Submission to the UK Press Complaints Commission

Complaint from Dr Andrew Wakefield about the Sunday Times article *"MMR doctor Andrew Wakefield fixed data on autism"* of February 8th 2009, by Brian Deer.

The articles on pages 1 and, 6 and 7, of the *Sunday Times*[1] *"MMR doctor Andrew Wakefield fixed data on autism"* of February 8th 2009, made extremely serious allegations against me.

The articles presented, as fact, allegations that I committed scientific fraud inasmuch as I "*changed and misreported results in* [my] *research*"[2] in a paper in the medical journal *The Lancet* in 1998, with the clear implication that this was intended to create the appearance of a possible link between MMR vaccination and autism and that I did it for money.

These allegations are false and/or misleading and will have a hugely adverse effect on my credibility as a scientist and my ability to ever practice again in my chosen field. More importantly, the impact of Mr. Deer's false and misleading claims upon the perception of medical professionals of the medical disorder suffered by the Lancet children and therefore, the provision of adequate care for autistic children, is potentially devastating. Further, as the author, Mr. Deer has sat through the on-going General Medical Council hearing, where these matters and others have been aired in considerable detail; he knew that these allegations were either false or misleading, based on incomplete records – or, at the very least, open to question. A journalist has a duty to report fairly and accurately on such proceedings, but in this case not only was my response and evidence omitted from the *Sunday Times* report – but crucially, so was that of my colleagues. (As will be seen below, one of the serious inaccuracies in the reports is the suggestion that I was involved in either the formulation of the diagnostic conclusions reported in the Lancet or the recording of the 'data' referred to in the article). This is, as is well known to Mr Deer through the evidence adduced at the GMC, totally untrue.

It was, in fact, Mr Deer, who in February, 2004, initiated the investigation by the GMC in the first place - three days after he published his first article in the

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[1] The *Sunday Times* February 8, 2009 "MMR doctor Andrew Wakefield fixed data on autism" Brian Deer

[2] Wakefield AJ, Murch SH, Anthony A, Linnell J, Casson DM, Malik M, Berelowitz M, Dhillon AP, Thomson MA, Harvey P, Valentine A, Davies SE, Walker-Smith JA. Ileal lymphoid nodular hyperplasia, non-specific colitis and pervasive developmental disorder in children. *The Lancet* 1998;351:637-641

Sunday Times alleging wrongdoing by myself and two colleagues at the Royal Free Hospital in London[3]. This, and subsequent articles by Mr Deer which alleged deceit, unethical experimentation on children, undisclosed conflict of interest, fraud, and profiteering, was also factually inaccurate and highly defamatory. I was forced to abandon my action for libel, after an interim ruling in the High Court ordered that it had to run concurrently with the GMC case, which my lawyers advised was physically impossible. We naturally decided the priority was to concentrate our efforts on the GMC hearing.

Mr. Deer's latest article was based upon 'evidence' that he claims was presented at the GMC hearing - which started in 2007, is due to conclude sometime in 2009 - without disclosing the fact that it was he who brought the original complaint. He therefore has an undeclared interest in its conclusions. Failure to have disclosed this conflict to readers of the *Sunday Times* is misleading.

The PCC code of conduct states that the Press must take care not to publish inaccurate, misleading, or distorted information and that while 'free to be partisan' it must distinguish clearly between comment, conjecture, and fact.

The articles complained about are full of inaccurate, misleading, and distorted information and fail to distinguish between what are allegations and conjecture and 'fact' and I seek, in accordance with the PCC code, appropriate corrections and an apology.

Further, I was given less than 24 hours notice to respond to what are clearly very complex issues in an article which had inevitably taken some considerable time to put together. This was clearly insufficient time to consult properly with the lawyers handling these issues on my behalf at the GMC to seek their considered advice, and to access the documentation needed to formulate a proper and thorough response.

Details of the factual inaccuracies in the *Sunday Times* of February 8th 2009.

Page 1. *"MMR doctor Andrew Wakefield fixed data on autism"*

"THE doctor who sparked the scare over the safety of the MMR vaccine for children changed and misreported results in his research, creating the appearance of a possible link with autism, a Sunday Times investigation has found."

There was no misreporting or changing of results by me (as will be demonstrated below).

"Confidential medical documents and interviews with witnesses have established that Andrew Wakefield <u>manipulated patients' data</u>, which triggered fears that the MMR triple vaccine to protect against measles, mumps and rubella was linked to

[3] The Sunday Times. February 22nd 2004.

the condition."

The clear implication of this statement is that:

- I deliberately manipulated data on some or all of the 12 children who were the subject of the Lancet paper and that this manipulation triggered an MMR vaccine scare; and,
- That this manipulation has been established through confidential medical documents and interviews with witnesses.

There is no basis in fact for any suggestion that I "*manipulated patients' data*" at any time.

None of the evidence presented during the GMC hearing over the past year-and-a-half supports any allegation of manipulation of data by either myself or any of the other 12 co-authors on the paper. The specifics of this allegation are dealt with below.

"The research was published in February 1998 in an article in The Lancet medical journal. It claimed that the families of eight out of 12 children attending a routine clinic at the hospital had blamed MMR for their autism, and said that problems came on within days of the jab."

This claim is factually inaccurate. The paper states that, "Onset of behavioural symptoms was associated, by the parents with measles, mumps, and rubella vaccination in eight of the 12 children…" (see paper)

"The team also claimed to have discovered a new inflammatory bowel disease underlying the children's conditions."

This is also factually inaccurate. Nowhere in the Lancet paper is such a claim made. (see paper)

"However, our investigation, confirmed by evidence presented to the General Medical Council (GMC), reveals that: In most of the 12 cases, the children's ailments as described in The Lancet were different from their hospital and GP records."

The documents relevant to the evidence presented in the Lancet paper are clearly identified in that paper. These included the Royal Free Hospital records and, where available, the prospective developmental records from parents, Health Visitors and General Practitioners (GPs). The team therefore relied on the totality of the information available to them, as stated in the paper. This is entirely normal practice. Since then further records have been collated for the GMC enquiry, which were not available to the hospital team at the time of writing the paper.

The records that were before the GMC included a complete set of the children's local hospital records, a full set of the GP records to include all GPs who had been

involved the child's care, as well a the Royal Free Hospital records and any other records relating to the child e.g. school medical records.

Reliance on differences between these data sources, i.e. those relied on by the Lancet authors and those relied upon by Mr. Deer in his allegations, is disingenuous and misleading since the majority of the latter records were not available to the Royal Free doctors at the material time.

Accordingly, the authors of the Lancet paper cannot and should not be held responsible for any alleged 'differences' between the records available to them and the full set of records as set out above. But that is not to say that Mr. Deer's interpretation of any differences is accurate. Rather, he has "cherry picked" differences with a view to undermining the credibility of the Royal Free doctors and the *Lancet* paper. This will be illustrated by reference to specific instances. Some discrepancies are inevitable because of the evolving nature of developmental disorders that, for any particular child, may involve a number of different diagnoses during the course of their disease progression or remission.

"Although the research paper claimed that problems came on within days of the jab, in only one case did medical records suggest this was true, and in many of the cases medical concerns had been raised before the children were vaccinated."

There are two parts to this allegation.

- *"the research paper"*

This was not a *"research paper"*. It was a clinical 'case series' that contained additional research elements[4]. Labeling it as a research paper is intended to convey the impression that the children were investigated purely for the purposes of experimentation; an allegation that formed a central part of Mr. Deer's original complaint to the GMC[5]. In contrast, the paper reported on clinical referrals who were investigated on the basis of the presenting symptoms. [6]

- *"…that problems came on within days of the jab, in only one case did medical records suggest this was true. In many of the cases medical concerns had been raised before the children were vaccinated."*

Here Mr. Deer misleadingly conflates *"problems"* with *"medical concerns"*. With respect to *"problems"*, the Lancet paper was quite specific in referring to the timing of onset of "behavioural problems" in relation to MMR exposure. Nowhere in the paper was any reference made to the onset of *"medical*

[4] The detailed research review of tissue pathology under the microscope (Histopathology review)
[5] Deer's allegation to GMC re unethical experimentation: Letter of Deer to Tim Cox-Brown February 25th 2004 p3. "Therefore, the was, in my view, neither ethical approval, nor clinical indication for the invasive investigation of some children."
[6] Walker-Smith JA The Lancet. 2004;363:822-823

concerns." The latter is an entirely non-specific expression that might relate to anything that caused a child to present to a doctor and the use of this term to reflect what had been said in the Lancet is entirely misleading.

For clarity, the paper stated that the reporting of the onset of the 'behavioural problems', coming on within a mean of 6.5 days after vaccination, was based upon the parental history as given to the clinical team at the Royal Free, lead by Professor Walker-Smith – and not to me.

As will be shown below, the implication by the *Sunday Times* that these children were exhibiting signs of autism before vaccination is shown to be false when one looks at the details of the specific children cited by Mr Deer.

"Hospital pathologists, looking for inflammatory bowel disease, reported in the majority of cases that the gut was normal. This was then reviewed and the Lancet paper showed them as abnormal."

The substance of this latest allegation illustrates how rigorous clinical and scientific investigation is vulnerable to misrepresentation. I am accused of a grave scientific misdemeanor - falsifying data. As an example of the fallacy of this allegation, a detailed explanation is provided of the process by which the pathology in tissue biopsies from these children was diagnosed and reported. Crucially, I played no part in the *diagnostic* process at all. Further, the fact that a review of the samples took place is clearly spelled out for all to read in the Lancet paper itself. (See below). There was no sinister attempt to hide any initial assessments as implied by the *Sunday Times*.

Biopsies were initially reviewed by duty pathologists who often had no specialist expertise in gastrointestinal disease, particularly in children. Professor John Walker-Smith, the senior clinician, who has an unparalleled experience of the appearances of bowel disease in children, as was his normal clinical practice, reviewed all biopsies at a weekly clinico-pathological meeting of his team. This was undertaken with the assistance of histopathologist Dr. Sue Davies. At these meetings Professor Walker-Smith pointed out the fact that inflammation had been overlooked in some cases.

It was decided that the senior consultant histopathologist with expertise in intestinal disease (Dr. Dhillon) should review all biopsies from autistic children, and that pathology should be graded on a proforma (or grading sheet) designed by him[7]. Thereafter, a regular review of biopsies took place involving Drs. Dhillon and Anthony, a trainee pathologist. I was also in attendance. Dr. Dhillon's diagnosis formed the basis for what was reported in the *Lancet*; long antedating Mr. Deer's allegations. This process has in fact been described in the relevant medical literature[1,8] (see below) and it was also presented in evidence by me in Mr. Deer's presence to the GMC hearing (see below). Once the paper had been

[7] See statement of Dr Dhillon below, footnote 16.
[8] Wakefield AJ. Autistic enterocolitis: is it a histological entity? *Histopathology* 2006;50:380-384

written in draft form by me to include Dr. Dhillon's and Dr. Anthony's findings, it was circulated to *all* authors (including Drs. Dhillon and Anthony) for their modification and approval. Mr. Deer must have been aware of these facts before he published his claims, because he sat through the evidence and because, as I have already said, it is all set out in some detail in the paper itself.

Documented below and available to Mr. Deer at the time of writing his article, are the specific references to this diagnostic process in published papers from the Lancet 1998 paper and two subsequent ones in 2000 and 2004.

Lancet[9]:

Ileal lymphoid nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

Formalin-fixed biopsy samples from ileum and colon were assessed an reported by a pathologist (SED)[10] Five ileocolonic biopsy series from age-matched and site-matched controls whose reports showed histologically normal mucosa were obtained for comparison. All tissues were assessed by three other clinical and experimental pathologists (APD, AA, AJW)[11]

The following paper contains data on the 12 Lancet children (as stated in the paper).

Enterocolitis in Children With Developmental Disorders[12]

Materials and Methods

Mucosal biopsies were taken from the ileum, cecum/ascending colon, transverse colon, descending/sigmoid colon, and rectum. Hematoxylin and eosin-stained histological sections from all biopsies were reviewed in the routine pathology laboratory, followed by independent review and scoring on a standard proforma (Table 1)[13]. In those cases where there was disagreement between these two reports, sections were examined and reported by a third senior pathologist, whose arbitration provided the final

[9] Wakefield AJ, Murch SH, Anthony A, Linnell J, Casson DM, Malik M, Berelowitz M, Dhillon AP, Thomson MA, Harvey P, Valentine A, Davies SE, Walker-Smith JA. Ileal lymphoid nodular hyperplasia, non-specific colitis and pervasive developmental disorder in children. *The Lancet* 1998;351:637-641

[10] Dr Sue Davies, Consultant Histopathologist, Royal Free Hospital

[11] Amar P Dhillon, Andrew Anthony, Andrew Wakefield.

[12] Wakefield AJ, Anthony A, Murch SH. Enterocolitis in children with developmental disorders. American. Journal of Gastroenterology 2000; 95;2285–2295.

[13] Appendix. Pathology proforma designed by Dr Dhillon (supplied upon request)

score. In an identical manner, histological sections from the ileum and colon of children without developmental disorder were scored (median age 11.5 years; range 2-13). These included 22 consecutive ileocolonoscopic biopsy series that had been reported as normal after routine histopathology assessment. All children in this non-IBD control group had undergone ileocolonoscopy for investigation of intestinal symptoms and are included in the 37 endoscopic controls, as described above. To validate further the evaluation and scoring, 10 coded ileocolonic biopsy series (five affected children and five non-IBD controls) were reviewed at another institution by a senior pathologist in an observer-blinded fashion. Data from these independent assessments were compared.

The results section of this same paper documented a high degree of agreement between independent pathologists in an 'observer-blinded' analysis i.e. where the person scoring the biopsy was unaware of the diagnosis in the individual from the biopsy came and the score given to the same biopsy by other observers. The following is abstracted from the results section of the same paper.

Results

Ten ileocolonic biopsy series were reviewed and scored in an observer-blinded fashion at an independent institution. No indication was given of how many samples came from each patient group. Cases *[autistic children's biopsies]* were clearly distinguished from controls *[non-autistic children's biopsies]* by the blinded reviewer[14]. Out of a possible total of 15 points, independent scores were identical for the same criterion in four of 10 cases (40%), within one point of each other in five of 10 cases (50%), and within two points of each other in one of 10 cases (10%) (Spearman rank correlation 0.79; $p < 0.006$). No reviewer scored systematically higher or lower than the other.

The following paper (para 3) provides a detailed review of the diagnostic process, specifically referring to the role of Drs. Dhillon and Anthony in the process. It also refers to the 'clinicopathological meeting' and the fact that histopathological findings were frequently modified as a consequence of this expert and thorough review process.

Autistic enterocolitis: is it a histopathological entity?[15]

[14] A pathologist who is unaware of the details of the person from whom the biopsies were obtained.

[15] Wakefield AJ. Autistic enterocolitis: is it a histological entity? *Histopathology* 2006;50:380-384. This was an invited response to a paper by MacDonald and Domizio that questioned the validity of the bowel disorder in autistic children.

> For the purpose of clarification, children with developmental disorder were seen in the Department of Paediatric Gastroenterology at the Royal Free for evaluation of their gastrointestinal symptoms. Definitive and appropriate assessment included ileo-colonoscopy, upper gastrointestinal endoscopy and histopathalogy. Biopsy specimens were subjected to routine assessment by the duty pathologist and subsequent detailed review with scoring on a semiquantitative scale as illustrated in the manuscript of MacDonald and Domizio. The proforma was designed by Professor A. Dhillon of the Department of Histopathology, who with Dr A. Anthony evaluated the sections for the purposes of completion of this proforma. The interobserver variation using the histopathology proforma was high and is described in detail.[1] Both pathologists have an extensive, published track record in mucosal histopathology. In addition, all diagnoses were routinely reviewed at a weekly clinicopathological meeting involving clinicians and pathologists, and frequently modified as a consequence.

The details of the diagnostic process were also described by myself during evidence (Days 49 and 50) at the GMC with Mr. Deer in attendance.

> Transcript of Dr. Wakefield's evidence on Day 49 of the GMC hearing
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> Q I want to come on now to what you, in anticipation, describe as "Research tests", and we see that under the heading of "intestinal biopsy research" there are references in the right-hand column on page 221 to histology, and we see that on the first page of this document, in the fourth column down, there was also a reference to histology. Why is histology captured under this heading of "Research tests" with the source reference at page 221? What is the difference between the two?
> A Standard routine histopathology is involved in the clinical diagnosis of disease in these children. Dr. Paul Dhillon as part of his contribution to this decided at a relatively early stage that, in light of the findings in these children, in light of the apparent novelty and subtlety of some of the changes, a pro forma driven analysis would be necessary in order to provide a semi-quantitative estimate of what was going on in their intestine, and to this end he designed a histology pro forma which could be scored as, for example, zero for no inflammation; one for mild inflammation; two for moderate inflammation, and three for severe inflammation, and he took the various categories of changes in the intestine and set them out under those numbers, normal, mild, moderate and severe. And that was used in a detailed histopathological review

by Dr. Dhillon and Dr. Anthony, principally, with me looking over their shoulders to learn, and that formed the basis of the research histopathology.

Q So we have, is this right, Dr. Wakefield, a strata of clinical histopathology but also a strata of research histopathology?
A Correct.

Day 50
Q I have two other short matters to deal with. When it came to the drafting of *The Lancet* paper, can we just identify together the materials that you would have had available? First of all, would you have had the referral letters?
A Yes.

Q Would you have had the clinical notes generated at the Royal Free, including correspondence to and from the Royal Free?
A Yes.

Q Would you have had the clinical histopathology documentation generated by the histopathologist including Dr. Davis?
A Yes.

Q Just simply to illustrate the point, and I am not going to do this with each and every one of these children, perhaps we could just set the scene for what you mean by that. If you look at page 248, would you have the endoscopy report?
A Yes.

Q A histology written on the right-hand side?
A Yes.

Q Then if you turn on to 263a running through, with the exception of 269 (slightly out of order) but down into 270, would you have had all those documents, and 270a?
A Yes, I would. One thing I would say just by way of clarification is that the information in *The Lancet* paper was based upon the first colonoscopy and the first histology and some of the information that comes up here is from the November colonoscopy and histology.

Q I am not for the moment attempting to fine-tune anything; I am just dealing with the general principle.
A Yes.

Q Would you have had the product of any Friday afternoon amendments in the notes?
A Yes.

Q We have heard about the role of Dr. Dhillon. Did you have the product of Dr. Dhillon in relation to this child prior to the drafting of *The Lancet* paper?
A Yes, indeed; Dr. Dhillon's detailed research, overview, in the pro forma driven format that I have talked about last week was available and in fact was the final determinant of the diagnosis in these children.

Q Just for completeness, would you take volume 7 of the Panel bundles, and look at tab 16? In general terms, what is tab 16?
A Some time during the course of the investigation of these children it became clear that there was a possible new syndrome emerging, that bowel disease was indeed being found, immunological abnormalities were being found. By way of our training in academic medicine, which is largely pro forma driven and database driven, it was felt appropriate to develop a system, albeit rather primitive at the time, to make sure that all the relevant information was being captured. This is not necessarily a research exercise, although it can be; it is a way of making sure that you have ticked the boxes, that you have captured the relevant information in a consistent way across a group of patients. So this is a pro forma or these are draft pro formas in various states of preparation the design of which was mine. What I have attempted to do in this is to capture the salient features of his child's history, the demographic information, their infancy, their childhood development, their infectious and vaccine exposure, their histology and so on and so forth.

Q Did it include the product from Dr. Dhillon?
A Yes. If you turn to page 243, you will see an example of the histology pro forma that I mentioned to you. Now this is a summary pro forma. Each individual biopsy, and there may be seven or eight of them from the colon of a particular child, has one page like *this*. You will see the designation down the left-hand column of: acute inflammation, chronic inflammation, epithelial or laminar propria changes, et cetera. These are just histological matters of interest. Then across the top, if there were none of these features of interest present, there was a zero score. If they were present and mild, then a score of 1, moderate 2, severe 3, and then a total score given. This is Dr. Dhillon's contribution to his work. This was done in co-operation with Dr. Andrew Anthony.

Dr. Dhillon's role in the diagnostic process is confirmed in a statement he provided to the GMC and signed by him on the 28th July 2006.[16] This key

[16] Signed statement of Dr A Dhillon to the GMC. 17. In quite a different way [to routine diagnostic histopathology], when a histopathologist provides systematic observations for research purposes, it is best practice to be unbiased and not to see the clinical details of the patient who has provided the sample. In the context of inflammatory bowel disease, the histopathologist might put more order into his observations and may say whether there is acute inflammation, chronic inflammation, ulceration, or architectural changes. He/she will also comment on the extent to which these things can be seen on the slide. Histopathologists sometimes record their observations as a "score" ranging 0-III, where '0' could represent no inflammation, 'I' could represent mild inflammation, 'II' could represent moderate inflammation, and 'III' could represent severe inflammation.

18. I often use this type of scoring system when I am asked to undertake a systematic review for research purposes. I will look at each slide down the microscope and record the relevant features for each slide in a table. I may record a score for some of the relevant microscopical features in the table as well.

19. The different scores of 0-III representing for example, different degrees of inflammation, are not necessarily reproduced in a published research paper unless a specific referee requests it.

20. My appointment in the Medical School requires me to undertake research activities. Around 1997, I was asked by Dr Wakefield to review a series of slides of gut biopsies from patients from the paediatric gastroenterology department. …Biopsies would have been taken from different parts of the gut from each patient, and I would have looked at the whole series of biopsies for each patient.

21. For my research review of slides, I was not given any clinical details about the children who had provided the samples. I made microscopical observations and recorded these observations using the system described above. The observations were given to Dr Wakefield.

22. When I was asked to do this review of slides, I did not know what symptoms the children had. The review of the slides was straightforward and was a matter of saying whether there was inflammation or not as well as other relevant microscopical observations.

23. The idea to publish the series of children described in the 1998 Lancet paper had arisen probably in 1997. It was then that I learned more about the clinical syndrome which the children (included in the slide series which I had reviewed) apparently had. My clinical colleagues told me that this was a group of children with a syndrome that included gut problems, endoscopic changes and a particular histological appearance. These children had delayed or regressed development. The syndrome became more coherent to me when I saw a draft of the paper.

24. The paper contained histology paragraphs and a table which includes a column where the histological findings for the 12 children have been written up. I did not write the histology section of the paper and I cannot remember whether I made any amendments to the draft paper which would have been circulated to all of the authors. I do not know if any other histopathologists undertook the same review exercise with the slides as me, and I did not see their observations.

25. The person who wrote the histological findings may have looked at the observations which I provided to Dr Wakefield. The person writing the research paper may have translated the Roman numeral scores which I may have used into something readable. For example, the term "lymphoid nodular hyperplasia" is synonymous with "increased or enlarged lymphoid follicles", and this in aspect of chronic inflammation.

document confirms his role in making the diagnosis in the Lancet children in the most stringent way i.e. by a 'blinded review', where the reviewer is unaware of the patient's disorder.

There should have been no doubt in anyone's mind at the GMC hearing as to the extraordinary diligence with which the diagnostic process was undertaken and the fact that I was not in any way responsible for the final tissue diagnosis in the Lancet children.

Through his lawyers, Wakefield this weekend denied the issues raised by our investigation, but declined to comment further."

As I have said before, Mr. Deer's serious allegations were only provided to me on the morning of Friday 6th February. I was given a deadline of Saturday 7th February, midday London time i.e. 6.00 am Central Standard Time in Texas, leaving no adequate time for me, or my legal team, to deal with the matter. In fact, Mr. Deer sent an email with detailed questions that required far more time to answer adequately than the lateness of his inquiry would allow.

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The following section deals with the accompanying inside story that appeared in The *Sunday Times* of February 8, 2009. It is concerned with specific allegations in respect of individual children.

"Hidden records show MMR truth
A Sunday Times investigation has found that altered data was behind the decade-long scare over vaccination.

Wakefield still insists there is a potential link between MMR and autism

Brian Deer

On a Monday morning in February 1997, a taxi left the Royal Free hospital, in Hampstead , northwest London. It turned out of the car park and headed to the renowned Institute of Cancer Research, six miles southwest in Fulham.

In the back of the cab sat a California businessman, whose commercial interests lay in electroplating, but whose personal crusade was autism. On his lap was a

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26. The paper was published in the Lancet in February 1998 and was entitled "Ileal-lymphoid nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children" ("the Lancet paper"). I was named as one of the authors on this paper because of the blinded review of the series of slides which I undertook in a research capacity.

plastic pot, in which snips of human tissue floated in protective formalin.

The snips were biopsies taken from the gut of the man's five-year-old son, then a patient on the hospital's Malcolm ward. The boy, Child Eleven, as he is known to protect his privacy, had been enrolled in a programme to investigate alleged risks of the three-in-one measles, mumps and rubella (MMR) vaccine.

"I'm an engineer," said Mr Eleven. "And my doctor here [in California] suggested I should cross-check the Royal Free's results with another lab. Just to be sure."

Child Eleven was one of a dozen children who were enrolled in the programme at the hospital."

Child 11 was not enrolled on any 'programme' which is synonymous with a research programme (and therefore misleading) when in fact it was a *clinical* investigation. On the contrary he was referred by his doctor in the US to Professor Walker Smith for investigation of his intestinal symptoms.

"Its research caused one of the biggest stirs in modern medical history when its results were published in The Lancet medical journal. The five-page paper suggested a potential link between MMR and what the doctors called a "syndrome" of autism and inflammatory bowel disease."

"The children were not named in the tables of results. Eleven boys and one girl, aged between 2½ and 9½, were said, for the most part, to have a diagnosis of regressive autism, where children appear to develop quite normally, but then, terrifyingly, lose their language skills. The bowel disease was described as nonspecific colitis, a severe form of inflammation.

The dynamite in The Lancet was the claim that their conditions could be linked to the MMR vaccine, which had been given to all 12 children."

The Lancet paper did not "claim that their conditions could be linked to the MMR vaccine". This is complete fabrication. No such claim was ever made in paper, on the contrary it was explicitly stated that no association had been proved between MMR and the syndrome described. It reported only that the parents said symptoms onset started after MMR vaccine in 8 of 12 cases

"According to the paper, published on February 28, 1998, the parents of eight of the children said their "previously normal" child developed "behavioural symptoms" within days of receiving the jab.

"In these eight children the average interval from exposure to first behavioural symptoms was 6.3 days," said the paper.

At face value, these findings were more than grounds for the panic that took off over MMR. If such startling results were obtained from two-thirds of a group of

previously normal children turning up at one clinic at just one hospital, what might be happening, unreported, all over the world? This might be the first snapshot of a hidden catastrophe, a secret epidemic of vaccine damage.

To launch the findings, the Royal Free held a press conference, and issued a video news release. The researchers' leader, Dr. Andrew Wakefield, then 41, was emphatic in his comments to the assembled media.

"It's a moral issue for me," he said. "I can't support the continued use of these three vaccines, given in combination, until this issue has been resolved."

Eleven years later, the fallout continues around the world. The paper triggered a public health crisis. In Britain, immunisation rates collapsed from 92% before the Lancet paper was published, to 80% at the peak of Britain's alarm. Measles has returned as officially "endemic"."

With less than 95% of the population vaccinated, Britain has lost its herd immunity against the disease. In 1998 there were 56 cases reported; last year there were 1,348, according to figures released last week that showed a 36% increase on 2007. Two British children have died from measles, and others put on ventilators, while many parents of autistic children torture themselves for having let a son or daughter receive the injection.

"There's not a day go by I don't cry because of what happened," said the mother of a severely disabled 12-year-old girl. "I shouldn't have took her [for the MMR], and you know everyone will say, 'Don't blame yourself', but I do. I blame myself."

Yet the science remains a problem. No researchers have been able to replicate the results produced by Wakefield's team in the Lancet study.

It is not true to say there has been no replication of the work as stated above; three independent groups have reported on intestinal inflammation (ileitis and colitis) in children with autism since the initial Lancet 1998 publication (Gonlzalez L et al.2005, Balzola F et at, 2005; Krigsman A et al, 2004) [17]

Some used statistics to see if autism took off in 1988, when MMR was introduced.

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[17] Gonzalez, L. et al., *Endoscopic and Histological Characteristics of the Digestive Mucosa in Autistic Children with gastro-Intestinal Symptoms.* Arch Venez Pueric Pediatr, 2005;69:19-25.
Balzola, F., et al., *Panenteric IBD-like disease in a patient with regressive autism shown for the first time by wireless capsule enteroscopy: Another piece in the jig-saw of the gut-brain syndrome?* American Journal of Gastroenterology, 2005. 100(4): p. 979- 981.
Krigsman A et al.
http://www.cevs.ucdavis.edu/Cofred/Public/Aca/WebSec.cfm?confid=238&webid=1245 (last accessed June 2007) (paper submitted for publication)
Balzola F et al . Autistic enterocolitis: confirmation of a new inflammatory bowel disease in an Italian cohort of patients. Gastroenterology 2005;128(Suppl. 2);A-303..

It did not.

Others used virology to see if MMR caused bowel disease, a core suggestion in the paper. It did not.

This claim is misleading and betrays either ignorance or an attempt to mislead. Virology has been used for the detection of measles virus and other viruses in the intestinal tissues of children with autism. Whether measles virus is present or not, 'virology', as used, cannot "*see if MMR caused the bowel disease*", it can only determine presence or absence on a particular virus. Presence of, for example, the measles virus in intestinal tissues does not make it the cause of any concomitant bowel disease.

Yet more replicated the exact Wakefield tests. They showed nothing like what he said.

This is false; firstly, the tests reported in the Lancet paper are not in any manner "*Wakefield tests*", but clinical investigations that were deemed necessary by the appropriate clinicians. Referring to the tests in this way is intended to mislead the reader into thinking that I was responsible for these tests. No details are provided in support of Mr. Deer's claim, nor are the assertions attributed to any expert. His claim is false: those studies that have looked for bowel disease in autistic children with gastrointestinal symptoms have found it.[17]

"Wakefield himself, however, stands by his results, insisting that a link between MMR and autism merits inquiry. The 12 other doctors whose names were attached to the Lancet paper, which was written by Wakefield, were not involved in preparing the data used."

Once again, this is completely false: the other authors generated and 'prepared' all the data that was reported in The Lancet. I merely put their completed data in tables and narrative form for the purpose of submission for publication. All authors were provided with drafts of the paper for the purpose of checking their data and making amendments as necessary, prior to submission. This example alone shows either egregious incompetence or malice on the part of a journalist whose work is presumed by the public readership to be in pursuit of fairness and objectivity.

"This study created a sensation among the public that was impossible to counter, despite overwhelming evidence to the contrary," says Professor Gary Freed, director of the child health research unit at the University of Michigan, who has watched the scare take off in America.

"Overwhelming biologic and epidemiologic evidence has demonstrated conclusively that there is no association between the MMR vaccine and autism, and yet this thing goes on."

Aspects of the project are now before the General Medical Council (GMC), the

doctors' disciplinary body.

Wakefield and two professors, John Walker-Smith, 72, and Simon Murch, 52, are charged with carrying out unauthorised research on the 12 children. The charges, which they strongly deny, relate to the ethics of the treatment of the 12 children, not the results of the research.

In evidence presented to the GMC, however, there has emerged potential explanations of how Wakefield was able to obtain the results he did. This evidence, combined with unprecedented access to medical records, a mass of confidential documents and cooperation from parents during an investigation by this newspaper, has shown the selective reporting and changes to findings that allowed a link between MMR and autism to be asserted.

Mr. Deer's statement is clearly intended to convey the impression that it was I who "*obtained the results*", and that these results were obtained by my "*selective reporting and changes"* with the clear implication of scientific fraud on my part, for the purpose of allowing "*a link between MMR and autism to be asserted.*"

I did not obtain any results. The results were obtained by the clinicians investigating these children. I had no role in "*obtaining*" these results. The process by which the clinicians obtained the results has been described in great detail to the GMC hearing, attended by Mr. Deer.

These results were obtained by the clinicians in a manner that is transparent and described in the Lancet paper. In contrast, as illustrated below, Mr. Deer is highly selective in cherry-picking results to make his case, makes basic errors of understanding, and relies upon documents that were not available to doctors at the Royal Free at the time the paper was complied and written (see below).

Finally, the only thing that "*allowed a link between MMR and autism"* to be suggested was the parental history. This was faithfully reported in the Lancet.

MR ELEVEN'S taxi dash was a small ride in his desperate quest to find an answer for his son's condition. Today, Child Eleven is much improved: at 17, he is a terrific scholar, although too nervous to drive.

The extra tests on his biopsies produced striking results. His father asked the cancer institute to look for the measles virus, which lay at the heart of Wakefield's concerns over the vaccine. According to a theory that underpinned the project, this virus in MMR was the cause of bowel disease, which then did damage to children's brains.

Mr. 11 and his US physician sought a referral to Professor Walker-Smith for clinical investigation of his intestinal symptoms, occurring in association with Child 11's autism. Entirely independently of the Royal Free doctors, Mr. 11's doctor had asked for viral studies to be undertaken by the team of Professor Robin Weiss at the Chester Beatty Institute in London on a biopsy from his son. When

these tests were done, they were determined to be negative for measles virus. There was nothing "striking" about these results at all.

"It took a big fight to get the information," said Mr. Eleven. "They told me there was no measles virus. I had the tests repeated three times at different labs in the US, and they all came back negative."

The fight that Mr. 11 had was with Professor Weiss and not with anyone at the Royal Free.

"This struck a different note from what Wakefield suggested when describing his research to the world.

"We would not have presented this paper to The Lancet had we not undertaken extensive virological studies already," he told the 1998 press conference."

The absence of measles virus in the intestine of Child 11 had no bearing on the Lancet paper or on Dr. Wakefield's reference to virological studies performed at the Royal Free which were of an entirely different nature from those performed by the team of Professor Weiss. As such Mr Deer's claim is misleading.

"At face value, this is an anomaly. In science, however, these are endless and can sometimes eventually be explained. This is why studies are usually repeated. But at the heart of Wakefield's findings The Sunday Times found more discrepancies, inconsistencies and changes."

The information which follows, as prepared by Mr. Deer, comes from the medical records of disabled children: confidential records held by Mr. Deer but intended solely for use by clinicians involved in the child's care. The *Sunday Times'* allegations are two fold: the history of the relationship of MMR to the pattern of onset of the children's symptoms and the pathology examination of the children's tissues.

1. In respect of the "MMR link" it relies on evidence with regard to children 1,2,6,7 and 8 of the 12 Lancet children.

It is essential to note that the Lancet paper clearly stated that the history of the onset of behavioural symptoms was associated by the parents with MMR in 8 of the 12 children and it is the initial behavioral symptoms described by the parents, that was reported in the Lancet.

"The first, in the Lancet tables, concerned the first child in the paper: Child One, from Cottesmore, Leicestershire. He was 3½ years old and the son of an air force pilot. In November 1995, his parents had been devastated after receiving a diagnosis of autism.

"Mr and Mrs [One]'s most recent concern is that the MMR vaccination given to their son may be responsible," their GP told the hospital in a letter.

In the paper this claim would be adopted, with Wakefield and his team reporting that Child One's parents said "behavioural symptoms" started "one week" after he received the MMR."

Child 1.

Developmental History

Child 1 is reported as suffering "fever and delirium". This delirium, which started one week after MMR and lasted for 3 days[18], refers to his first 'behavioral symptom', as specifically stated in *The Lancet*[19]. With respect to his subsequent clinical course, Professor Walker-Smith's letter to the GP goes on to say:

> "Between the age of 1 year and 18 months his development slowed and then deteriorated."[20]

Evidence from Child 1's GP, at the GMC hearing confirmed that Mrs 1's view was that her child had developed normally until he had his MMR. This was recorded in the medical records, which formed the basis of the information contained in the Lancet paper. The facts reported in the Lancet are entirely accurate.

"The boy's medical records reveal a subtly different story, one familiar to mothers and fathers of autistic children. At the age of 9½ months, 10 weeks before his jab, his mother had become worried that he did not hear properly: the classic first symptom presented by sufferers of autism." "Child One was among the eight reported with the apparent sudden onset of the condition."

A review of the additional GP records (not available to the Royal Free Team at the time of writing the Lancet paper. These records were first seen by me and my co-defendants in the lead-up to the 2007 GMC hearing) shows that, with respect to his claim about Child 1's hearing, Mr. Deer fails to mention the crucial fact that in the entry that documents his mother's concerns about Child 1's hearing, his mother's additional concern was about a discharge from Child 1's left ear, indicative of an ear infection at some stage.[21] This concern is not suggestive of an incipient developmental disorder but of a possible recent ear infection which would have been more than enough for his mother to express possible concerns about Child 1's hearing. This is an example of Mr. Deer's highly selective reporting of results that were not available to the authors of the Lancet paper at the material time. Time after time throughout the course of his reporting and

[18] Clinic note of Professor Walker-Smith 20 June 1996. Royal Free Hospital Records 13.
[19] Wakefield AJ, Murch SH, Anthony A, Linnell J, Casson DM, Malik M, Berelowitz M, Dhillon AP, Thomson MA, Harvey P, Valentine A, Davies SE, Walker-Smith JA. Ileal lymphoid nodular hyperplasia, non-specific colitis and pervasive developmental disorder in children. *The Lancet* 1998;351:637-641

[20] General Practice Records p54
[21] General Practice Records. p6.

narrative, Mr Deer appears to selectively rely on data to support his premise that I have perpetrated a fraud. Fair journalism does not pivot on a premise nor its proof. Even if that were the case, Mr Deer would have been unable to prove his preconceived notions had he looked at the evidence.

Child 1's Royal Free Hospital records contain no reference whatsoever to any hearing difficulties. These records include the referral letter from the GP to Professor Walker-Smith. The only reference to Child 1's hearing is in the Royal Free Hospital clerking note of 21 Jan '96 where his hearing is reported as being "normal"[22].

The Health Visitor Records[23] were available to the Royal Free Team and are described below.

11.3.93 [age 2 months] Health visitor record:

> "Hearing and development normal."

12.8.93 [age 7 months] Health visitor record:

> "Hearing and development normal."

"So was the next child to be admitted. This was Child Two, an eight-year-old boy from Peterborough, Cambridgeshire, diagnosed with regressive autism, which, according to the Lancet paper, started "two weeks" after his jab."

"However, this child's medical records, backed by numerous specialist assessments, said his problems began three to five months later."

Child 2

Developmental history
The Lancet paper described the onset of Child 2's first 'behavioral symptoms' two weeks after MMR vaccination. The first reference to onset of 'behavioral symptoms', as correctly stated in the Lancet is found in the assessment of Child 2 by consultant child psychiatrist Dr. Mark Berelowitz in Child 2's Royal Free Hospital records and described in a letter to Dr. Simon Murch.[24]

> "Thank you for asking me to see [Child 2] who I saw on the ward on the 5th of December 1996. I saw him at the request of yourself and Andy Wakefield… his milestones in the 1st year were normal. At the age of 13 months she said he had 25 words, but he gradually lost his words over the next 7 to 8 months. … his Fragile X was negative his brain scan is normal as his EEG… reiterated that

[22] "Hearing" followed by a horizontal arrow which designates "normal" in medical clerking.
[23] General Practice Records p14
[24] Letter 30/9/1996. Royal Free Hospital Records pp 143-144

> [Child 2] started head banging about 2 weeks after the MMR and hasn't looked right since [emphasis added]… I thought that the history and presentation were very typical of autism or a related disorder… …"

This is confirmed in the Royal Free records 'discharge summary'.

> "Until 20 months of age … normal developmental progress. … Mum does recount that at 13 months of age he had had his MMR immunisation and 2 weeks following this had started with head banging behaviour and screaming throughout the night. He subsequently seemed generally sickly."[25]

The problem became progressively more severe with loss of language, incoordination and other features of developmental regression but the first "behavioral" symptoms was, as correctly stated:

> "head banging about 2 weeks after the MMR" [emphasis added].

There are additional references in the Royal Free Hospital records from the senior medical authors of the paper to his subsequent developmental deterioration. These include an outpatient note from Professor Walker-Smith note:

> "had MMR at 15[26] months, went down hill ever since." [27]

And, a letter from Berelowitz dated 30.09.96:

> "had 25 words at 13 months which he then lost, began to get a bit clumsy at 15 months."[28]

"The difference between 14 days and a few months is significant, according to experts. Autism usually reveals itself in the second year of life, when the vaccine is routinely given. If there was no sudden onset after the MMR injection, as claimed for the "syndrome", the condition could be ascribed to a conventional pattern."

The sudden onset of Child 2's behavioral symptoms means that his condition could not be ascribed to "*a conventional pattern*." In fact, elsewhere in his records, not referenced by Mr. Deer, experts describe his regressive pattern of autism as "unusual".[29] Not surprisingly, Mr. Deer failed to include this

[25] Royal Free Hospital Records page 145
[26] This is an error by JWS that should read 13 months
[27] Royal Free Hospital Records page 25
[28] Royal Free Hospital Records page 143
[29] Letter from Dr Robert Surtees paediatric neurologist at Great Ormond Street Hospital to Dr Hilary Cass as Harper House. 23rd August 1996. General Practitioner Records p146.

perspective.

"More apparent anomalies lurked among the following 10 children, as they arrived at the Royal Free hospital between September 1996 and February 1997."

"Child Six, aged 5, and Child Seven, aged 3, were said to have been diagnosed with regressive autism, with an onset of symptoms "one week" and "24 hours" after the jab respectively.

But medical records show that neither boy was "previously normal", as the Lancet article described all the children, and that both had already been hospitalised with brain problems before their MMR."

The Lancet article described these two children as having "*normal development followed by loss of acquired skills*". It did *not* say that they were "*previously normal*" which is a non-specific term, potentially covering all aspects of their health. The paper did not state that these children had been diagnosed with *regressive autism* as Mr. Deer reported. In fact, at the time that paper was written, *regressive autism* was not a recognized diagnosis. Over the years they were diagnosed with various behavioral labels within the autistic spectrum including autism, Asperger's syndrome, and pervasive developmental disorder (PDD). The clinical history and the medical records confirm that they underwent developmental regression, having been previously developmentally normal. Child 6 had suffered febrile convulsions; these are not uncommon in children and are *not* symptomatic of autism or a risk of autism. It is notable that this child should not have received MMR vaccine.

Child 6

"Child Six received his vaccine at the age of 14 months, but had twice previously been admitted with fits.

Whether or not Child 6 suffered from "fits", this point is irrelevant to that his early development prior to MMR was considered normal. His fit (there is only one available record of such) was a febrile convulsion[30] which is not uncommon in children with fever and is certainly not indicative of an underlying brain problem or incipient autism.

Child 6's early development prior to MMR was normal according to documents supplied to the Royal Free.[31]

It is notable that he should not have received MMR vaccine in view of his In a letter to the Consultant Community Paediatrician on the 19th May 1997 Child 6's doctor wrote from the RFH:

[30] East Suffolk Health Authority dischanrge note. 16.3.93 "febrile convulsion"
[31] Health Visitor Records. Appendix (to be supplied upon request)

"Mum gave a history in [Child 6] of changes in social interaction following on immediately from his MMR vaccination."[32]

Consistent with the changes in social interaction, Child 6's initial behavioral symptom was confirmed by his mother and was described in the Lancet included:

"gaze avoidance.."[33]

Child 6 's initial behavioral symptom was accurately reported in the Lancet.

Child 7

Child Seven was given his at the age of 20 months but, again, problems already showed.

He developed well, had social smiling and was responsive to his mother," a psychiatrist wrote. "But he began to have pale episodes and ? [sic] petit mal [convulsions], and had an EEG [an electroencephalogram, a common test for epilepsy] done at 15 months, which was abnormal."

Once again, *The Lancet* paper specifically reported on the developmental status of children and Child 7 was developmentally normal prior to his MMR. It is also notable that in view of his history of fits, he should never have received MMR vaccine.

Health Visitor records are available from 21.12.94 at 10 months of age showing that his development is entirely normal, with no concerns whatsoever.[34]

There is an entry in his GP records on 27.9.95 at 19 months of age that states:

'happy baby'[35]

This confirmed by an entry in his GP records stating:

"Development normal"[36]

This was documented on 12 10.95 at just under 20 months (DOB 24.2.94).

Child 7 received his MMR at 21 months of age on 24.11.95[37]. In May 1996 his GP record states:

'bowel problems, constipation and bleeding. MMR Nov 95, quieter

[3232] Royal Free Hospital Records. p80. Letter from Dr Casson to Dr Bennett, Community Paediatrician. 19.5.1997.
[33] Lack of eye contact is a cardinal feature of autism
[34] Health Visitor Records 21.12.94 Appendix (supplied upon request)
[35] General Practice Records p23
[36] General Practice Records p24. "Development N (circled) standing for "normal".
[37] General Practice Records p296

> since, never happy, does not laugh. Cry or whine all day, falling, unsteady'.[38]

He continued to deteriorate and on 29.1.96 his local hospital records state:

> "Significant change in behaviour past 2 weeks." He became aggressive and incontinent'.[39]

The change following MMR is described in a letter from Professor Walker-Smith to Child 7's GP in response to his referral.

> "Many thanks for referring [Child 7]. I was very interested to hear the history of this child in which there does seem to be a clear relationship between symptomatology and the MMR. He had the MMR rather later than the usual at 21 months. His mother tells me that 24 hours afterwards he had a fit-like episode and slept poorly thereafter and she attributes changes in his behaviour to this event."

Meanwhile, neither was diagnosed with regressive autism, or even nonregressive classical autism. Three of the children had been diagnosed with Asperger's disorder, in which language is not lost, and which is not regressive: nothing like what afflicted One and Two. This was also the diagnosis for Child Twelve in the series, a six-year-old boy from Burgess Hill, West Sussex.

Child 6

This is false. Based upon this child's records he received various diagnoses on the autistic spectrum over the years, including autism[40] and autistic spectrum disorder.[41]

Evidence of Child 6's regression can be found at various places in his records.[42]

Child 6's GP confirmed the mother's perception of the relationship of Child 6's autism to MMR in his evidence to the GMC on 20th July 1997.

> Q As far as you understood, Doctor, did this child's mother have beliefs as to the reason why Child 6 was autistic?
> A Yes.

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[38] General Practice Records p296
[39] Local Hospital Records p111-112
[40] General Practice Records p28 – "autism". RFH17 – diagnosed with autism at age 3 years by Bennett (Community Paediatrician).
[41] Correspondence from J.W.S. to X.N. summarizing Child 6 as within the autistic spectrum and having chronic-bowel symptoms. 2/10/1996
[42] General Practice Records p244 – reference to regressive nature of the problem. General Practice Records p309 – sequence of regression described in detail.

> Q Can you tell us what they were and, if you can remember, when she first made them clear to you?
> A I am not sure when she first made them clear, probably from an early stage. She was convinced that it was to do with the MMR vaccination. She said he was fine before then.

And Seven would be diagnosed with an odd behavioural condition called "pathological demand avoidance syndrome" [PDA]. *This usually manifests as social manipulativeness, and is nothing like the "syndrome" being claimed. It is sometimes marked by a child putting his hands on his ears, while singing "lah-lah-lah, can't hear you".*

Child 7's records confirm that he was developmentally normal prior to MMR[43].

In contrast to the claim that Child 7's clinical course was "*nothing like the syndrome being claimed*", his history is captured in Professor Walker-Smith's letter to referring GP of 21 January 1997 as described above (p33).

There are many references to Child 7's behavioral and developmental regression the records:[44]

And in contrast with Mr. Deer's claim that Child 7 did not have an autism diagnosis, his records show that, as with other children, Child 7's diagnosis changed over time as his condition developed, and included not just PDA, but 'autism', and 'autistic spectrum disorder'. [45]

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[43] General Practice Records p218 – no concern about early developmental milestones.

[44] General Practice Records p86 – at 21 months saying 3-4 word sentences, following MMR speech stopped – "flat effect", "completely babyish".
General Practice Records p219 – regression in language skills at about 2.5 years (see also GPR220).
General Practice Records p357 – Professor Neville: behaviour a problem at 20 months, after MMR. Stopped speaking and lost bowel control.
General Practice Records p279 – letter from Professor Walker-Smith: mother gives history of fit following MMR and changes in behaviour.

[45] General Practice Records p222 – 09/98: diagnosed with "Pathological Demand Avoidance in the autistic spectrum" (see also GPR230).
General Practice Records p276 –02/97 –GP thinks he has "autism/autistic spectrum".
General Practice Records p239 – "diagnosis of autistic spectrum disorder somewhere between high functioning autism and Asperger's."
General Practice Records p59 – "autistic spectrum" diagnosis.
General Practice Records 417 – "pervasive developmental disorder".
General Practice Records 353 – "pervasive developmental disorder".
General Practice Records 222 – "pervasive developmental disorder in the autistic spectrum."
General Practice Records 135, 141, 163, 169, 189, 239, 276, 357. General consensus by early 1997 that he has autism spectrum disorder

"Only one was a girl, Child Eight, aged 3, from Whitley Bay, Tyne & Wear. She was reported in the journal as having suffered a brain injury "two weeks" after MMR.

Her medical records did not support this. Before she was admitted, she had been seen by local specialists, and her GP told the Royal Free of "significant concerns about her development some months before she had her MMR."

"Mrs 8 expressed concerns about 8's health and development from an early stage."

Child 8

Child 8 was reported in the Lancet as:

> "The only girl (child number 8) was noted to be a slow developer compared with her older sister[46]. She was subsequently found to have coarctation of the aorta. After surgical repair of the aorta at 14 months, she progressed rapidly, and learnt to talk. Speech was lost later."

Based upon the diagnosis of Dr. Berelowitz she is reported in the Lancet as having a possible post-vaccinial encephalitis (brain inflammation). In contrast with the newspaper's false assertion, her medical records confirm exactly the history that was reported in *The Lancet*. This report is supported by her records of what Dr. Berelowitz interpreted as a likely encephalitic episode.

> Within 2 weeks of MMR at 19 months developed rash and febrile convulsions…followed by behavioural deterioration, loss of words and vocalisation, screaming, hyperacusis, ataxia and nocturnal myoclonic jerks[47]

And,

> "MMR Jan 95, grand mal convulsion Feb 95 2 weeks after MMR, never the same again."[48]

The description of Child 8 in *The Lancet* is an entirely accurate representation of her history as documented in her clinical record and described below. In particular, Mr Deer omits the critical fact that because of the concerns of developmental delay, she was assessed twice prior to MMR by a Developmental Peadiatrician (Dr. Houlsby) who reported he considered her to be within the

[46] Confirmed in letter from Dr Houlsby to Dr Tapsfield, attached to statement of Dr Jelly DJ2
[47] Royal free Hospital discharge summary 27 Jan 1997.. DJ10 attached to statement of Dr Jelly.
[48] General practice records p25

normal range for development on both occasions[49]. These assessments took place at the age of 10.5 months (20 May 1994) and 17 months (16th December 1994). In December 1994 her development was considered age appropriate.

Child 8 suffered from coarctation of the aorta. This would readily account for her mother's concerns about her slow development. The mother's concerns about Child 8's development were with reference to her development relative to her sister[50] as reported in the Lancet.

Of note is her GP's comment in her referral letter to the Royal Free Hospital of 3.10.96 that:

> "[Child 8's] development did appear to get worse following the MMR" [51]

Child 8's GP comments in her statement made to the GMC[52] that Child 8 received her MMR on 27th January 1995 and that since then Mrs 8 "*perceived a definite reversal*" in Child 8's development. What is striking is that in February 1995 (seen on 17th February. Letter dictated 2nd March 1995) '*a matter of weeks after her MMR*' she was once again reviewed by the same Developmental Pediatrician (Dr. Houslby) who now determined that she was '*globally developmentally delayed functioning at about the one year level*'[53].

Thus, within the space of one month Child 8 had deteriorated considerably. She has gone from functioning at around the 18-month level to the one-year level in one month. Very little, if any, attention seems to have been paid to this. Child 8's reaction to MMR, although acknowledged, received no further consideration and no appropriate investigation.

There is a great deal of evidence of regression in Child 8's medical history and a clear paper trail of her mother's association of her problems with MMR, long before any contact with doctors at the Royal Free Hospital. This is corroborated by the following references in Child 8's records:[54]

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[49] Confirmed in letter from Dr Houlsby to Dr Tapsfield, attached to statement of Dr Jelly DJ2 and letter to Dr Hunter from Dr Houlsby 23 Dec '94: " felt that her abilities althought delayed on the average age of attainment were not outside the range of normal." DJ4

[50] Royal Free Hospital records p7; 19.1.96]

[51] Royal free Hospital Records p21

[52] Dr Jelly statement to GMC Day 29.

[53] General Practice Records p94

[54] General Practice Records 25 – "MMR Jan 95, grand mal convulsion Feb 95 2 weeks after MMR, never the same again."
General Practice Records p76 – discharge letter from RFH: dramatic deterioration from 18 months
General Practice Records p83 – GP letter: some developmental delay before MMR but mother adamant that she lost her speech after MMR.
General Practice Records p94 – at 17 months she was within the lower range of normal, at 20 months she was globally developmentally delayed functioning at about a "one year level".
General Practice Records p111 – letter from GP: regression after MMR.
General Practice Records p120 – loss of speech shown on video.

During the GMC hearing, Child 8's GP Dr. Jelly, gave the following evidence[55].

> Q. What was the mother of Child 8's perception of Child 8's reaction to the vaccine?
>
> A I felt that the mother was concerned fairly soon after the vaccine – I think I saw her at home on a home visit shortly after the vaccination – she had had a kind of feverish reaction to it. There obviously was no suggestion of delay at that point. Several months later her mum said she had been looking at a video when Child 8 had a little bit of speech before the vaccination and she felt that that had reduced post-vaccination.
> Q The incident you describe of the video was some time later, was it?
> A Yes.
> Q In terms of the more immediate reaction to the vaccine, you say that mum reported a fever.
> A Yes. I remember seeing her at home and then I think she was admitted with a febrile convulsion shortly afterwards.
> This is a letter from Dr. Bushby, the geneticist and it is to Dr. Tapsfield dated 31 July 1996. It states:
>
> "[Child 8's] mother came to the Genetics clinic recently without [Child 8]. Unfortunately we are still unable to reach a firm diagnosis to explain [Child 8's] developmental delay, coarctation

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General Practice Records p121 – clear evidence of regression prior to admission (see also GPR122).
General Practice Records p127 – concern over lack of speech (although continued to say a few words).
General Practice Records p130 – mother associates "setback" with MMR.
General Practice Records p131 – letter from paediatrician: at one year level on Denver Developmental Assessment.
General Practice Records p133 – letter from paediatric cardiologist: no speech whereas previously said single words.
General Practice Records p136 – evidence of regression
General Practice Records p139 –evidence of regression.
General Practice Records p142 – her speech has regressed.
Royal Free Hospital records p7 – admitted with history of developmental delay following dramatic deterioration.
Royal Free Hospital records p17 – letter to AW from Dr Berney: appears to accept abrupt post MMR regression.
Royal Free Hospital records p18 – mother reports "catastrophic deterioration" post MMR. Became a different person.
Royal Free Hospital records p20 – history of dramatic deterioration in referral to Berelowitz.
Royal Free Hospital records p49 – good evidence of regression.
Local Hospital records p20 – accepts that there were concerns re development prior to MMR but then makes clear that there was a subsequent deterioration.
Local Hospital records p45 – further evidence of regression.

[55] GMC hearing Day 29. Evidence of Dr Jelley.

of the aorta and slightly unusual face. Her mother reports that she is still without speech.

Much of our discussion recently centred around [Child 8's] mother's concerns that her problems stemmed from her MMR vaccination at 19 months. She tells me that a couple of weeks after the injection she developed a measles rash and was very poorly with it. She subsequently fitted and was admitted to hospital where she was found to be dehydrated. [Child's 8] mother is aware that there may be an underlying cause for [Child 8's] problems but is obviously also anxious that the MMR injection either caused her developmental delay or exacerbated it. She has been in touch with an organisation Jabs and is in contact with a mother of a child who similarly feels that her child's problems date from the MMR immunisation. Interestingly [Child 8's] mother feels very strongly that [Child 8's] speech was coming on well before she had her immunisation and that she had several words at that stage which she subsequently lost."

In summary, the reporting of Child 8's behavioral and developmental history in the Lancet paper was entirely accurate. Mr. Deer's allegation that her medical records did not support her description in the Lancet is false.

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Allegations of changing histopathological[56] findings in the children's biopsies.

With regard to the alleged misrepresentation of the pathology Mr. Deer relies on evidence with regard children 3, 8, 9 and 10

In order to deal with this grave and erroneous allegation, it is essential to understand the meticulous process by which the pathology in tissue biopsies from the children described in the Lancet was diagnosed and reported.

The diagnostic process leading to the description of pathology in the Lancet has been described in detail above.

"WHEN the children first arrived at the Royal Free, in addition to autism, they were also reported with constipation, diarrhoea or other common bowel complaints. This was the reason given for them travelling between 60 and 5,000 miles to London to enter the care of Wakefield's team."

The children described in the Lancet paper all had a period of apparently normal development and lost their acquired skills including communication. They all had gastrointestinal symptoms including abdominal pain, diarrhoea, bloating and in

[56] Histopathology is the process of making a microscopic diagnosis on tissues taken from a patient

some cases food intolerance.

It is another important factual error to suggest that they entered the care of "*Wakefield's team*." A reference to the "*Wakefield team*" is intended to cause the reader to think that I was guiding a group of gullible or deceptive physicians and researchers. Mr. Deer, having made the complaint to the GMC and attended nearly every day of the hearing (over 130 days) is well aware that all of these children were under the clinical care of Professor John Walker Smith's team of paediatric gastroenterologists at the Royal Free. At no time were they under the care of "*Wakefield's team".*

"Wakefield, now 52, a former gut surgeon, was at the time doing academic research in the Royal Free's medical school on Crohn's disease, an ulcerating inflammation. In 1995, he had developed a theory that this condition was caused by the measles virus, which is found live in MMR. The theory has since been discounted.

This work was the bedrock on which he based his new claims. Yet this too appears problematic. The children were supposed to have a new inflammatory bowel disease, written up in the Lancet paper as "consistent gastrointestinal findings" involving "nonspecific colitis". Wakefield said that this inflammation of the colon caused the gut to become "leaky", allowing food-derived poisons to pass into the blood-stream and the brain.

There are a number of errors here. The Lancet paper did not claim that the children were supposed to have a *new* inflammatory bowel disease.

I did not say that, "*this inflammation of the colon caused the gut to become "leaky", allowing food-derived poisons to pass into the blood-stream and the brain.* This was merely a hypothesis that was presented as such in the discussion section of the paper.

"The uniformity of the intestinal pathological changes and the fact that previous studies have found intestinal dysfunction in children with autistic-spectrum disorders, suggests that the connection is real and reflects a unique disease process," the Lancet Paper explained of the "syndrome".

"Yet pathology records of samples taken from the children show apparent problems with this evidence. The hospital's consultants who took biopsies from the children's colons concluded that they were not uniform but varied and unexceptional."

"For Child Eight, the pathology report said: "No abnormality detected", while the Lancet paper said: "Nonspecific colitis". This pattern was repeated for two of the other children."

Child 8

Child 8's routine report, undertaken by a neuropathologist (an expert in brain pathology) in fact described:

> "minimal inflammatory changes".[57]

This was confirmed in a letter from Dr. David Casson of 27/11/97 noting that:

> "All pieces of colonic tissue demonstrated minimal inflammatory changes" [58]

When the biopsies were reviewed and scored by experts in bowel pathology, namely Drs. Dhillon and Anthony, these doctors determined that there was mild inflammation in the caecum, ascending colon, and rectum.[59] This was correctly reported as "nonspecific colitis" in *The Lancet*.

Child 9

Child 9's routine histopathology report was reported in the routine pathology laboratory as showing "no histological abnormality"[60]. Professor Walker-Smith reviewed Child 9's biopsies directly with Dr. Dhillon on this occasion. In his evidence to the GMC on Day 81, p12, Professor Walker-Smith was asked:

> Q We have got up to 11 December 1996. You have told the Panel in general terms and in relation to individual children about the review of histology which you carried out with Dr. Dhillon?
> A Yes.
>
> Q In December 1996, so in the period with which we are now concerned, in which we are looking at this child's investigation. Was this child one of the children whose histology you reviewed with Dr. Dhillon after he did his blinded assessment of the slides?
> A Yes.
>
> Q If we look at the penultimate page in the clip that we have, D14. Professor, just under half way down in that not of the way you deal with a brief summary of the history, then the blood results. Then, under "Endoscopy," what have you written?
> A I have written:
>
> "Lymphoid nodular hyperplasia terminal ileum."

[57] Royal Free Hospital records p61
[58] Royal Free Hospital records p15
[59] Proforma report of Child 8
[60] Royal Free Hospital records p48

Then "Histology" underneath that?
A I have written:

"Prominent lymphoid follicles
Dhillon moderate to mild increase in intra epithelial lymphocytes.
Increase in chronic inflammatory cells through the colon –
superficial macrophages not quite granuloma".

Then my overall clinical opinion:

"Indeterminate colitis."

The standardized scoring by Drs. Dhillon and Anthony recorded:

> "Increase in chronic inflammatory cells, cryptitis, reactive follicular hyperplasia, and increase in intraepithelial lymphocytes."[61]

Professor Walker-Smith subsequently communicated this information to Child 9's paediatrician. Again on Day 81, p13, of the GMC hearing he was asked in relation to this:

Q 31 December 1996 and I think your letter, when you were going through Child 3's case, you wrote a letter on the same day to the general practitioner.
A Yes, this was a quiet period between Christmas and New Year in which I was going through these records carefully and acting as necessary.

Q So this is to Dr. Spratt.
A Yes.

Q "Child 9 as duly admitted. Endoscopy revealed a marked increase in size and number of prominent lymph nodes in the terminal ileum i.e. lymphoid nodular hyperplasia. The colon was endoscopically normal except for an area at the hepatic flexure which was slightly erythematous."

Is that drawn from the colonoscopy report, so we are talking only at this stage about the macroscopic view?
A Yes.

[61] Child 9 Draft proforma report.

Q "Histologically there was an increase in chronic inflammatory cells throughout the colon with a moderate increase in intra-epithelial lymphocytes."
A Yes.

Q Again, putting that alongside what you have said in this handwritten note at D14, is that taken from that handwritten note?
A It is.

Q Because you have said:

"Moderate to marked increase in intra-epithelial lymphocytes. Increase in chronic inflammatory cells throughout the colon."

A revised diagnosis of "indeterminate colitis" was made which was communicated to the child's doctor. This diagnosis was reported in *The Lancet*.

Child 10

Child 10's routine histopathology report was provided by an expert in gynaecological pathology. It read:

"No significant histological abnormality"[62]

When reviewed by Professor Walker-Smith's clinical team it was evident to them that the biopsies showed abnormality and a supplementary report was requested by them. This was addressed by Professor Walker-Smith in his evidence to GMC hearing on Day 81:

Q If we look at 59A it sets out what the original finding was of Dr. Jarmulowicz. Then microscopic description supplementary report at the bottom of the page.
A Yes.

"These biopsies have been reviewed following a clinicopathological meeting. The ileo biopsy shows confluent lymphoid aggregates within otherwise unremarkable small intestine. The large bowel biopsies show a very subtle scattering of chronic inflammatory cells within the lamina propria. The superficial lamina propria contains focal nuclear debris and the surface epithelium appears slightly degenerate. No active inflammation is seen. More levels have been cut and no granulomas have been identified.

Comment: Minor abnormalities. ? Significance."

[62] Royal Free Hospital Records Vol 2, p47

And that is countersigned on this occasion by Dr. Davies as well as by Dr. Jarmulowicz.

A Yes.

Q What, if anything, is the difference between those two sets of findings?

A The principal difference really is in the large bowel report – a very subtle scattering of chronic inflammatory cells within the lamina propria is a clear indication of chronic inflammation. And the so-called focal nuclear debris, that tells us that there has been some damage in the past; and the surface epithelium said to be slightly degenerate also tells us that there has been some damage, but there is no evidence of active inflammation. Curiously, this report actually leaves out an important observation which Dr. Jarmulowicz made in the first report, saying that the lymphoid tissue shows reactive changes, which I regard as rather important.

Q The conclusion from the second report, the amended or updated report is:

"Minor abnormalities. ? Significance."

Who makes the decision as to the interpretation overall of the abnormalities, if there are abnormalities, on the slides?

A The clinician.

Q How does that work? You have a report from a histopathologist in which he sets out in detail what the findings are for individual sections, or groups of sections, and then comes to his conclusion; but in terms of the management of the patient how does the decision get made?

A The histology report gives the objective evidence of things that are seen down the microscope in a descriptive term. The histopathologist do offer their opinion as to possible significance, but the clinician is the person responsible for putting together the clinical features – that is the signs and the symptoms – the endoscopic features and the observed histopathological features.

Q If we look at Dr. Casson's note at page 17 in volume 2. We have seen the top half of this note before, which is written on the printed form for endoscopy – it is under histology.

"Colonic biopsies – normal crypt architecture; very mild distribution of chronic inflammatory cells. Decreased goblet cells. Focal

abnormalities of epithelium, i.e. tufting. Nuclear debris in sub-epithelium deposits."

A Yes.

Q That is again a slightly different description.
A Yes.

Q But in what circumstances would that have been written?
A Presumably that was written by David Casson at the time of the histopathological meeting as a record as he saw it.

Q Then at the last line he does those arrows leading from one thing to another, so there is an arrow and then:

"Enough chronic inflammation to merit treatment with sulphasalazine."

A I think this might be a quotation from myself.

Q Perhaps you could explain how it comes about?
A Usually I and my two consultant colleagues would come to a view as to the clinical significance of the findings which we observed at the clinicopathological meeting because one of the junior doctors did in fact present the history and findings. Then the relevant consultant endoscopist would tell us about the endoscopic findings; then we would see in front of us on the screen what the histopathology was. Then the clinicians and indeed the junior doctors would discuss together what was the way forward because the parents are usually waiting in the ward after the meeting, and Dr Casson would go and speak to them. I believed on the total picture that it was appropriate to use sulphasalazine and, although it is not written there, I was obviously making a diagnosis of indeterminate colitis.

The biopsies were reviewed by Drs. Dhillon and Anthony who reported:

> Mild chronic inflammation in the caecum, ascending, transverse, and sigmoid colon, and rectum[63].

This was correctly reported in the Lancet.

The most striking change of opinion came in the case of Child Three, a six-year-old from Huyton, Merseyside. He was reported in the journal to be suffering from regressive autism and bowel disease: specifically "acute and chronic nonspecific colitis". The boy's hospital discharge summary, however, said there was nothing untoward in his biopsy.

[63] Proforma report Child 10

Child 3

In contrast with Mr. Deer's claim that there was "*nothing untoward in his biopsy*" Child 10's initial routine histopathology report, provided by Dr. Dhillon, was abnormal. It read:

> "Small bowel mucosa shows an increase in intra-epithelial small lymphocytes"; and, "Mild inflammatory and reactive changes in the small bowel samples."[64]

Following his review, Professor Walker-Smith noted:

> "Marked increase in IEL's [intra-epithelial lymphocytes] in ileum with chronic inflammatory cells. Increase in inflammatory cells in colon and IEL's increased."[65]

The biopsies were reviewed and Drs. Dhillon and Anthony reported:

> Mild chronic inflammation in the caecum, and ascending and sigmoid colon, and rectum, with mild-to-moderate inflammation in the transverse colon.[66]

These findings were communicated by the clinical team to Child 3's GP in a Letter of 4/10/1996 from Dr. David Casson (Lecturer in Pediatric Gastroenterology) to Dr. Shantha.[67]

> Small bowel mucosa showed an increase in intra-epithelial lymphocytes but there was no architectural abnormalities. Histology of the terminal ileum showed prominent lymphoid follicles. Colonic histology was all reported as within normal histological limits. Overall there appeared to be therefore mild inflammatory reactive changes in the small bowel samples.

In other words, even in his initial discharge summary it did not say that there "*was nothing untoward in his biopsy"* as Mr. Deer falsely alleges. Certainly Mr. Deer cannot have missed this blatant contradiction between what he reported and what the documents proclaim which, again, raises the question not just of journalistic ethics, but motivation for his story.

Once the biopsies had been reviewed by Professor Walker-Smith's clinical team, the histological findings were revised and a letter was sent to Child 3's GP informing him of this change and the resulting treatment

[64] Royal Free Hospital Records p86 and 87
[65] See presentation to Wellcome Trust meeting Dec '06.
[66] See proforma report. Child 3
[67] Royal Free Hospital records p27

recommendations. In a letter of 31.12.1996, Professor Walker-Smith wrote to Dr. Shantha:

> "You remember you kindly referred [Child 3] to me and we sent a discharge summary to you on the 4th of October, 1996. Further critical analysis of histology results have led to an amendment to the discharge summary which I am now enclosing. Our final diagnosis is of indeterminate ileocolitis with lymphonodular hyperplasia [emphasis added]. In the light of these histological findings and if gastrointestinal symptoms persist, treatment with a drug such as Asacol might be of some therapeutic value…"[68]

The discharge summary was revised by hand by Dr. Hepstead to read:

> Diagnosis: indeterminate ileo-colitis and lymphoid nodular hyperplasia.[69]

Under Histology the revision reads:

> Ileal mucosa shows an increase in intra-epithelial lymphocytes but there are no architectural abnormalities. Histology of the terminal ileum showed prominent lymphoid follicles. Colonic histology revealed an increase of chronic inflammatory cells.[70]

Again, I stress, I played no part whatsoever in making these changes.

A Royal Free consultant pathologist questioned a draft text of the paper. "I was somewhat concerned with the use of the word 'colitis'," Susan Davies, a co-author, told the ongoing GMC inquiry into the ethics of how the children were treated, in September 2007. "I was concerned that what we had seen in these children was relatively minor."

The newspaper report fails to mention that Dr. Davies was referring, in her evidence to the GMC hearing, to her use of the term colitis only in terms of "active colitis" (involving an increase in pus-forming cells) rather than chronic colitis, or when she saw "a pattern of changes that suggest a specific diagnosis."[71] Later in her evidence on Day 32 she clarifies how, as a distinct pattern of pathological changes emerged in the autistic children (particularly following a blinded review she undertook with Dr. Murch) that came to be termed 'autistic enterocolitis'.

> Q. Yes. You touched on the earlier – that you gained more

[68] General Practice Records p99
[69] Royal Free Hospital records p35
[70] Royal Free Hospital records pp35 and 36
[71] GMC hearing. Evidence of Dr Sue Davies. Day 32.

> experience. Also, presumably, you gained more experience in looking at something which was not classical IBD [inflammatory bowel disease] and was much more subtle, but it appeared to have a link with the autistic children.
>
> A. Yes. I think, I would say, I began to recognise the pattern within the subsequent children coming through in a routine way. This is something I would use for teaching purposes to feed back to the other pathologists saying "had you seen these features", and they said "Yes". I said, "This is what we think the significance of them is." You would see later reports talking about autistic enterocolitis being generated from the department.

Mr. Deer completely omits to mention the fact that as the pattern of disease that was common to the autistic children came to be increasingly recognised, its description as autistic enterocolitis became part of the routine practice in the Department of Histopathology. Instead, he implies in his article (below), that Dr. Davies issued a "*challenge*" to the diagnosis of colitis that was later revised by ''Dr. Wakefield's *team*", when in fact the explanation he refers to below came later in the evidence, rather than later in the diagnostic process. There is totally misleading.

However, after her challenge, it was explained, <u>Wakefield's team</u> [emphasis added] *met for a "research review" of the biopsies. It was not an unusual move for a group of specialists to reconsider the evidence upon which their research was relying. It was nevertheless striking that their conclusion was that 11 of the children's bowels were in fact diseased when their colleagues had found no abnormalities in at least seven of the cases.*

There was no such entity as "*Wakefield's team*" that met for a "*research review of biopsies*". Deer deliberately seeks to create the impression that I was in charge of this process and therefore responsible for its actions and decisions. In fact the review was overseen by a senior pathologist Dr. Dhillon, who was independent of myself. He also fails to acknowledge the review by the clinical team lead by Professor Walker-Smith that was responsible for many of the revisions to pathology reports.

Further questions arise about the motivations of Wakefield. Five years ago this month, The Sunday Times reported that he worked for lawyers, and that many of the families were either litigants or were part of networks through which they would sue. Far from routine referrals, as they appeared, many of them had made contact with one another.

To reiterate the facts:

The clear implication of Mr. Deer's statement is that the children's "*far from routine referral*" involved the fact that their referral was motivated by the fact that

they were litigants. In fact, at the time of their referral to the Royal Free Hospital none of the children were litigants as far as anyone at the hospital was aware. Only one child (Child 12) received a Legal Aid Certificate in the interval between his referral to Professor Walker-Smith and his first attendance at the Royal Free.

The state of knowledge of doctors at the Royal Free Hospital was summed up in my evidence on Day 53 of the GMC hearing.

> Q. Thank you very much. Can I turn from medical matters and research matters to the question of legal aid? There is a reference to legal aid that I would like you to look at in volume 1 of the Panel bundle at page 242. This is a legal aid certificate for Child 12 and for my purposes the only thing I need from this is the date, at the bottom right-hand corner, 9 October 1996. Did you ever get to know that this child had a legal aid certificate?
> A Yes.
>
> Q When did you get to know that?
> A No, I cannot remember, but as it turns out this is the only child who was, to our knowledge involved in litigation – subsequent knowledge. It turns out that this is the only child who had a legal aid certificate prior to their referral and investigation at the Royal Free Hospital.
>
> Q But at the time of the referral or about the time of the referral and investigation did you know then that he had a legal aid certificate?
> A I have no memory of it.
>
> Q Did this child become one of the Legal Aid Board children?
> A Yes, I think he did.
>
> Q Did you have any understanding or appreciation of any litigation motivation by the mother at or about the time of referral.
> A No, the mother's motivation is evident in the letters that she has written to Professor Walker-Smith and that is the gastrointestinal symptoms and problems that she felt were present in her child.

"Child Six and Child Seven were brothers from East Sussex; Child Four, a 9½-year-old from North Shields, Tyneside, was registered with the same GP as Child Eight. In short, the 12, none of whom came from London, fetched up far-from-routinely at the hospital."

Irrespective of where they lived, the children were referred, as stated in The Lancet, by their GPs or paediatricians, as is routine practice in the National Health

Service. As had already been described, this was a group of children referred to an expert team in a tertiary referral center with a particular expertise in bowel disease in childhood for investigation of the intestinal symptoms. Their referral had absolutely nothing to do with litigation[72] as implied by Mr. Deer. This is pure speculation and there has been no evidence produced by Mr. Deer in support of this claim. This matter has been discussed extensively at the GMC hearing. In his evidence on Day 73, Professor Walker-Smith confirmed the clinical basis of the the Child's investigations.

> Q As far as you were concerned and your colleagues, Dr. Murch, Dr. Thomson and the junior doctors involved in your department, what was your role going to be?
> A Our role was a purely clinical role, inasmuch as we would see the children and it would be me in this particular case, I would

---

[72] Letter from 8 of the 12 parents. One lives in the US and 2 could not be contacted. The third remaining parent sent a email of support but wished to remain anonymous.

An Open Letter: To Whom It May Concern
We are writing to you as parents of the children who, because of their symptoms of inflammatory bowel disease and associated autism, were seen at the Royal Free Hospital Paediatric Gastroenterology Unit by Professor Walker-Smith and Dr Simon Murch with the involvement of Dr Andrew Wakefield on the research side of their investigations. Our children became the subjects of a paper published in The Lancet in 1998.

We know these three doctors are being investigated by the General Medical Council (GMC) on the basis of allegations made to them by a freelance reporter. Among the many allegations made are the suggestions that the doctors acted inappropriately regarding our children, that Dr Wakefield "solicited them for research purposes" and that our children had not been referred in the usual way by their own GPs. It is also claimed that our children were given unnecessary and invasive investigations for the purpose of research, and hot in their interest. We know this was not so. All of our children were referred to Professor Walker-Smith in the proper way in order that their severe, long-standing and distressing gastroenterological symptoms could be fully investigated and treated by the foremost paediatric gastroenterologists in the UK. Many of us had been to several other doctors in our quest to get help for our children but not until we saw Professor Walker-Smith and his colleagues were full investigations undertaken. We were all treated with utmost professionalism and respect by all three of these doctors. Throughout our children's care at the Royal Free Hospital we were kept fully informed about the investigations recommended and the treatment plans which evolved. All of the investigations were carried out without distress to our children, many of whom made great improvements on treatment so that for the first time in years they were finally pain-free.

We have been following the GMC hearings with distress as we, the parents, have had no opportunity to refute the allegations. For the most part we have been excluded from giving evidence to support these doctors whom we all hold in very high regard. It is for this reason we are writing to the GMC and to all concerned to be absolutely clear that the complaint that is being brought against these three caring and compassionate physicians does not in any way reflect our perception of the treatment offered to our sick children at the Royal Free. We are appalled that these doctors have been the subject of this protracted enquiry in the absence of any complaint from any parent about any of the children who were reported in the Lancet paper. '

> see all of the children where possible myself in the out-patient clinic. I would then make a decision as to whether I thought the children had any kind of bowel inflammation, whether Crohn's disease or other bowel inflammation. If I thought clinically that the child required investigation on clinical grounds, I would then recommend ileocolonoscopy. Then I would also move towards considering other investigations which may be undertaken. We had formed the impression that neurological disease, which presented in a manner similar to autism, had to be excluded in these children. There had been quite a lot of discussion about this, particularly involving Dr. Mike Thomson, who in our discussions had discussed this with us. These investigations were obviously clinical drawn, but we had not actually finalised precisely what was going to be the way forward at that time.

He was later the same day asked whether the children were genuinely ill.

> Q Did it prove to be the case, that they were seriously sick children?
> A They were. They were in some ways really quite shocking, in the sense that the parents had had a child which was perfectly well and then, quite dramatically, over a short period of time, major behavioural problems and bowel problems had appeared. There was video evidence and photographic evidence of the children before and after in some cases.

"The mothers of Child Two and Child Three told me what others said in medical records: they had heard of Wakefield through the MMR vaccine campaign, Jabs."

Thus, when they arrived on Malcolm ward, and produced the "finding" about MMR, it was by no means a random sample of cases.

The Lancet 1998 paper described the findings of what was clearly stated to be a "self referred group" of patients. It has never been suggested by any of the authors that this was a "*random sample of cases*".

"What parents did not know was that, two years before, Wakefield had been hired by Jabs's lawyer, Richard Barr, a high-street solicitor in King's Lynn, Norfolk. Barr had obtained legal aid to probe MMR for any evidence that could be used against the manufacturers. He is adamant that at all times he acted professionally, and diligently represented his clients."

Specifically, I had agreed to act as an expert to the Courts in possible MMR litigation.

Mr. Deer's claim that parents did not know "*that* [I] *had been hired by Richard*

Barr." Mr Deer has no knowledge of the parent's state of mind. While he presents his claim as fact, it is pure speculation and is contrary to the published facts. He advances this speculation in order to convey the impression that I acted covertly and deceitfully. In distinct contrast with Mr. Deer's position, my role in the MMR litigation was widely known at an early stage. For example, the *Independent* newspaper carried a story on 27/11.96 called "A shot in the dark". The second paragraph opened with:

> "William is one of 10 children taking place in a pilot study at the Royal Free Hospital in London, which is investigating possible links between the measles vaccine with the bowel disorder Crohn's disease, and with autism."[73]

A string of Sunday Times reports have exposed how Wakefield earned £435,643 through his work with Barr, plus funding to support his research.

There is no suggestion the other doctors knew of Wakefield's involvement with Barr.

This is false and is intended once again, to convey the impression that I was acting covertly and in an underhand way. The state of knowledge of my colleagues is clearly documented in papers, which are in the possession of Mr. Deer, and this all came out in evidence to the GMC.

Specifically, I wrote to Professor Walker-Smith about Child JS (not a child in the Lancet paper) in November 1996 informing him that this Child had been awarded funding from the Legal Aid Board that would, if necessary, cover the costs of his investigation.[74] This is clarified in my evidence on Day 53 of the GMC hearing.

> Q. Can I now leave that background material, and move back to the Royal Free records, page 76. On 6 November you wrote to Professor Walker-Smith about this patient, in these terms:
>
> "This is a child that I would like to be included in our study if you consider him suitable. His community paediatrician, Dr Mills, was initially enthusiastic about referring him. He now seems to have gone cold on this. Nonetheless, JS has been awarded Legal Aid, who will pay for the investigations and this is [in] hand. I would be grateful if you would therefore arrange to see him as an outpatient to assess him for possible investigation in our trial."

In the event this funding source was not necessary since his investigations were paid for by the NHS. The clinical records of Child JS show that JWS knew that

[73] Grania Langdon-Down. "A shot in the Dark". *Independent* 27.11.96
[74] Child JS Royal Free Hospital records p76

some children were in receipt of legal aid for the purpose of funding his investigation in November 1996.

Dr. Wakefield then had a meeting on 21st January 1997 with the clinical team as part of a joint Tuesday interdepartmental meeting. Professor Walker-Smith and Dr. Simon Murch were in attendance. Dr. Wakefield informed his colleagues that he had agreed to act as an expert in the MMR litigation.

This was followed up by a letter from Dr Wakefield to Professor Walker-Smith on 3rd February 1997 reiterating Dr. Wakefield's position with respect to acting as an expert, and describing his reasons for agreeing to act in this capacity. This letter was read into the evidence by Dr. Wakefield at the GMC hearing with Mr. Deer in attendance. The evidence was as follows:

> Q Quite apart from those references in November 1996 and April 1997, was the question of you acting as an expert in litigation ever raised with your clinical colleagues?
> A We had a meeting in January 1997 where the issue was discussed. My clinical colleagues were, in fairness, very reluctant to become involved in litigation in any form. I perfectly appreciated that.
>
> Q Who was present at the meeting?
> A My memory is that Professor Walker-Smith and Simon Murch were there. I will be advised or corrected but I do not remember specifically who else was there. I believe others may have been there.
>
> Q I am not going to ask you to speculate or guess. If you cannot remember, just tell us.
> A I cannot remember.
>
> MR COONAN: I am going to ask you to produce an exchange of correspondence relating to this discussion. We have numbered this to go into the chronological bundles. There are numbers on the bottom of the coloured sheets. (New bundle handed and marked) Dr. Wakefield, the first document is a letter dated 3 February 1997. Was that a letter from you to Professor Walker-Smith?
> A Correct.
>
> Q It is a direct reference to a meeting of Tuesday 21 January. I am going to ask you this time, rather than me, to read it. Would you be so kind as to read this out? It is your letter.
> A Certainly.
>
> "Dear John

re: Enterocolitis and regressive autism

Further to our meeting on Tuesday 21 January, I thought it important to write to you to clarify my role in the legal issues. I fully appreciate your desire not to become involved in the legal aspect of these cases, but I feel that it is important to express the reasons that I do feel obliged to become involved.

The future for the children with whom we are dealing is very bleak indeed. Not only are the provisions for these children within the community inadequate at present, but looking ahead to the future, there will come a time when the parents of these children die, and the patients, as chronically disabled adults, left to fend for themselves in an extremely hostile world. Were there any long-term institutions left for such children, then that is where they would end up. Since these hospitals are being closed on an almost weekly basis around the country, these hopeless individuals will be left to 'care in the community'. One does not like to imagine how it will all end. Maybe their only hope is in people taking the possible organic basis of their disease seriously enough to investigate it and institute the appropriate therapies where possible.

Vaccination is designed to protect the majority, and it does so at the expense of a minority of individuals who suffer adverse consequences. Although the case against MMR is far from proven it is one that we are obliged to investigate in view of the consistent history given by these patients' parents and by the observations made in the United States. If this disease is caused by the MMR vaccination, then these children are the few unfortunates that have been sacrificed to protect the majority of children in this country. If this is the case, our society has an absolute obligation to compensate and care for those who have been damaged by the vaccine for the greater good. This is an inescapable moral imperative and is the principal reason that I have decided to become involved in helping these children pursue their claims. I have considered this issue in great depth and, whilst it may not be the wish of others within the group to become involved, it falls to me to make sure that their legal cases are presented in the best possible light. Fortunately, this is entirely consistent with best clinical practice which, I believe, you are providing for these children.
I felt it important, however, to let you know of my feelings on this, and the position that I feel I am obliged to adopt to support these children.
Without our help, I genuinely believe that the medical profession would otherwise put them to one side, as it appears to have done in many cases already. My present fears for these children are much less than the horrible imaginings if they do not receive the appropriate help that is due to them at this stage. However, I am an optimist, and I believe that this project will turn out to be both enlightening and rewarding for all those

who have been involved, and I am most grateful for your help and encouragement.

Kindest regards & best wishes,

Yours sincerely"

Q Did Professor Walker-Smith reply to your letter on 20 February 1997, with a copy to Dr. Murch?
A Yes.

Counsel put it to Dr. Wakefield:

Q Dr. Wakefield, I think you may have dealt with this already, but so that the Panel has your response in the round in the light of your answers, was there any way in which your involvement with the Legal Aid Board was kept secret?
A No.

What has not been reported is that the nature of the project had been visualised before any of the children were even admitted to the Royal Free.

In June 1996 – the month before Child One's arrival at the hospital – Wakefield and Barr filed a confidential document with the government's Legal Aid Board, appearing already to know of a "new syndrome".

The document to which Mr. Deer refers[75] describes a research proposal for detecting measles virus in biopsy tissues. It involved the analysis of biopsies from 5 children with Crohn's disease where there is a well-established intestinal disease entity, and 5 children with autistic regression and intestinal symptoms. This was a separate piece of work from the Lancet paper

The document states in para 3, page 1:

Briefly these conditions consist of Crohn's disease (and inflammatory bowel disease); there are also persistent reports of children suffering symptoms akin to autism (here described as disintegrative disorder) coupled with inflammatory bowel disease.

The document only makes reference to reports of symptoms and makes no claim to the existence of the syndrome that was described in the Lancet paper i.e. 'ileocolonic lymphoid nodular hyperplasia, nonspecific colitis and pervasive developmental disorder in children.'

The document makes it clear in para 3, page 2, that what distinguishes the

[75] Proposed Protocol and Costing Proposals for testing a selected number of MR and MMR vaccinated children. 'LAB protocol".

children with Crohn's disease and those with the putative enteritis/disintegrative disorder syndrome, is the presence of "a prima face gastrointestinal pathology" in the children with Crohn's disease. Mr. Deer claim is misleading since it seeks to convey the impression that I was 'aware' of the syndrome eventually described in the Lancet paper before children with the *possible* syndrome were ever investigated and hence he had predetermined that it should be present .

Referring to inflammatory bowel disease, and then bowel problems with autism, Wakefield and Barr wrote to the board, successfully seeking money.

"The objective," they wrote, "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 who are seeking compensation."

I did not write this final document: it was made clear during the GMC hearing, in Mr. Deer's presence that Mr. Barr was responsible for describing the legal aspects of this submission to the Legal Aid Board and accordingly, it was he who wrote the paragraph above. My evidence on Mr. Barr's input into the relevant legal aspects of this documents are provided on Day 49 of the GMC hearing

> Q Is that a correct way of approaching matters? That using that protocol it will be possible to establish the causal link between the administration of the vaccine and the conditions outlined in this proposed protocol and costing proposals?
> A Yes. This is his document and these are his words, and they are crafted in a legal way. In other words, they are not necessarily what a scientist might say. For example, it would be possible to establish "the causal link". Now, it is more accurate to say that it would be possible to establish an association, for example, or a possible causal association, that would be scientifically more accurate, but the difference with this document is that one was dealing with a balance of probability argument, which is a legal argument and something with which I had no familiarity at all. I was used to dealing with scientific levels of proof and not balance of evidence arguments, so, as I say, these are his words, his interpretation, and it is framed in a way that would be understandable to presumably colleagues at the Legal Aid Board.

Twenty months later, the Royal Free team delivered with the paper that had found a "new syndrome".

The "*new syndrome*" that Mr. Deer refers to could only have been described after the children had been investigated, and could not have been anticipated in June

1996 as he insinuates. At this stage the evidence for a possible syndrome was symptoms of autistic regression and inflammatory bowel disease. This syndrome ultimately described is the combination of autistic regression, swelling of the lymph glands in the last part of the small intestine (ileum) and inflammation of the ileum and/or colon.

Mr. Deer conflates the presentation of intestinal symptoms in children with autistic regression that gave rise to the *possibility* of intestinal disease, by June 1996, with the clear demonstration by the clinicians of intestinal disease in the 12 Lancet children by January 1997. He does so in order to lead the reader to believe that I had already made up my mind about a new syndrome as early as June 1996, before the children had ever been investigated – which is grossly misleading.

TODAY, the 12 children are mostly teenagers. At least three are bloggers, two in support of Wakefield, while others have limited skills. The wrongful stigma of disability hangs heavy on most, and heaviest on the families with the misguided burden of guilt that the vaccine scare has visited on them.

Wakefield has left Britain to live in Austin, Texas, where he runs a clinic offering colonoscopies to American children. He tours the country, giving lectures and speeches against the vaccine, and attracting a loyal following of young mothers.

In Wakefield's view, the Lancet paper was accurate, including reasonable reassessment of findings. Other doctors, including an experienced pathologist concurred with his judgment on the revised reports of nonspecific colitis, he has said.

This statement is false and deliberately misleading. I have never used this form of words. In fact it is I who have concurred with the judgment of others – qualified histopathologists who generated the revised reports – not the other way round as the article reports. *Behavioural diagnoses, meanwhile, involved a confusing array of technical names, and he trusted what the parents told him. The fact that they said the problems followed MMR implied that regression was involved.*

This is intentionally misleading and is designed to create the impression that I was involved in making a clinical judgment on the behavioral diagnoses on the one hand, and that if a parent had cited MMR as the proximate trigger for their child's illness, it had been assumed without reference to other records, that regression was involved.

I was not involved in making any diagnosis on any child. The Lancet paper documents the basis for making the developmental diagnoses: this required a full clinical history, reference to records of early development, and in the majority of children, review by a Child Psychiatrist.

"When our allegations were put to him last week, he did not respond, but his

lawyers replied on his behalf. They said the GMC hearings were nearing conclusion and our revelations risked prejudicing these proceedings.

"You also know that, at this juncture in the GMC process, it would be inappropriate for Dr Wakefield to give a detailed response to you," they said. "He has denied the allegations and gave a detailed response over many days to the GMC panel."

Many of the parents of the original 12 children continue to support him and campaign vigorously on his behalf. But others whose children took part in the Lancet project are too burdened and traumatised for campaigning.

One mother told me that, before her son's MMR jab, he could say "night, night mummy", but all language slipped away "some time" after the injection. To this day, she remains convinced it was the vaccine that did it. She believes it was the rubella component.

When asked why his parents took him to the Royal Free, his father answered: "We were just vulnerable. We were looking for answers."

****

Allegation: Undisclosed conflict of interest

Mr. Deer has an obvious, overwhelming, and undisclosed conflict of interest as the person who initiated the GMC's investigation of Dr. Wakefield. Failure to disclose his role in initiating the GMC proceedings against me misled readers of the *Sunday Times*.

Below is a chronology of Mr. Deer's complaint to the GMC

On February 25, 2004, three days after his first article attacking me had been published in the *Sunday Times*, Mr. Deer wrote to the GMC in the following terms:

> *"Following an extensive inquiry for the Sunday Times into the origins of the public panic over MMR, I write to ask your permission to lay before you an outline of evidence that you may consider worthy of evaluation with respect of the possibility of serious professional misconduct on the part of the above named registered medical practitioners.* [Andrew Wakefield, John Walker Smith, and Simon Murch.]" [76]

[76] email from Brian Deer to Tim Cox-Brown, Caseworker GMC, 12.16 pm 2.25.04. This is a six-page letter concluding with the statement "*As a matter of public duty, I write to offer this outline of my main findings, and to offer the GMC my fullest cooperation in getting to the bottom of these matters*".

This reads as a spontaneous and intentional contact with the GMC for the purpose of requesting to put before them the substance of his complaint and in fact, doing so i.e. making a *complaint*. This is confirmed by the GMC's letter to Dr. Wakefield of April 8th 2004 that stated:

> "I am writing to confirm that we have received *complaints* about you from a number of sources."[77]

The GMC's letter to me continued by reiterating Mr. Deer's complaints almost verbatim from his letter of February 25th 2004. As part of the 'unused material' from the GMC proceedings, to which I am entitled, I was supplied with two complaints[78] in addition to that of Mr. Deer. Only the complaints of Mr. Deer's were formulated into allegations and subsequent charges by the GMC.

Mr. Deer followed up on his original complaint letter with a further email to the GMC dated July 1st 2004.[79] This is a 14-page document that elaborates upon his earlier allegations and provides numerous links to documents and statements on his website. The letter opens:

> *"Dear Tim,*
>
> *Following my previous communications, I wish to report to the GMC claims made by the above doctors in statements published by the Lancet under the editorship of Dr Richard Horton, a former Royal Free Hospital colleague of the above, on February 20 2004."*

The letter ends with:

> *"I hold copies of any documents not available at my website, and am willing to provide them to the GMC, or to give any other help that may be required.*
>
> *I trust that you will notify me, in whatever way is appropriate, of how my concerns are progressed.*
>
> *With best wishes*

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[77] Letter from Tim Cox-Brown, Caseworker GMC to Dr Wakefield 8th April 2004..

[78] The two additional complaints included one from an R. Sarkel. James Walsh of the GMC responded saying that the GMC "will not be taking any further action at this stage". The second was anonymous, purportedly from the Royal Free Hospital. In a memo of 18th March 2004 Tim Cox-Brown of the GMC wrote, "I don't think there's much we can do with it, but it looks as though it should probably be kept with the Wakefield papers."

[79] Letter from Brian Deer

Brian Deer"

The allegations formulated by the GMC against me were received by me from the GMC on August 27th 2004. These were formulated based almost entirely upon Mr. Deer's original complaint, his subsequent elaborations on these complaints, and extensive documentation supplied by him to the GMC[80] – much of which was downloads from his website.

According to Justice Eady (see below), Mr. Deer wrote again to the GMC as part of his complaint on 12th March 2004 and 1st July 2004[81]. Additionally, he presented his findings to GMC staff in person on 24th Feb 2005[82], in a meeting lasting 2 hours and 10 minutes, and again on 7th March 2005[83] in a meeting lasting five hours. He made subsequent detailed written representations to the GMC on 12th February 2007[84], and March 6th 2007[85]. These communications were intended to convince the GMC of my culpability and to urge them in the strongest terms to prosecute me (these communications will be discussed in detail under "Objectivity", below).

Conflict of interest: Mr. Deer had and continues to have an irreconcilable conflict of interest in the reporting of the GMC hearing against me - on the basis that he was the person who made the original complaint against me, and my colleagues in the first instance. In addition, he has crossed a boundary of propriety in his profession, which is built upon a standard that the only material journalists willingly surrender to regulatory authorities is the published or broadcast version. Source material is not provided without force of law or subpoena, in most cases.

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Matters of Objectivity and Fairness

[80] Letter from Blake Dobson, Assistant Registrar GMC, to Dr Wakefield, 27th August 2004.

[81] In a libel ruling in November 2006 arising from a Channel 4 Dispatches programme about the Wakefield affair, Mr Justice Eady noted that: "Well before the programme was broadcast [Mr Deer] had made a complaint to the GMC about the Claimant. His communications were made on 25 February, 12 March and 1 July 2004. In due course, on 27 August of the same year, the GMC sent the Claimant a letter notifying him of the information against him."

[82] Attendance note Matthew Lohn and Jessica Owen with Brian Deer. GMC 24th February 2005

[83] Attendance note Matthew Lohn, Kate Emmerson, Jessica Owen and Brian Deer. GMC 7th March 2005

[84] Letter Brian Deer to Peter Swain GMC on 12th February 2007

[85] Letter Brian Deer to Kate Emmerson, GMC March 6th 2007

Mr. Deer's reportage regarding me raises fundamental questions, not just about basic journalism and objectivity, but also regarding the craft of reporting in the digital age. Mr Deer is breaking new and questionable ground. In the traditional print versions, where his stories have their widest circulation, he operates under the imprimatur of fairness through the reputation of the *Sunday Times*. However, on his web site and in attendant responses to various questions about his work, Mr. Deer betrays an unconventional bias against the subject about whom he is writing.

The evidence shows that Mr. Deer's comportment as a purported journalist is far from objective or fair. He crosses a boundary that few reporters ever consider approaching. He not only surrenders documentation and alleged evidence to regulatory authorities, the evidence shows that he approaches them and asks them to consider the material generated by his work. Mr. Deer, instead, sought to prompt investigations under his own name and offered his information, flawed as it is, to the regulatory body. He has been complicit in every act of that body subsequent to the moment he provided it with his information. How can a journalist write objectively or fairly about a matter in which he is intimately involved and which his own requests have prompted? Mr. Deer asked the GMC to consider his material, Mr. Deer has presented before the GMC[86] about his own findings, and then Mr. Deer claims to be objective in his reportage in the *Sunday Times*.

Further, off the pages of the newspaper that commissions his reports, Mr. Deer uses terms of derision at the same time he is claiming to write unbiased work in the *Sunday Times*. On his web site and in other writings Mr. Deer often refers to me and others doing autism research using pejoratives and other language that is fundamentally dismissive and he consistently ridicules the work of serious educated physicians and researchers, even though he has no expertise in their fields. Indeed, this is at the heart of the problem with much of his journalism; he writes about medicine and epidemiology and histopathology and autism as though he has the educational portfolio to speak with authority. Were he to quote other experts in his journalism, who were critical voices with expertise, Mr. Deer's own background as a philosophy major would be of lesser consequence. However, in much of his work, he acts and writes with conclusive authority about protocols for sample collection, symptoms of diseases, time periods for regression, the impact of live viruses, and even the nature and symptoms of various diseases. While any topic can be adequately researched by any journalist, Mr. Deer writes with an expressed expertise on diseases and symptoms as though he were the final source. His story narratives are nearly devoid of quotations from experts and rely almost entirely on his own unqualified interpretations, which are uniformly flawed.

[86] Attendance note Brian Deer and GMC representatives 24th February 2005. Meeting 2 hours 10 mins
Attendance note Brian Deer and GMC representatives 7th March 2005. Meeting 5 hours.

In both his communications with the investigating body of the General Medical Committee and during five years of writing blog posts, Mr. Deer betrays a profound bias that ought to prompt any reasonable editor to remove him from an assignment reporting on my case. Examples of this bias are far too numerous to list in their totality in this document but there are several to make the point that Mr Deer is completely devoid of objectivity or even a pro forma attempt at fairness.

Mr. Deer also consistently contradicts himself with regard to public statements he has made relating to his involvement in the GMC's work regarding me. As an example of this, in a 12 February 2007 letter to the GMC and copied to Field Fisher Waterhouse (FFW), the prosecuting law firm acting for the GMC, Mr. Deer, who has repeatedly denied being the complainant in the case against me, writes, **"**My first mail was dated 25 February 2004, summarizing my findings as of that date…..it is clear that considerable investment has been committed to looking into the matters *I've raised"* [emphasis added]. In the same letter, Mr Deer cavalierly reveals his bias as an alleged journalist by saying, **"**I've written to FFW about two other outings for *Wakefield's deceit* [emphasis added]…papers 1999 and 2001".

Indeed, even as Mr. Deer was preparing lengthy reports for the *Sunday Times* that were to be published as though they were impartial investigative journalism, Mr. Deer had already reached his conclusions prior to writing the first word. On page 17 of the same letter he informs the GMC "I have never found Wakefield to be substantially truthful in any matter whatsoever. To me he appears to pile deceit upon deceit, like a compulsive gambler: at each stage returning to the table thinking his next bet will recover what's lost"

Mr. Deer's communications and involvement with the GMC and various transcripts of hearings show he makes even no pretense of objectivity regarding the subject matter of my situation. His "journalism" flows from a premise, which he has clearly set out to prove, regardless of contradictory information. Nonetheless, he presses on regardless with both his stories and his uninformed testimony. In the above referenced letter, Mr. Deer, acting more as an interpreter and analyst than a reporter, begins to tell the GMC what he "believes." He writes, "Wakefield sexed-up data prior to publication. He made numerous further alterations. I believe that these alterations followed consultation and correspondence between Wakefield and Barr in August 1997 during which the latter invited the former to strengthen the appearance of an unequivocal link between the vaccine and autism……." These allegations, without any substantiation, are doubly damning as testimony and then as uncorroborated charges published in the *Sunday Times.* What any reporter "believes" is irrelevant. A journalist's task is to present information for readers or an audience to process and reach their own conclusions based upon reliable facts. Regardless, Mr. Deer's beliefs and unfounded assertions in his testimony and communications

with the GMC add further data to the incontrovertible body of evidence that there has been nothing impartial, objective, or fair about Mr. Deer's reporting on me.

Mr. Deer, however, refuses to relent in his onslaught against me. His predilection for jumping to conclusions using unfounded interpretations keeps revealing itself in his communications. In a 7th March 2007 letter to Kate Emmerson of FFW Mr. Deer asserts without any foundation in fact, "Wakefield and a number of the litigant-parents (who by my analysis are effectively co conspirators in fabricating the worldwide alarm) are presently preparing a public relations case and media onslaught against the GMC alleging that the case against me is somehow politically motivated" Accusing people you are reporting about of being "co-conspirators" and of being responsible for "worldwide alarm" can hardly be considered journalism and, even if labeled analysis when published, moves dangerously in the direction of libel and malice of forethought. Mr. Deer's analysis, regardless, ought to be of no consequence to either the GMC nor, most especially, his editors at the *Sunday Times.* He is without medical training to offer authoritative analysis.

Mr. Deer's letter further inaccurately and unfairly characterizes me on page 2 as a "fraudster" and then accuses me of a scientifically heinous crime that would be the end of any researcher's career. He does this without any evidence or substantiation and concludes with his opinion of a necessary governmental action. "Any proper case against Wakefield rests on the charge that he is a research fraudster who repeatedly faked evidence against the vaccine….I submit that practitioners may not baselessly fabricate then propagate the appearance of, even a potential link between a drug and a medical condition and that those who are caught doing so should be struck off the register." After making such statements, how can Mr. Deer be considered worthy of practicing the craft of impartial journalism on the pages of a major publication?

In his blog posts, Mr. Deer is even more blunt and consistently relies on pejoratives to characterize the individuals who dare question the potential dangers of vaccines. On his blog, New Year's Day 2007, he writes fondly of commenters on his web site and people who are supportive of his reporting while using a scatological reference to be dismissive of the other side of his story. "These folks," he writes, "aren't putting up with this vaccine scare shit….." In the same post, Mr. Deer suggests one of his online critics is "prodding his anus for something fresh to say."

The web site that same day also shows Mr. Deer has reached harmful conclusions without evidence regarding other principals in the GMC hearing. He appears indignant about a critic of his BBC report that wrongly suggested I was being paid to make a case against the MMR vaccine. The critic, Jackie Fletcher, is portrayed as a "dope," which is also the derisive tag Mr. Deer uses to malign Professor John Walker-Smith. He writes, "My personal belief is that Jackie *didn't* know: [that, as

Mr. Deer alleges, Wakefield was being paid to be anti-MMR] she's what underworld circles call 'the dope'. This is a homely person of basic honesty and conviction, who is maneuvered into fronting a game. (In case you're a true MMR anorak, I feel much the same about Professor John Walker-Smith." In spite of this characterization, Mr. Deer continued to write in the *Sunday Times* as an unbiased correspondent.

Mr. Deer's website, an essential source for understanding the nature of his biases, consistently attacks me with terminology he cannot place in the newspaper, but that reveals his desire to destroy any notion of fair treatment. In one instance, he says I am "slippery as a condom lube." He uses his site to accuse a "Wakefield supporter" of "reheating scraps from Wakefield's strange table," and writes his own inaccurate and unsubstantiated headlines like, 'Guilt Tripped: How Wakefield's Scare Caused Mothers to Blame Themselves." Indeed, even Mr. Deer's footnotes on his website are erroneous and biased in a manner that belies his attempts to suggest he is even-handed and just reporting the facts. Here is his reference to me: "An ex-surgeon, embittered after his theory that measles virus caused Crohn's diseases was scorned. Published a string of false and misleading reports, seeking to discredit MMR….."

Conclusions

The basic tenets of journalism are objectivity and fairness. Both the standards and practices of journalism and its traditions require a concerted effort to provide both sides of a story. Mr. Deer's statements to a professional regulatory body (GMC) and on his website postings are ample evidence he has not been able to sustain even the slightest pretense of fairness. He is a campaigning reporter who is ignoring any information that is contradictory of his premise, namely that I am determined to pull off an impossible scientific and medical scam. Indeed, the notion that any researcher can cook such data in any fashion that can be slipped past the medical community for his personal benefit is patent nonsense. Such an idea is absurd on its face and unravels before the evidence (as has happened at the GMC hearing), which is consistently ignored by Mr. Deer. Scientific rigor requires repeatability for verification of any research and Mr. Deer's implications of fraud against me are claims that a trained physician and researcher of good standing had suddenly decided he was going to fake data for his own enrichment.

The larger and more disturbing issue behind the work of Mr. Deer is his voluntary involvement with governmental institutions and their reliance on his faulty investigative skills. The GMC case investigating me began with Mr. Deer, a "journalist," offering up to the agency information he had gathered and interpreted to serve as the basis for a complaint. The traditional and sound practice of reporting, publishing, and broadcasting is that the information publicly reported and resting in the public domain is all that the media ever surrender to governmental bodies. Generally, what is on the pages of a paper or in a broadcast leads the government to launch its own investigation. Historically, if a critical

piece of evidence is needed by any governmental body, a subpoena is often issued to the media that prompted the investigation. Established law and basic societal rights protect journalists and their employers from any demands that source materials or interview subjects be turned over without a legal fight. Indeed, many journalists have chosen jail rather than give up this information. A regulatory body ought to be able to find such data on its own if, in fact, such a feat can be accomplished by a solitary journalist. Instead of resisting calls for information that might have been prompted by his reporting, Mr. Deer preempts the GMC by willingly offering his source materials and thus violating a code of ethical behavior that is at the very foundation of the craft of journalism. He seemingly wants the government to rely on his work, either as a form of validation or an act of vanity. He will, of course, claim public interest. None of this mitigates his obligation to disclose his conflict.

Mr. Deer's apparent transgressions, however, do not stop at acting as an investigator and a source for an agency whose work he will later write about in the *Sunday Times.* In fact, he continued to urge the GMC to prosecute me more aggressively over the course of the proceedings. This fact alone ought to lead to his dismissal by the newspaper for a conflict of interest since Deer's statements before the investigating body are all critical of me, though without basis in fact. Nonetheless, even after being compromised as an informant and a provider of material to facilitate the GMC investigation, Deer makes the high-profile pages of the *Sunday Times* where his work is passed off as unbiased and balanced. Further, he uses his insider's perspective and documents obtained during the course of the GMC inquiry to buttress his attack on me. Even though Mr. Deer's interpretation of much of his source material is completely without foundation, he utilizes it in an exclusive fashion because he alone has access and other reporters do not because Deer has privileges of proximity afforded a principal in the matter before the GMC. Additionally, he has used materials in his reporting that were acquired through the discovery process in a defamation case against him brought by me. Even though the suit was dropped for logistical reasons, Mr. Deer employs information that, if not a violation of a court order placing him in potential contempt, is, at a minimum, ethically questionable.

Finally, Mr. Deer's practices in his gathering of information are most insidious when it comes time to seek out a comment from his subject. For the purpose of writing his latest article in the *Sunday Times*, Deer did not contact Dr. Wakefield to ask him questions regarding the allegations being made against him. In fact, his tactic was to send a lengthy email with convoluted questions just a matter of hours before his deadline. The nature of these emails and the questions posed require hours of work and research by me and my team of attorneys and there is virtually no hope of them being effectively answered in the narrow window provided by Mr Deer. The result of this is that Mr. Deer publishes his narratives with a standard disclaimer that "Wakefield's attorneys have advised him not to comment pending the results of the GMC hearing." This further characterizes me

as elusive and hiding behind his legal team, no doubt a profile Mr. Deer's work willingly advances.

Actual Extracts from Mr Deer's website

Did she know about the dough?

After the release of new figures for Andrew Wakefield's legal money to attack the MMR vaccine, it's time for Jackie Fletcher (left) of JABS to make the position clear on what she knew

COMMENT by BRIAN DEER: New Year's Day 2007

..... first the good news - from the neurodiversity movement. These folk aren't putting up with this vaccine scare shit, believing that autistic kids (often their own) deserve better. As 2006 drew to a close - and The Sunday Times propagated online - the blogosphere fairly crackled with discussion of my report on Andrew Wakefield's dough. King of the Hub Kevin Leitch led the pack on new year's eve with kind words (the cheque's in the post):

"Luckily, Times reporter Brian Deer is an actual reporter – i.e. one who investigates his findings and sources his facts. Today he published the findings of his latest investigation into Andrew Wakefield and the associated people that support his vaccine/autism/legal financial business."

Even while Kevin Leitch was probably updating his blog for new year, and Erik Nanstiel was prodding his anus for something fresh to say, Ms Soderburg demanded:

"Why are you trying to invalidate Dr. Wakefield's findings? Of course he received funds, he worked... Who hired you to write these articles? How much are you getting paid?"

Linda got no reply. Life's too short.

Did the esteemed Jackie Fletcher (and indeed John Stone and Jonathan Harris) know about Wakefield's dough when they launched their indignant crusade against a minor BBC news story…

My personal belief is that Jackie *didn't* know: she's what underworld circles call "the dope". This is a homely person of basic honesty and conviction, who is manouvered into fronting a game. (In case you're a true MMR anorak, I feel much the same about Professor John Walker-Smith

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…… pure Wakefield: as slippery as condom lube.

Ah, I see: he gave the dough away. And he can prove this intention. *Wey-hey!* So either Thoughtful House, or the Royal Free hospital, received a whacking pile of money?

I say: *what?*

Not surprisingly, however, his admirers have pounced on this claim as evidence of their man's core integrity. Although exactly what he did - *or didn't* - do with the money is of no relevance to what lawyers would call his "pecuniary advantage", the idea of him handing over everything but "tax and out of pocket expenses" to good causes has the aura of a hero, does it not? My first thought is that he may be setting up a situation where his pals in America might read the statement to say that he donated the money in Britain, while his British associates think it says some Americans got it.

But you could knock me down with an endoscope. Riddle me this Jackie. I can't work it out. Do you know where the bodies are buried? How could Wakefield have proposed in March 1995 any venture relevant to the topic in hand? This was before he'd even heard of MMR's autistic Patient Zero: one William Kessick, son of Nanstiel clone Rosemary Kessick

But we don't need to get nasty like Nanstiel. Andy was captain of rugby, at a fee-paying school. I shivered on the sidelines, at a comprehensive. He's a good six foot. I'm five feet nine.

Ms **Heather Mills**, author of much of the work, had nourished her recent career reheating scraps from Wakefield's strange table

Mills: The makers of Channel 4's MMR: What The Never Told You in the Dispatches strand should perhaps have thought twice before engaging journalist Brian Deer to present a hatchet job on Dr Andrew Wakefield.

Deer: Presumably, they would have done better engaging Ms Heather Mills of Private Eye, to give Dr Wakefield a long, slow... well, we'll leave it there.

Recipe for madness?: Wakefield's claims for a safer measles vaccine, and treatments for bowel disease and autism, were not only bold, but were bizarre. The technology involved is of so-called **"transfer factors"**, a now largely abandoned fringe conjecture based on a curious theory that special substances can be harvested from white blood cells. The Royal Free's recipe advised injecting mice with measles, extracting and processing white cells, injecting the result into **pregnant goats**, milking them after kid-birth and turning the product into capsules for kids. Mmmm, delicious

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Guilt tripped: How Wakefield's scare caused mothers to **blame** themselves

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Lancet kids all litigants: Wakefield's research on autistic children was begun for a legal contract. Of 12 reported in a Lancet paper in 1998, 11 **sued** drug companies (one was American), with this never disclosed before Deer's inquiries

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N**o good cause:** Wakefield's **call** for single shots dropped "out of the blue"

The now-discredited doctor, Andrew Wakefield, who made the allegations, appeared to all the world as an independent researcher. Deer discovered, however, that Wakefield had been employed by a lawyer for two years before he launched his public attack on the vaccine in a paper dated **28 February 1998** in the Lancet medical journal. Although the nature of their deal was unknown to the public, their joint aim was to undermine MMR for a speculative (and subsequently failed) class action lawsuit, which was the financial engine for the alarm. This was a gross conflict of interest for Wakefield.

Wakefield was directly, but confidentially, funded via Barr [audio], using money from the government's Legal Aid Board/Legal Services Commission. This funding included a grant of £55,000, applied for by Barr and Wakefield in **June 1996**, for the express purpose of conducting "clinical and scientific" tests on children to try to prove the existence of what Wakefield had predetermined to be a "new syndrome" caused by the vaccine. US courts would later find that this "syndrome" did not exist.

Andrew Wakefield:
An ex-surgeon, embittered after his theory that measles virus caused Crohn's disease was scorned. Published a string of false and misleading reports, seeking to discredit MMR. Financed via Barr

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