaiman KF, Ashwal S. Pediatric neurology: principles and practice. *3rd ed. Mosby*, 1999.
[13] Lord C and Rutter M. "Autism and Pervasive Developmental Disorders," in Rutter M et al (eds), Child and Adolescent Psychiatry, 3rd ed.

developmental disorder" as Wakefield repeatedly invoked as the foundation of his public campaign, and also for private business ventures.

206. The effects on the *Lancet* paper of this misreporting are, as ever, dramatic. They allowed Wakefield to promulgate his results as if they were largely from a group of children with regressive autism. This was integral to his effort to prove the existence of a coherent "new syndrome" caused by MMR. To substantiate claims in product liability litigation, the plaintiffs' relatives would need to show that the children acquired autism after vaccination, and hence any autism *must be* regressive. They would also need to evidence some recognizable constellation of symptoms and signs identifiable as vaccine damage.

207. The effect of the misreporting can be illustrated in the following pie charts. First, the diagnoses as recorded at the Royal Free, showing the 12 to be roughly evenly, and unhelpfully, matched between autism and various other behavioural issues, suggesting an eclectic patient group:



208. But after the three Brighton area children were dishonestly reclassified by Wakefield as suffering from regressive autism, the children looked more like a coherent group, which would be essential to any purported post-vaccine "syndrome":

209. I believe that Wakefield knows the meaning of a medical "diagnosis". He knows that any mention of a medical condition, or any hearsay relaying of information from one doctor to another, is not a diagnosis, and nor is the recording in records of information supplied to doctors by parents Developmental diagnoses in the UK are complex, usually multi-disciplinary, assessments by specialists. Thus, for example, GPs do not diagnose developmental disorders, and nor do parents. Indeed, Wakefield made clear at his GMC hearing (Ex. 54) that his own recording of another doctor's diagnosis was *not himself* making a diagnosis.

210. Nobody required him to design any tables (or, perhaps apart from Mr Barr, even to write any paper). But those tables he *did* design could have been filled in accurately and honestly with the behavioural diagnoses issued by developmental specialists, logged in Royal Free records, including the pro formas, or, where these diagnoses were not available, by the child psychiatrist Dr Berelowitz. If that meant the "syndrome" was not as convincing to the Legal Aid Board as Wakefield might have wished, and failed to incite public alarm, then that would have been the price of honest research.

211. As Professor Fombonne noted, Asperger's disorder is not recognized by specialists to be a regressive disorder. Moreover, DSM-IV explicitly states of Asperger's:

> Criteria are not met for another specific Pervasive Developmental Disorder or Schizophrenia.

212. And yet, Wakefield's claim that the children had "regressive autism" was set out *ad nauseam*, both inside and outside of litigation. For example, in February 1997, a year before the paper, he issued to doctors what he called a *"Rationale for our investigation of children with regressive autism and bowel symptoms,"* (Ex. 55). This was a considered document, supplied to the medical profession, purporting to explain what was going on at the hospital. Among other things, it said:

> Finally we hope that the possible role of MMR will be elucidated and that further insights into the pathogenesis of regressive autism will be provided.

> All children exhibited features of severe developmental regression.

213. Also before the paper was published, he wrote in a letter, dated 23 May 1997, to the director of finance of the Royal Free, identifying the research and explaining (Ex. 11):

> My group, The Inflammatory Bowel Disease Study Group, is currently involved in the investigation of a cohort of children with regressive autism and inflammatory bowel disease.

214. On 29 December 1999, he gave a public speech, referring to his paper. I attach a webpage concerning this (Ex. 56):

> We've presented a paper in the *Lancet* two years ago on 12 children who came to us with 'regressive autism'. This is the key phenotype that we've been looking at – that is, children who are normal for the first year to 18 months of life and then regress either dramatically or over a period of months.

215. Even the *Lancet* paper itself reported (at the penultimate page, 640):

> Gupta commented on the striking association between measles, mumps and rubella vaccination and the onset of behavioural symptoms in all the children that he had investigated for regressive autism.

Wakefield Distinguished Autism from Asperger's Syndrome

216. Despite his posturing, Wakefield has made clear, over many years, his understanding that, under the classification system *he* explicitly stated that he relied upon, Asperger's and autism, *in his judgment*, were different diagnoses. Indeed, once the *Lancet* paper had accomplished its prime task of securing legal funding, triggering public anxiety such that he and the lawyers who retained him were deluged with families offering their children for tests, and laying ground to launch private venture-capital companies, Wakefield and his associates were glad to extend the frontiers of vaccine damage from autism to Asperger's and, indeed, any other developmental issue that came their way.

217. Most striking of his statements in this regard are those he has made in his book, *Callous Disregard,* (the relevant chapter of which is attached as Exhibit 57), where he explained (my emphasis):

> A fundamental aspect of Asperger's ***that distinguishes it from autism*** is the normal acquisition of speech, and a diagnosis of Asperger's requires cognitive function within the normal range for age.

The Lancet Paper

218. As with enormous numbers of papers in biomedical journals, the *Lancet* paper makes clear that its developmental diagnoses were in accordance with the DSM-IV criteria. Self-evidently, the *Lancet* is a specialist journal directed at doctors and biomedical scientists, whose readers would expect that vital neuropsychiatric assessments had, indeed, been conducted against the criteria stated.

219. Table 2 also made it clear that Wakefield knew the proper nosology of developmental disorders. For example, he tabulated Child 4 with the "behavioural diagnosis:"

> Autism?
>
> Disintegrative disorder?
>
> These are two different disorders under DSM-IV.

220. Similarly, Child 9 is reported in the paper with a less precise behavioural diagnosis, which again illustrates that Wakefield knew the correct terminology:

> Autistic spectrum disorder

This is the spectrum that includes autism, Asperger's syndrome, Rett's syndrome, disintegrative disorder and PDD-NOS (pervasive developmental disorder, not otherwise specified, including atypical autism). Wakefield's use of this expression plainly shows that in 1997 he was aware that, in the event of uncertainty or mixed features, there are vaguer diagnoses, as, rightly or wrongly, he reported for Child 9.

Wakefield's Claim of "Regressive Autism" in the Brighton Area Cases

Child 6

221. As with 11 of the 12 *Lancet* patient cases (excluding the American), this child's records were extensively reviewed and repeatedly read into the record of the GMC hearing. I was present for most of the hearing, including the entire laying down of the records, and

almost from the beginning of records suggesting developmental concern, he was suspected to be a case of Asperger's syndrome.

222. A letter from South Downs Health, dated 13 December 1995, when Child 6 was aged 3½, was read into the GMC record, stating that he had undergone a "Griffiths Assessment" – which I understood to mean a structured evaluation lasting perhaps two hours – demonstrating "a rather uneven development profile" and noting that he had particular skills with remembering sequences and sentences. The letter said (Ex. 58):

> At home it is clear that [Child 6]'s behaviour is very difficult. His parents find it difficult to reason with him and he does not respond to the usual discipline measures. His mother was particularly concerned that he is not developing good peer relationships. All these features confirm that [Child 6]'s difficulties lie within the Autistic spectrum and he probably has Asperger's Syndrome, although this will become clearer as he becomes older. I explained to his parents that it is difficult at this early stage to predict how [Child 6] will be in the future.

223. There was no reference anywhere to any "regressive developmental disorder," which Wakefield stated to be characteristic of the *Lancet* children.

224. While this child's case, as in many cases of children with developmental disorders, contains much confusion, casual use of language and information of uncertain provenance, further clarity surfaced at the GMC hearing. There, a letter to Wakefield, dated 4 October 1996, from Walker-Smith, the paediatrician who admitted the boy to the hospital, directly recorded the diagnosis. The assessment, moreover, was by a child development specialist elsewhere. The letter begins (Ex. 59):

> Dear Andy, I was very interested to see [Child 6] in the clinic. This is a child who has been diagnosed as Asperger's syndrome.

Elsewhere, the letter says:

> He subsequently was diagnosed as Asperger's syndrome by Dr Bennett.

225. This boy was also seen by Dr Berelowitz, the Royal Free's child psychiatrist. Although I learnt from evidence during the GMC hearing that the proper assessment of developmental disorders is a multidisciplinary task, takes a great deal of time, and usually involves several specialists, Dr Berelowitz was a general child psychiatrist and told the panel

that his main job at the hospital was to support children being admitted for medical care by other departments. Nevertheless, the record shows that he issued a speculative opinion, dated 3 June 1997, following an interview with the mother and some form of assessment at the hospital, which had taken place some six months previously. He wrote to Wakefield (Ex. 60):

> Because of the mother's uncertainty about the timing of his developmental history, it is a little hard for me to be as confident as I would like about the diagnosis. However, it would seem that the most likely diagnosis is Asperger's Syndrome.

Subsequently, Wakefield himself wrote to the mother (Ex. 61):

> The diagnosis for [Child 6] was likely to be Asperger's Syndrome.

Child 7

226. This child is the brother of Child 6, and his case seemed to me, when writing the "Secrets" reports, to be an elegant example of Wakefield's dishonest and irresponsible conduct.

227. The GMC record (Ex. 62) shows that the GP had referred Child 7 to Walker-Smith at the Royal Free in a letter which began:

> I would be grateful if you could see this boy who is a child whose brother you have recently investigated as part of your programme for colonoscopy for children with autistic problems. He himself probably does not have autism although this is not certain at present but he does have convulsions which I believe may make him eligible for your study.

After seeing the boy with his mother, Walker-Smith replied to the GP, among other things stating (my emphases):

> He had the MMR rather later than usual at the age of 21 months. ***His mother tells me*** 24 hours afterwards he had a fit like episode and slept poorly thereafter and she attributes changes in his behaviour to this event. I understand that he has not been fully investigated although I understand it is your opinion he could be within the autistic spectrum although ***it is not your view that he does have autism***.

Id.

228. Thus, Child 7 arrived with no autism diagnosis. At the Royal Free, he was seen by Dr Berelowitz, who concluded that the boy had a "developmental disorder", but did not know what it was and suggested further inquiries. Developmental disorders are a much wider

terrain than autism, or even the autistic spectrum of disorders. They embrace an enormous range of issues where cognitive or motor skills are challenged, and I knew from my general research that this included ADD, ADHD and even Down's Syndrome.

229. On 3 June 1997 Dr Berelowitz wrote to Wakefield recounting how he had seen the boy and the boy's mother, with various pieces of information gleaned from the mother. I attach this letter (Ex. 63)**,** which, among other things, says:

> At 18 months he had a febrile fit during a chicken pox programme. He was unconscious for about 20 minutes and lost the use of one side for a while. He then had his MMR at 20 months. On the same night as his MMR he had what his mother thought was another fit, but I am not sure about this. From then on he became quiet with a decrease in spontaneous speech, less social engagement, less eye contact and poor language.

Dr Berelowitz told Wakefield in the letter that, during the assessment, he saw "some lovely imaginative play" between Child 7 and his brother:

> lining up the chairs in the office and pretending they were a train. They also played hide-and-seek. Mother took the lining up of the chairs to be a sign of the children's obsessionality, but in fact I did not think this and I thought it was a good example of imaginative play. I should add that there were other aspects of what the mother called [Child 7's] repetitive play which I thought was probably normal toddler behaviour.

230. Berelowitz told Wakefield (incidentally making clear that Asperger's and Autism are different diagnoses):

> Notwithstanding these comments, I do think [Child 7] suffers from a developmental disorder, perhaps somewhere between Asperger's and Autism. However, I would want Andrew Lloyd Evans' [a paediatric neurologist and specialist in development] views on the development following the febrile convulsion. I also retain some uncertainties about the strength of the conclusion that we should draw from some of the historical features.

231. Thus, the word "perhaps," and the proposal for a specialist opinion are crucial in understanding what Dr Berelowitz was telling Wakefield. For simple comparison, a doctor saying that a patient "perhaps" has cancer, and needs more evaluation, is not a diagnosis of cancer. For a third party doctor to relay to the patient that they have cancer on such a basis might, I suspect, produce a lawsuit. But that is exactly what Wakefield then did. He wrote to the mother, changing Dr Berelowitz's diagnosis to what he, Wakefield, wanted it to be.

232. In a letter read to the GMC panel, Wakefield told her (Ex. 64):

> Further to our conversation the other day, I am writing to confirm that following assessment of your children at the Royal Free, in particular by Dr Berelowitz, the Consultant Child Psychiatrist, the behavioural diagnosis in [Child 7] is of a developmental disorder on the autistic spectrum between Asperger's and autism.

233. Firstly, Dr Berelowitz made no mention of the autistic spectrum, which Wakefield added to the diagnosis. Secondly, "perhaps" has gone. Thirdly, there is no suggestion that what Dr Berelowitz had called the "strength of the conclusion" was tentative. And, of course, there is no indication of the psychiatrist's view that the boy needed more appropriate assessment.

234. But, even on Wakefield's own altered, misleading account to the mother, he cannot square even his own correspondence with what he later reported in the *Lancet*. In Table 2, Child 7 is stated to have been given a "behavioural diagnosis" of "Autism." There is no mention of *possible* Autism, or *possible* Asperger's syndrome, or question mark, as Wakefield uses (or omits) elsewhere in his reporting of children in the *Lancet*. To me, the conclusion was inescapable: he had sexed-up the case, changing it so as to make it appear to fit better with the "new syndrome" he and Mr Barr had promised in their 1996 legal grant application before a single child was admitted.

235. And yet there is more. As indicated previously, Wakefield also claimed in the 1998 paper to have discovered evidence of just the kind of inflammatory bowel disease that he had told the Legal Aid Board about in 1996. Table 1 documents "non-specific colitis" in 11 of the 12 children reported. And, with regard to Child 7, in December 1998, he issued a letter headed "TO WHOM IT MAY CONCERN." (Ex. 65):

> This is to confirm that [Child 7] is one of a number of children investigated at the Royal Free suffering from a newly identified syndrome comprising of chronic bowel inflammation and autism. The long term natural history of this condition is yet unknown but it is likely that the bowel disorder as well as the autism will require long term medical supervision.

236. But not only did Child 7 have no diagnosis of autism, reference to Table 1 of the paper reveals that he was, *on Wakefield's own account*, the only patient in the series who *did not* have bowel inflammation.

Child 12

237. This child was thoroughly assessed by an appropriate expert before being seen at the Royal Free. He received no diagnosis of autism, but instead was given a diagnosis of a language impairment (which is not even on the autistic spectrum).

238. Although Wakefield called no parent (or indeed any witnesses at all) to give evidence at the GMC hearing, Child 12's mother was called by the prosecution. She produced correspondence showing that on 19 July 1996, Wakefield wrote to her (as noted in transcript also previously exhibited as Ex. 20):

> Dear [Mrs 12], Thank you for your letter regarding your son. We have recently taken a profound interest in this subject, particularly in view of the link between bowel problems and Asperger's Syndrome.

239. The following day, the family's general practitioner, sent a referral letter to the Royal Free, marked for Wakefield's attention. Among other things, this said:

> He has seen Dr Richard Ing, our local Consultant Child and Adolescent Psychiatrist, who has expressed the opinion that [12] may well have Asperger's Syndrome.

240. Dr Berelowitz issued no report or letter with regard to Child 12, but he made a note on 10 January 1997:

> Language delay, ?ADD; ? features of Asperger's.

241. Moreover, Wakefield affirmed under cross examination that he too had relied on a pre-existing diagnosis of Asperger's syndrome for this child. I attach this portion as Ex. 67.

242. For the GMC hearing, Professor Michael Rutter reviewed this boy's case. He was asked by counsel whether there was any indication of "why it might have been thought that there was any significant regressive elements about his behavioural disorder?" Rutter answered:

> No, no evidence that I could identify.

Once again, there was no diagnosis of autism, must less any evidence of "severe developmental regression." And yet Wakefield claimed both for this child.

G. Wakefield's Gross Misreporting: The "Abnormal" Test Results

243. Unusually, in one aspect of the paper, Wakefield published data that could be checked without the massive resources brought to bear by the GMC. He listed in Table 1 what he called *"abnormal laboratory tests"* for ten children, and gave measurements. However, *Lancet* readers quickly spotted that with regard to six children (Child 1, Child 4, Child 6, Child 7, Child 8, and Child 12) Wakefield had reported as *abnormal* results which were actually *normal* (Ex. 68). With no hiding place, Wakefield responded (*id.*):

> These errors do not affect the conclusions of the paper…

H. Wakefield's Gross Misreporting: "Chronic" Enterocolitis

244. "Enterocolitis" means inflammation of both the small bowel (enteritis) and the colon (colitis). The *first sentence* of the *Lancet* paper reads (my emphasis):

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

245. In the *last paragraph*, the paper claims:

> We have identified a ***chronic enterocolitis*** in children that may be related to neuropsychiatric dysfunction.

Enterocolitis was one of three critical elements in the purported fingerprint of vaccine damage invented by Wakefield.

246. The Royal Free pathology service, however, reported findings consistent with *possible* enterocolitis in only *two* of the 12 children (Child 2 and Child 6). The subsequent research review in the medical school by Dr Dhillon (which Wakefield, in his various complaints and publications, claims he relied upon in writing the paper) reported enterocolitis in *none* of the 12. Raw data from both the hospital and the medical school were put out by the *BMJ* for expert review (in the latter instance after publication of the "Secrets" series of January 2011). The reviewers reported identifying data supporting histological findings of enterocolitis in *none* of the children (Exs. 69). Indeed, in 2004 I interviewed Dr Murch, the paper's second author, and he told me that the claim children had enterocolitis was wrong.

Children Did Not Have Histologically-Determined Colitis

247. In Table 1, the paper claims "histological findings" of non-specific colitis for all children except Child 7. The hospital pathology service, however, actually reported that nine of the 12 children's guts were histologically *normal*. A paediatric gastroenterologist, Professor Ian Booth of Birmingham University, England (with whom I have never had any dealings), reviewed the hospital results as an expert witness for the GMC, and was so concerned by this mismatch that he stated in a report dated 8 November 2006 (my emphases):

> In only one case was the ***altered histology report*** subsequently noted in the patients' clinical record. Had these been clinically relevant ***alterations*** one would assume that they would have been. It is therefore ***not possible on the basis of the information I have seen to exclude scientific fraud*** in this area of the Lancet publication.

248. I did not see these pages from Professor Booth's report, and had no knowledge of his views, until September 2011, when they were supplied to the *BMJ* by Dr David L Lewis, a cohort of Wakefield. I attach Professor Booth's pages as Exhibit 70.

249. In about August 2011, Lewis supplied the *BMJ* with raw data from the medical school "research review" of the bowel histology (which he obtained from Wakefield), mistakenly believing they supported the claims in Table 1. However, almost all these data were *normal*, and Dr Dhillon subsequently issued a statement to the *BMJ* confirming, among other things, that he had *not* made histological findings of colitis (Ex. 71). He had previously stated to the GMC that he did not write the histology section of the paper (Ex. 72).

250. The "histological findings" column of Table 1 is thus established to be false by reference to the original data from both the hospital pathology service and from the medical school review.

I. Wakefield's Gross Misreporting: Information Withheld

Withheld: Normal Blood Tests for Inflammation

251. Among the most egregious withholdings of critical information from this research – research which purported to identify a putative new inflammatory bowel disease –

were the results of standard noninvasive blood tests for *inflammatory bowel disease*. Such tests (which would have been keenly studied by editors, peer reviewers and specialist readers of the *Lancet*) are routinely performed by gastroenterologists to screen out cases where invasive procedures are probably unwarranted. These tests came up *normal* for most of the patients, but Wakefield persuaded clinicians to simply go ahead regardless, admit the children, anaesthetize them and push tubes as far as their small intestines (as well as needles into their spines). I learnt that later in the Royal Free series (not included in the *Lancet*), one autistic child was seriously injured, leading to litigation and a major financial settlement.

Withheld: the Children's Principle Gastroenterological Problem

252. One of the most extraordinary features of the paper is that *it did not report the children's principle gastroenterological problem*. As born out during the GMC panel's child-by-child review of medical records, the main clinical finding in these children was that "nearly all" suffered from "severe constipation". This was evidenced in a letter to the *Lancet* in 1998 from three of the authors (excluding Wakefield), perhaps moved by conscience or challenge. I attach this letter as Exhibit 73[14]. Specifically, records studied by the GMC panel found unreported diagnoses of constipation for Child 1, Child 2, Child 3, Child 5, Child 6, Child 7, Child 8 and Child 10. Remarkably, however, the paper (purporting to be a clinical report) included no finding, reference, use of the word "constipation", or even the slightest hint of this issue. This is particularly surprising in that this principle gastroenterological symptom or sign might, self-evidently, have been of interest to readers caring for children with developmental disorders.

253. Moreover, this withholding of information unhelpful to Wakefield's mission can be seen in the context of the parallel non-reporting of the normal inflammatory indices. As

[14] Walker-Smith *et al*, March 21 1998. "Plain radiography confirms severe constipation with acquired megarectum in almost all affected children, despite many receiving treatment for constipation. Most parents note a honeymoon period of behavioural improvement after the bowel preparation for colonoscopy and this is maintained if recurrent constipation is prevented."

with normal blood tests, findings of constipation are generally considered by doctors to contribute to a differential diagnosis raising doubt as to any presence of inflammatory bowel disease (Ex. 74). Therefore, as with the blood tests, reporting constipation in these children would likely have raised the eyebrows of gastroenterologists who read the paper, and might well have triggered questions from editors and peer reviewers with regard to the robustness of the reported histology.

J. Wakefield's Claim Not to Have Seen the Records that Are Inconsistent With His Paper

254. The overarching deceit which lay behind the paper not only extended to concealing from peer-reviewers, editors and readers the true source and status of the children, the funding agency behind the project, and Wakefield's manifest conflict of interest. Nor was it confined to the manipulation by alteration and omission of critical data on the children.

255. He also made direct false statements in the paper, the ultimate falsity of which, though long the subject of professional suspicion, have only been finally proven after publication of the "Secrets" series. One egregious example was the claim – which, having interviewed the peer reviewer Professor Candy, I believe was essential to securing publication – that Wakefield had conducted a thorough, professional inquiry into the children's medical histories. Beginning at line 8 of the first page, the paper stated:

> Children underwent gastroenterological, neurological, and developmental assessment and review of developmental records.

Beginning at the fifth line of the second column of the first page, it elaborated:

> Developmental histories included a review of prospective developmental records from parents, health visitors, and general practitioners.

256. In other words, the critical 14-day maximum temporal link which connected MMR with autism , was held out to be records-based, and not merely the reporting of what parents volunteered when they turned up at the hospital. Even my journalistic work, personal experience and common sense tells me that people often tell things to doctors which, for a

variety of reasons, may not be accurate or germane, particularly when recalling events and dates from years past. For a learned report in a biomedical journal, raising profound issues of public health, further inquiry would clearly be expected.

257. However in paragraph 4.11 of his petition, Wakefield now denies that he carried out inquiries into medical records which the paper explicitly claims he performed, and which I have no doubt would be expected of a doctor asserting in a preeminent journal of medical science the putative discovery of a new syndrome and "unique disease process" caused by a vaccine given to countless millions of children.

258. If, as is the case Wakefield now asserts in his petition, by failing to consult the children's extensive medical records, he published wrong information in the *Lancet*, then that is his responsibility. Indeed, it is plain that this was his intent. The omission of due care was hardly likely to have been a question of him being too busy. The children were admitted between July 1996 and February 1997. There were only 12. And the GP records, requisitioned by the GMC, revealed him telephoning and writing both to GPs and to parents, briefing them on the reason for referrals and discussing the kinds of things parents might choose to raise with clinicians when they got to the hospital.

K. Mr 11

259. Some years ago, a freelance journalist called Daniel Olmsted was let go from his job with the news agency of Sun Myung Moon's Unification Church (popularly known as the "Moonies"). Olmsted has subsequently operated a blog at which he claims not only to have discovered the cause of autism to be mercury poisoning, but also claims his discovery of a putative "real" cause of poliomyelitis. He currently promotes Wakefield at his blog with some 300 pages of material about him. Following the "Secrets" series, Olmsted obtained through a breach of patient confidentiality the identity of the family of Child 11 in my report, who live in California. The father was concerned that his privacy had been betrayed, but

thinking that Olmsted was interested in autism, met with him. At this meeting, the father shared a document which he had not previously shared with me, giving the date in 1997 when he first approached Wakefield. It also referred to the supply to Wakefield of a medical report by American doctors. (*See* Ex. 48.) This letter expressed the father's view in 1997 as to when his son's first symptoms of autism began. Unsurprisingly, this date is different to the dates suggested in the Royal Free record which the father had given to me, and which I quoted in the *BMJ*.

260. As my *BMJ* report correctly stated, Wakefield claimed in the *Lancet* paper that Child 11's "first behavioural symptom" began "*1 week*" after MMR. The hospital discharge summary, however, indicated a process beginning *before* MMR. This is also supported in the Royal Free pro forma report, which dates the boy's normality only to 13 months – which was before he was vaccinated – and states (evidently on the basis of the American medical report supplied to Wakefield): "?one history says symptoms from 13 months".

261. The father's 1997 letter (which he supplied to me on 30 October 2011), meanwhile, stated that his son's problems began some three to four months *after* his MMR.

262. Despite the plain falsity of the *Lancet* paper, by any account, Wakefield, relying on Olmsted's material, alleges at 4.13 of his petition:

> Indeed, the child's father has since written Deer and the BMJ to explain that Deer was misrepresenting facts about child 11, yet Deer and BMJ have printed no retraction, correction, or mention of this fact.

263. Neither I nor (to my knowledge) the *BMJ* has received any letter from this father accusing me of "misrepresenting facts." Nor have we received any request from this father asking for any retraction, correction, or for us to take any action at all. On the contrary, the father confirms the terms of the medical record (which he gave me at a meeting in California in September 2007), but disagrees with the accuracy of that record. The matter is thus purely

a (very common) situation where parental recall and medical records do not coincide, and naturally parents believe their recollection to be right.

264. As will be found elsewhere in my report, I have been diligent in reporting differences between medical records and parental recollections, since this is an important part of the vaccine scare story. Had the father given me the letter, or even told me its content, I would have included that information.

265. Last March, the father wrote to Olmsted and myself – effectively really copying me in to a letter he sent to Olmsted following their meeting – among other things stating (Ex. 49) (my emphasis):

> While the inaccuracies in the Royal Free discharge summary may be chalked up to sloppy record keeping, ***if my son really is Patient 11, then the Lancet article is simply an outright fabrication***. My son's autistic behaviors did NOT begin a week after administration of the vaccine, in fact they began several months afterwards, with several medical complications occurring in between.

266. In November 2011, Mr. 11 wrote to me, criticizing Olmstead and signing off:

> Next time I'm in London, I will give you a call. I have learned quite a bit from you on quality investigative reporting. We need more of it here in USA !

Ex. 85.

267. Wakefield, too, has had more to say on this matter, which cannot be reconciled with the false claim he made in the *Lancet*. In his book – which was written after his lawyers disclosed information to me in *Channel 4* confirming that the paper's temporal link for this child was untrue – he abandoned his false claim that Child 11 developed his first symptoms "1 week" after MMR at "15 months". Instead the book says (Ex. 57 at p.39):

> He came to us with a history of developmental regression starting at 18 months of age.

268. In short, not even Wakefield now stands behind the information he put in the *Lancet* to cause the vaccine crisis.

L. A Child-by-Child Summary of the Gross Misreporting

269. In the *BMJ* editorial of 5 January 2011, Dr Godlee *et al* accurately stated:

> Deer unearthed clear evidence of falsification. He found that not one of the 12 cases reported in the 1998 Lancet paper was free of misrepresentation or undisclosed alteration, and that in no single case could the medical records be fully reconciled with the descriptions, diagnoses, or histories published in the journal.

The following review non-exhaustively summarises evidence which more than justifies this observation.

Child 1 – Legal Aid No 08/01/97/07352/A/Z/1[15]

270. I reviewed this case at paragraphs 51-57 (time of first behavioural symptom), 148-155 (Royal Free report) and 191 (in *Channel 4*).

Child 2 – Legal Aid No 08/01/96/11360/A/Z/1

271. Child 2's mother, Ms Kessick, told me that her son's disorder began up to *six months* after MMR, and not *two weeks* as she had apparently told Royal Free clinicians in an inaccurate 1996 history (included in the *Lancet*) after she was briefed by Wakefield. The correct time-frame, in months, is supported in multiple *plaintiff* expert reviews of Child 2's records that Ms Kessick disclosed in the UK MMR litigation (for example, Ex. 75), as well as in a GP record (Ex. 76).

272. With regard to the boy's "behaviour", Table 2 reports the *"age at onset of first symptom"* as "*13 months"*. But plaintiff experts, who reviewed the records for litigation, state that the boy received MMR at *15 months* (Ex. 77), and this is also dated in his GP records (Ex. 76).

273. With regard to the boy's bowels, Table 2 reports the *"age at onset of first symptom"* as *"20 months"*. But medical records, reviewed by plaintiff experts, reveal incidents of significant doctor-notified bowel symptoms at 13 months – *before* MMR (Ex. 77).

[15] Extracts from a register of MMR vaccine litigation claimants as of July 14, 2005, containing Legal Aid numbers for each *Lancet* child from the U.K. (Child 11 is a U.S. citizen), is attached as Exhibit 29.

Child 3 – Legal Aid No 08/01/97/09354/K

274. Table 1 reports *"histological findings"* of *"acute and chronic non-specific colitis"* for Child 3. But no such findings were reported by the responsible consultant histopathologist (Dr Dhillon), who examined biopsy samples on separate occasions: first for the hospital pathology service (Ex. 78) and later in a medical school research review (Ex. 79) claimed by Wakefield to be definitive (Ex. 80). The diagnosis was subjected to undisclosed alteration, and the basis for the changes was not recorded in the child's medical records.

Child 4 – Legal Aid No 08/01/96/21056/A/Z/1

275. Table 1 reports *"histological findings"* for Child 4 of *"chronic non-specific colitis"*. But no such findings were reported by the two responsible consultant histopathologists: the first (Dr Davies) for the hospital pathology service (Ex. 81), and the second (Dr Dhillon) in the later medical school review (Ex. 82).

276. Table 2 reports the *"first behavioural symptom"* as *"immediately"* following MMR, with the boy's *"age at onset"* given as *"4.5 years"*. It also reports that, following a previous *single measles vaccine,* at age 15 months, "his development slowed". But multiple medical records reveal developmental concerns throughout the boy's earliest years, and the boy's GP alerted Wakefield to preexisting concerns (Ex. 83).

Child 5 – Legal Aid No 08/01/97/17522/A/Z/1

277. Table 1 reports an *"endoscopic finding"* of *"LNH of T ileum"* (lymphoid nodular hyperplasia – swollen glands – in the small bowel). However, the report of the endoscopist (Dr Murch) for Child 5, seen by Wakefield, *explicitly denied* this[16] (Ex. 47).

278. The *Lancet* table reports *"histological findings"* of *"chronic non-specific colitis"*. But no such findings were reported by the responsible consultant histopathologists, first for the hospital pathology service, and later during the medical school review.

[16] Endoscopy report by Dr Simon Murch: "not sufficient to call lymphoid hyperplasia".

279. The paper's *first* "finding" reports that parents of *"eight of the 12 children"* associated the onset of behavioural symptoms with MMR. However, additional to these eight, Child 5's parents were among three more families recorded at the Royal Free making this association, but whose critical parental disclosures, entered in Royal Free records at the time, were withheld from the paper. (*See supra* at 181-184.)

Child 6 – Legal Aid No 08/01/96/27182/T

280. I reviewed this case at paragraphs 156-166 (Royal Free report), 193 (in *Channel 4*) and 221-225 (not diagnosed with autism). In addition, post-MMR, the first known GP record of behavioural symptoms was taken *six months* after vaccination. (Ex. 86).

Child 7 – Legal Aid No 08/01/96/27183/A/Z/1

281. I reviewed this case at paragraphs 194 (in *Channel 4*) and 226-236 (not diagnosed with autism).

Child 8 – Legal Aid No 08/01/96/19054/A/Z/1

282. I reviewed this case at paragraphs 58-60 (developmental concerns before MMR) and 134 (endoscopy report changed). In addition, Table 1 reports *"histological findings"* for Child 8 of *"acute and chronic non-specific colitis"*. But no such finding was reported by the responsible consultant histopathologists, either for the hospital pathology service or during the medical school review. (*Exs. 93-94*.)

Child 9 – Legal Aid No 08/01/97/06433/A/Z/1

283. I reviewed this case at paragraphs 61-64 (parental disclosure omitted from paper). In addition, Table 2 reports the *"age at onset"* of the first *"behavioural symptom"* as *"18 months", but* Royal Free records document the age as *18-20 months*. (*See supra* at paragraph 63.)

Child 10 – Legal Aid No TELSADYY2H93/A/Y/1

284. I reviewed this case at paragraph 195 (in *Channel 4*). In addition, Table 1 reports *"histological findings"* for Child 10 of *"chronic non-specific colitis"*. But no such finding was reported by the responsible consultant histopathologists, either for the hospital pathology service (which even checked them a *second time*) (Exs. 87, 88), or during the medical school review (Ex. 88).

Child 11 – US Citizen

285. I reviewed this case at paragraphs 172-180 (Royal Free report), 196 (in *Channel 4*) and 259-268 (father says paper "an outright fabrication").

Child 12 – Legal Aid No 08/01/96/21422/A/Z/1

286. I reviewed this case at paragraphs 167-171 (Royal Free report) and 237-242 (not diagnosed with autism). In addition, Table 1 reports *"histological findings"* for Child 12 of *"chronic non-specific colitis"*. But no such finding was reported by the responsible consultant histopathologist for the hospital pathology service, or by another histopathologist during the medical school review. (Exs. 91-92).

V. My Attempts to Obtain Wakefield's Views

Direct Approach to Wakefield

287. As the first *Sunday Times* reports were prepared for publication in February 2004, the Times Newspapers' legal manager contacted Wakefield by phone, since Wakefield had made it clear that he would not speak to me. This produced generalised denials along the lines that his legal work began after the children were investigated, that no children were litigants, that the *Lancet* study was not sponsored by the Legal Aid Board and that ethical approval had been sought and obtained.

Formal Interview

288. Prior to my first reports, in February 2004, the *Sunday Times* editor directed that Wakefield must present himself for interview, but Wakefield said he would not attend if I was present, and therefore three other journalists interviewed him who had done no research on the subject. He gave much the same information as he did to the legal manager.

Prior to Dispatches TV Broadcast

289. In the summer of 2004, the TV production company working with me on a documentary in the Channel 4 "Dispatches" strand wrote to Wakefield seeking an interview. This was declined through lawyers. When it was clear that we would receive no written response, I travelled to Indianapolis to speak to Wakefield, who blocked the camera with his hand and fled, accompanied by what appeared to be retained "minders" who sought to physically intimidate me.

Before the 2009 Sunday Times Reports

290. As I have explained above, in February 2009 I wrote to Wakefield, setting out the allegations as they stood at that time (Ex. 89), and explaining that a report in the *Sunday Times* was imminent. He did not reply to the matters raised, nor ask for extra time to consider them. Although the stories were pegged to measles outbreaks in the UK, I have little doubt that, had he indicated an intention to respond, we would have considered delaying publication, as we had done in 2004. Instead, he published his response on the World Wide Web, in disingenuous terms. The *Sunday Times* reports covered the same ground as the first *BMJ* "Secrets" report, albeit for a general readership.

My Knowledge of Wakefield's Positions

291. From the beginning of my work on the "Secrets" series, I knew that Wakefield well understood that my door was open if he ever wanted to discuss my journalism. However, he never signaled to me in any way that he wanted to explain himself personally. Nor did he

ever seek any correction to my website, where all of my articles and findings were set out. Rather, I believed firmly by that time that he had no interest in ever actually explaining himself, much less subjecting those explanations to scrutiny.

292. As discussed earlier, several events led me to believe this: his 2005 libel case against me and the *Sunday Times* that he subsequently stayed and later dismissed; his 2005 libel case against me and Channel 4 that he tried unsuccessfully to stay and then quickly dismissed once I got access to the underlying patient records and details of his legal aid income; his filing of the PCC complaint and efforts to obtain summary adjudication before the *Sunday Times* had an opportunity to defend our reporting; his effective abandonment of his PCC complaint after the commission rejected his request for summary adjudication; his filing of an appeal of the GMC findings and sanction against him, only to later dismiss that appeal.

293. In essence, I believed that, as suggested by the judgment of Mr Justice Eady in 2005, Wakefield was more interested in issuing public denials to his supporters, filing lawsuits, making official complaints, and attempting to intimidate responsible journalists with the burden of meritless complaints than he was in actually engaging with them.

294. In the absence of any willingness on his part to give me an interview, I relied on his exhaustive PCC complaint, along with his book, *Callous Disregard*, to be an exhaustive exposition of his denial of the allegations against him in my *Sunday Times* reports – essentially the same allegations that were the subject of my reports for the "Secrets" series. I carefully considered his material and rejected his arguments on the basis of my independent consideration of the relevant evidence. Nothing in the PCC complaint or his book gave me any concern that my reporting in the "Secrets" series was false in any way. Quite the opposite.

295. I specifically included in the footnotes a cite to Wakefield's PCC complaint against me and the *Sunday Times*. Although I did not think there was any merit in this complaint, which by that time I viewed as having been effectively abandoned by him, I knew that the *BMJ* series covered the same ground, and I wanted to make sure readers could locate his positions. Moreover, in the body of the first article, I noted that he denied all of the allegations, and I summarized specific matters which he had denied. I thought this was fair treatment of his positions. In my editorial judgment, they were meritless and did not justify additional space in the body of the article. And, again, there was a link to the full complaint in the footnotes, allowing readers to simply click on it and read the whole thing.

VI. My Website

296. Since 2002, I have operated a website, briandeer.com, which contains a selection of my reporting on a wide variety of topics over many years. In paragraph 4.21 of his petition, Wakefield makes a number of references to this site, almost all of which are couched in false or misleading terms. Moreover, the challenged statements identified in the petition were published on the site well over one year before this case was filed.

297. Although I am unable to print archived versions of pages directly from my website, the content is accessible online from the WayBack Machine, web.archive.org. The April 2011 version, identified by Wakefield, is:

http://web.archive.org/web/20110422230140/http://briandeer.com/mmr/*Lancet*-summary.htm

By April 2011, that content had been posted for at least one year. For example, the 17 April 2010 version is:

http://web.archive.org/web/20100417171645/http://briandeer.com/mmr/*Lancet*-summary.htm

A true and correct copy of the 17 April 2010 content, accessible through the WayBack Machine, is attached as Ex. 90. I have reviewed that content and hereby testify, based on my own personal knowledge, that it is a true and correct copy of material published on my website prior to 17 April 2010.

VII. Conclusion

After 18 months of the "Secrets" reports being in publication, I am aware of only one error of fact: a two character spelling mistake in one online-only footnote, where a GP's first name "Andrea" is, in one of three instances, written as "Anthea." I remain entirely committed to and convinced of the truth and fairness of the reporting, just as I was at the time of publication.

I declare under penalty of perjury that the foregoing statements are true and correct.

Executed this 9th day of July, 2012.

Brian Deer

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