

**FITNESS TO PRACTISE PANEL HEARING
28 JANUARY 2010**

On 16 July 2007 a Fitness to Practise Panel considered the case of:

- A. Dr Andrew Jeremy WAKEFIELD
GMC reference number: 2733564**

- B. Professor John Angus WALKER-SMITH
GMC reference number: 1700583**

- C. Professor Simon Harry MURCH
GMC reference number: 2540201**

This case was considered by a Fitness to Practise Panel applying the General Medical Council's Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988

Panel Members: Dr S Kumar, Chairman (Medical)
Mrs S Dean (Lay)
Ms W Golding (Lay)
Dr P Moodley (Medical)
Dr S Webster (Medical)

Legal Assessor: Mr Nigel Seed QC

The Fitness to Practise Panel has heard this case under The General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules Order of Council 1988. It has considered which, if any of the facts not admitted by Dr Andrew Wakefield, Professor John Walker-Smith and Dr (now Professor) Simon Murch have been found proved and then went on to consider whether such facts found proved together with those admitted, would be insufficient to support a finding of serious professional misconduct.

The Panel wish to make it clear that this case is not concerned with whether there is or might be any link between the MMR vaccination and autism. It has not speculated and has concerned itself only with the evidence before it and the reasonable inferences that can be drawn from that evidence as an independent and impartial tribunal established by law. The Panel has taken care to avoid reading press accounts of the case. Members have put from their minds any media references that have come to their notice. The Panel comprised three doctors - a Consultant Psychiatrist, a Consultant Physician (retired) and a GP, and two lay members - a retired Local Authority Chief Executive and an independent Mediator/Arbitrator. All are experienced Panellists.

The issues in this Hearing were complex. That there was much to be said on both sides, is reflected by the fact that the Panel heard evidence and submissions for 148 days over a period of two and a half years. There were 36 witnesses as well as lengthy examination and cross examination of the three doctors. The Panel has deliberated in camera for approximately 45 days. There has been inevitable delay in this case and the Panel has taken that into account when deciding on the facts. It has drawn no adverse inference from any doctor's inability to recall certain matters and has only found a fact proved if it is sure there is other corroborating evidence.

The Panel has accepted in full the advice of the Legal Assessor as to the approach to be taken. The three doctors have nothing to prove, the burden of proof is on the GMC throughout. If the Panel were not sure beyond reasonable doubt, the sub-head of charge was found not proved in favour of the doctor, in accordance with the criminal, as opposed to the civil, standard of proof.

The Panel whilst in camera sought advice from the Legal Assessor on three occasions: to confirm an admission on behalf of the Defence, to notify of a proposed minor amendment to one of the charges and to seek clarification of the issue of joint enterprise. The Legal Assessor advised that if one of the parties to a joint enterprise carries out actions that had not been agreed by the other parties and/or without the other parties' knowledge, then those parties are not liable for such actions. All the legal teams were invited to comment on the advice given and there was no dissent.

The Panel received no further advice whilst deliberating.

It has concerned itself exclusively with the conduct, duties and responsibilities of each doctor at the material times. The Panel has been careful to judge the doctors' practice by the standards applicable at the time and has taken care to avoid judgement by hindsight.

Dr Andrew Wakefield was a Senior Lecturer in the Departments of Medicine and Histopathology at the Royal Free Hospital and from 1st May 1997 a Reader in Experimental Gastroenterology. He was an Honorary Consultant in Experimental Gastroenterology with a stipulation in his contract that he had no involvement in the clinical management of patients. Professor John Walker Smith was a Professor of Paediatric Gastroenterology at the Royal Free Hospital School of Medicine with an honorary clinical contract with the Royal Free Hampstead NHS Trust. Dr (now Professor) Simon Murch was a Senior Lecturer in Paediatric Gastroenterology with the Royal Free Hospital School of Medicine with an honorary consultant contract with the Royal Free Hampstead NHS Trust.

In coming to its findings the Panel has considered the concept of research ethics and research governance. It accepted the expert evidence in this case as to the principles guiding such ethics, in particular that contained in the guidance of the British Paediatric Association in relation to children (RCP, 1990) that if research is of no therapeutic benefit then it can be of no more than minimal risk. It noted that in 1996 NHS hospitals had independent Local Research Ethics Committees. If a doctor wished to carry out a research project involving NHS patients or the records of those patients, he had to seek ethical approval from the committee – in this case the relevant body was the Ethical Practices Sub-Committee of the Royal Free Hampstead NHS Trust (the Ethics Committee). The Panel considers that the responsibility of each doctor applying to undertake research is to be true and accurate and that the Ethics Committee should be able to expect such probity from any applicant doctor.

The Panel accepts the expert advice that amongst the responsibilities of a Responsible Consultant, is the requirement to conduct research within ethical constraints, and report it responsibly, accurately and fairly. At no stage should a doctor take any action that is contrary to the clinical interests of the patient involved.

The Panel has heard that ethical approval had been sought and granted for other trials and it has been specifically suggested that Project 172-96 was never undertaken and that in fact, the Lancet 12 children's investigations were clinically indicated and the research parts of those clinically justified investigations were covered by Project 162-95. In the light of all the available evidence, the Panel rejected this proposition.

The Panel has made findings on the basis that the notes and correspondence contained within the files were available to clinicians at the time; It has borne in mind that the documentation now available may also be incomplete.

The Panel has considered each head of charge separately and where a finding appears not to be self-evident, has offered a short explanation of how the Panel arrived at that decision. It has made the following findings:

A. Dr Andrew Jeremy WAKEFIELD

The Panel will inquire into the following allegation against Andrew Jeremy Wakefield, MB BS 1981 Lond:

“That being registered under the Medical Act 1983,

- ‘1. At all material times you were,
 - a. A UK registered medical practitioner,
Admitted and found proved
 - b. Employed by the Royal Free Hospital School of Medicine, initially as a Senior Lecturer in the Departments of Medicine and Histopathology and from 1 May 1997 as a Reader in Experimental Gastroenterology,
Admitted and found proved
 - c. An Honorary Consultant in Experimental Gastroenterology at the Royal Free Hospital;
Admitted and found proved
- ‘2. Your Honorary Consultant appointment was subject to a stipulation that you would not have any involvement in the clinical management of patients;
Found proved
The Panel has accepted the wording of the job description and the letter of employment (contract) sent to you, which show clearly that you would not be involved in a clinical management role with patients.

The Legal Aid Board

- ‘3.
 - a. In 1996 you were involved in advising Richard Barr, a solicitor acting for persons alleged to have suffered harm caused by the administration of the MMR vaccine, as to the research that would be required to establish that the vaccine was causing injury,
Admitted and found proved
 - b. Mr Barr had the benefit of public funding from the Legal Aid Board in relation to the pursuit of litigation against manufacturers of the MMR vaccine (“the MMR litigation”),
Admitted and found proved
 - c. You provided Mr Barr with,
 - i. costing proposals for a research study, which were then set out in a document entitled: “*Proposed protocol and costing proposals for testing a selected number of MR and MMR vaccinated children*” (“the Costing Proposal”),

Admitted and found proved to the words ‘vaccinated children’.

Found proved

The Panel has accepted, in the words of your own Counsel, that the title “The Costing Proposal” is “of no particular consequence” other than it is a convenient abbreviated term.

- ii. a protocol, giving details of the research study, entitled: “*Proposed Clinical and Scientific Study A new syndrome: disintegrative disorder and enteritis following measles and measles/rubella vaccination?*” (“the Legal Aid Board Protocol”),

which you knew or ought to have known Mr Barr required for submission to the Legal Aid Board,

Found proved

The Panel is satisfied with your evidence that you sent a protocol, which you assert was for information only. It also found that it comprised a research element, and that Mr Barr had a legitimate expectation that he could submit it to the LAB, which you ought to have realised was his intention.

- d. The Costing Proposal proposed a study which included five children with “*Enteritis/disintegrative disorder*” and sought funding in the sum of £57,750 for items which included,

Found proved

The Panel is satisfied that the wording of this head of charge does not exclude the other five children described in the proposal.

- i. £1,750 for four nights stay for the child and their parent (plus colonoscopy) in the Paediatric Gastroenterology Ward under the care of Professor Walker-Smith,

Found proved

- ii. £1,000 for MRI and evoked potential studies,

Found proved

in respect of each of the five children,

- e. The Legal Aid Board Protocol described a study on children who had,

- i. been vaccinated with the measles or measles/rubella vaccine, and

Found proved

- ii. disintegrative disorder, and

Found proved

- iii. gastrointestinal symptoms,

Found proved.

In reaching its decision in relation to the entirety of 3.e. the Panel accepts that anyone reading the document would have taken the words at face value, which is what the Panel has done.

f. On 6 June 1996 Mr Barr submitted copies of the Costing Proposal and the Legal Aid Board Protocol to the Legal Aid Board,
Found proved

g. On 22 August 1996 the Legal Aid Board agreed to provide a *maximum cost of £55,000* to fund the items in the Costing Proposal as proposed by you and as set out at paragraph 3.d.,
(amended) Found proved

h. The Legal Aid Board provided funding in two instalments of £25,000, in late 1996 and in 1999 respectively, which was paid into an account which was held by the Special Trustees of the Royal Free Hampstead NHS Trust for the purposes of your research generally,
Admitted and found proved

i. The money provided by the Legal Aid Board was not needed for the items listed at paragraphs 3.d.i. and ii. above, which were funded by the NHS;
Admitted and found proved

'4. a. You,

i. failed to cause the Legal Aid Board to be informed that investigations represented by the clinicians as being clinically indicated would be covered by NHS funding,
Found proved

The Panel is satisfied that you had a duty to disclose to the LAB, via Mr Barr, that clinically indicated investigations would be funded by the NHS, and that, despite having opportunities to do so, you failed in that duty.

ii. caused or permitted the money supplied by the Legal Aid Board to be used for purposes other than those for which you said it was needed and for which it had been granted,
Found proved in relation to the second instalment of £25,000.

The Panel is content that the first instalment of £25,000 was used for the purposes for which it was granted.

The Panel is convinced by documentary, and your own evidence, that you used the second instalment for, amongst other things, research staff wages, not the items listed in 3.d.i and 3.d.ii.

b. Your conduct as set out at paragraph 4.a.i. was,

i. dishonest,

Found proved

The Panel is satisfied that this action, was dishonest, judged by the ordinary standards of reasonable and honest people. It is further satisfied that you knew that some or most of the funds would not be used for the reasons you had stated, because you had agreed a process with Mr Barr by which children would be selected for the study from those who had already been investigated at the Royal Free Hospital and who would have therefore been funded by the NHS.

ii. misleading,

Found proved

c. Your conduct as set out at paragraph 4.a.ii. was a misuse of public funds and was,

i. dishonest,

Found not proved

The Panel is satisfied that the funds claimed were used in the furtherance of the research and not for your personal gain. Therefore, on the basis of the evidence before it, the Panel is not satisfied so that it is sure that both limbs of the test for dishonesty have been made out.

ii. in breach of your duty when managing finances, to ensure that the funds are used for the purpose for which they were intended,

Found proved

The Panel is satisfied that you had a duty to, but did not, use the funds for the purposes previously stated.

iii. in breach of your duty to account for funds you did not need to the donor of those funds;

Found proved

The Panel is satisfied that you had a duty to account accurately to the LAB for the funds provided, but even in your “interim report to the Legal Aid Board” of January 1999 you did not explain how the investigations on the children had been funded.

Research and Ethics Committee Approval

‘5. On or about 16 September 1996 an application, signed by you, was submitted to the Ethical Practices Sub-Committee of the Royal Free Hampstead NHS Trust (“the Ethics Committee”),

Admitted and found proved

a. Naming you, Professor Walker-Smith and Professor Murch as the responsible consultants,

Admitted and found proved

b. Seeking approval for a *project research study* involving 25 children entitled “A new paediatric syndrome: enteritis and disintegrative disorder following measles/rubella vaccination”,

(amended) Found proved

The Panel has used the wording within the application.

c. Describing a *project study* which entailed a programme of investigations, including invasive gastrointestinal and neurological tests, to be carried out on children who had,

(amended) Found proved

i. been vaccinated with the measles or measles/rubella vaccine; and

Found proved

ii. *manifested* disintegrative disorder, and

(amended) Found proved

iii. symptoms and signs of intestinal disease or dysfunction namely pain, bloating, alternating constipation and diarrhoea, steatorrhoea and failure to thrive,

Admitted and found proved

In reaching its decision in relation to the entirety of 5.c.the Panel is satisfied on the basis of the wording in the application document.

d. Indicating that all the procedures ~~you~~ *proposed to be undertaken* were part of normal patient care and clinically indicated,

(amended) Found proved for the same reason as set out at 5.c.

e. Indicating that you would be responsible for arranging a number of those procedures including MRI, lumbar puncture and EEG,

Found proved in respect of MRI and EEG.

Found not proved in respect of lumbar puncture.

f. Attaching an explanation of the proposed scientific and clinical study, a timetable of investigations, a handout of information for parents and a sample consent form,

Admitted and found proved

g. In answer to the question “*How are the substances for this study being provided, and how is the study being funded?*”, stating: “*Clinical research at the Royal Free Hospital (E.C.R.)*”;

Admitted and found proved

- '6 a. The application referred to at paragraph 5. above was allocated reference 172-96 ("Project 172-96"),
Admitted and found proved
- b. The Chairman of the Ethics Committee, on behalf of the Committee, raised with you and Professor Walker-Smith ~~concerns as to~~ reservations about the intensive regime that children who took part in the study would have to undergo,
(Amended) Found proved
The Panel was satisfied that the letter dated 15 October 1996 raising reservations was sent to Professor Walker-Smith and it was forwarded to you and Dr Murch by him for comment.
- c. In a letter dated 11 November 1996, and copied to you, Professor Walker-Smith informed the Chairman of the Ethics Committee that the children would have the investigations even if there were no trial and five had already been investigated on a clinical need basis,
Admitted and found proved
- d. On the basis of the information provided in the application documentation and in the letter of 11 November 1996, the Ethics Committee granted ethical approval for Project 172-96 on 18 December 1996 subject to conditions, as set out in a letter to Professor Walker-Smith dated 7 January 1997, including,
Admitted and found proved
- i. only patients enrolled after 18 December 1996 would be considered to be in the trial,
Admitted and found proved
- ii. the Ethics Committee was to be informed of and approve any proposed amendments to your initial application which had a bearing on the treatment or investigation of patients or volunteers,
Admitted and found proved
- iii. a copy of the consent form and the information sheet was to be lodged in the clinical notes of each patient,
Admitted and found proved
- e. In a letter dated 9 January 1997, and copied to you, Professor Walker-Smith confirmed acceptance of these conditions,
Admitted and found proved
- f. Between 16 September 1996 and 15 July 1998 no further applications were made to the Ethics Committee for approval in connection with Project 172-96 nor was the Committee informed of any amendments to your initial application, save as a set out in Dr

Wakefield's letter to the Chairman of the Ethics Committee dated 3 February 1997.

Admitted and found proved

g. As a named Responsible Consultant you had a duty to ensure that,

i. the information in support of your application to the Ethics Committee was true and accurate,

Found proved

Notwithstanding that yours was a shared rather than a sole responsibility and you could not be held responsible for factors outside your knowledge and control, the Panel is satisfied that this was within the parameters of the duties of a named responsible consultant.

ii. only children who met the stated inclusion criteria for the ~~research study~~ Project 172-96 were admitted to the study,
(amended) Found proved, as in 6.g.i. above.

iii. you were aware of and complied with the conditions attached by the Ethics Committee to any approval given,

Found proved

The Panel accepts your evidence where you agreed that you, with others, had a duty to comply with conditions attached to the project.

iv. the children ~~whom you~~ admitted under the protocol were treated in accordance with the terms of the approval given by the Ethics Committee,

(amended) Found proved

The Panel accepts that you did not admit children to the department but you had a shared duty as a named Responsible Consultant to ensure that the children were dealt with in accordance with the approval given. The Panel understands the word "treated" does not mean therapeutic treatment only.

v. you declared to the Ethics Committee any disclosable interest including matters which could legitimately give rise to a perception that you had a conflict of interest;

Found proved

The Panel has concluded that the concept of 'conflict of interest' should have been known to you and noted your own evidence that you should have declared relevant interests on the application form but did not.

'7 a. Project 172-96 covered the "*Enteritis/disintegrative disorder*" research funded by the Legal Aid Board referred to at paragraphs 3.c. to 3.g. above,

Found proved

In reaching its decision, the Panel is satisfied that the project 172/96 document is substantially the same as the protocol sent to the LAB by Mr Barr in June 1996.

- b. Your,
 - i. involvement in the MMR litigation as set out at paragraph 3.,
Found proved
 - ii. receipt of funding for part of Project 172-96 from the Legal Aid Board;
Found proved

constituted a disclosable interest which included matters which could legitimately give rise to a perception of a conflict of interest in relation to your involvement in Project 172-96 which you did not disclose to the Ethics Committee,

Found proved

The Panel accepts your evidence that you should have declared the funding from the LAB. It is satisfied that your involvement in the MMR litigation also had ethical implications and should have been disclosed.

- c. Your non-disclosure as set out in paragraph 7.b.i. and paragraph 7.b.ii.,
 - i. was contrary to your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 6.g. above,
Found proved in relation to both 7.b.i and 7.b.ii on the basis of the Panel's findings at 6.g.v.
 - ii. thereby deprived the Ethics Committee of information material to its consideration of the ethical implications of project 172-96;
Found proved in relation to both 7.b.i and 7.b.ii on the basis of the Panel's findings at 6.g.v.

Child 2

- '8. a. On 29 June 1995 Child 2 was referred to Professor Walker-Smith, at St Bartholomew's Hospital, by Dr Wozencroft, a Consultant in Child Psychiatry, who stated that,
Admitted and found proved
 - i. he knew that Child 2's parents had contacted Professor Walker-Smith and yourself,

Admitted and found proved

ii. Child 2's condition fell within the diagnostic category of Autistic Spectrum Disorder,
Admitted and found proved

b. On 1 August 1995 Child 2 attended an outpatient consultation with Professor Walker-Smith at St Bartholomew's Hospital following which Professor Walker-Smith concluded that there was no evidence of Crohn's disease or chronic inflammatory bowel disease and he did not arrange to see Child 2 again,
Admitted and found proved

c. On 16 May 1996 Professor Walker-Smith wrote to Child 2's mother asking to see Child 2 again and stating that he had had discussions about Child 2 with you and that you and Professor Walker-Smith had a plan for investigations,
Admitted and found proved

d. On 24 June 1996 Professor Walker-Smith wrote to you stating that Child 2 was the most appropriate child to begin your programme,
Found proved
The Panel interprets the word "your" to mean you, Professor Walker-Smith and others.

e. Child 2 was admitted to the Royal Free Hospital on or about 1 September 1996 under Professor Walker-Smith's clinical care,
Admitted and found proved

f. Child 2's admission clerking note recorded that he had been admitted for investigation of the possible association between gastrointestinal disease/autism/measles,
Admitted and found proved

g. Between 1 September 1996 and his discharge on or about 9 September 1996 Child 2 underwent a colonoscopy, a barium meal and follow-through, an MRI scan of his brain, a lumbar puncture, a Schilling test, an EEG and other neurophysiological investigations, and a variety of blood and urine tests,
Admitted and found proved

h. Of the tests set out in 8.g. above, on 2 September 1996 you signed the request form for the EEG and for other neurophysiological investigations to be undertaken on Child 2, stating that the reason for the request/relevant history included disintegrative disorder,
Admitted and found proved

i. Dr Berelowitz, Consultant Paediatric Psychiatrist, and

Dr Harvey, a Consultant Neurologist, assessed Child 2 after he had undergone the lumbar puncture, EEG and other neurophysiological investigations, referred to at 8.g. above;

Admitted and found proved

- ‘9. a. You caused Child 2 to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research,

Found proved

In reaching its decision, the Panel is satisfied that you had a number of conversations with Mrs 2 regarding Child 2’s condition, which resulted in the referral of that child to Professor Walker-Smith. After his assessment of Child 2 at St Bartholomew’s Hospital on 1 August 1995, Professor Walker-Smith concluded that gastro-intestinal investigations were not indicated and he did not arrange to see Child 2 again.

In May 1996, after you had further contact with Mrs 2 regarding Child 2’s condition and subsequent discussions with Professor Walker-Smith, Child 2 was re-assessed by him on 21 June 1996. Professor Walker-Smith recorded in the notes: “Arrange admission with Dr Wakefield.” After that out-patient consultation, Professor Walker-Smith wrote to Dr Cartmel (Child 2’s GP) (letter dated 28 June 1996) in which he states: “I think Crohn’s disease is unlikely. Dr Wakefield has the view that there may be some kind of other inflammation which may be a relevant factor in Child 2’s illness and we now have a programme for investigating children who have autism and a possible reaction to immunisation”. The Panel has concluded, on the basis of the medical records, that the programme of investigations that Child 2 underwent was for research purposes and for which there was no Ethics Committee approval.

- b. The programme of investigations carried out on Child 2 was part of the ~~research study~~ *project* referred to at paragraphs 5.b. and 5.c. above,

(Amended) Found proved

The Panel finds that the programme of investigations carried out on Child 2, and the reasons recorded in the clinical records for those investigations, follow closely the project protocol referred to at paragraphs 5.b. and 5.c. In coming to that view, the Panel has had regard to the letters of June 1996 from Professor Walker-Smith to yourself, in which he refers to child 2 as “the most appropriate child to begin our programme”. The medical records further indicate that at least four paired biopsies were taken at colonoscopy, which the Panel concludes was in accordance with the investigations described in the project.

c. ~~The research study was carried out on~~ Child 2 *was investigated under the project* without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(Amended) Found proved

The Panel is satisfied that there was no relevant Ethics Committee approval at the time when these investigations were carried out.

i. contrary to the conditions of approval for Project 172-96 Child 2 had been enrolled into the ~~research study project~~ before 18 December 1996,

(Amended) Found proved

Child 2 was admitted for investigations in September 1996.

ii. he did not qualify for the ~~research study project~~ as he failed to meet the inclusion criteria set out at paragraph 5.c.i. above,

(Amended) Found proved on the basis that Child 2 had been vaccinated with MMR.

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 2's clinical notes,

Found not proved

The Panel accepts that at the time of Child 2's admission in September 1996, you could not have known about the conditions of ethical approval, which had been set out in a letter dated 7 January 1997 from the Ethics Committee to Professor Walker-Smith, acknowledged by him on 9 January 1997, and copied to you on the same date.

e. By reason of the matters referred to at paragraphs 9.c. and 9.d. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 6.g. above,

Found proved in relation to paragraph 9.c. in relation to 6.g.(ii) only, which states the requirement to meet the inclusion criteria for Project 172-96.

f. You caused Child 2 to undergo a lumbar puncture without ensuring that he was first assessed by a clinician with the requisite neurological or psychiatric expertise to determine whether such an investigation was clinically indicated,

Found not proved

The Panel is not satisfied that this allegation has been made out to the requisite standard.

g. You ordered that the investigations set out at paragraph 8.h. above be carried out on Child 2,

Found proved

The Panel is satisfied that by signing the forms you did order the investigations and does not accept your explanation of your role as being purely administrative.

- i. without having the requisite paediatric qualifications to do so,

Found proved, as is evident by your CV.

- ii. in contravention of the limitations on your Honorary Consultant appointment as set out at paragraph 2. above,
Found proved on the basis of the wording of your job description and your letter of employment (contract).

- h. Your conduct as set out above was contrary to the clinical interests of Child 2;

Found proved

In reaching its decision, the Panel has had regard to its findings in relation to 9.a., 9.c. and 9.g.

Child 1

- '10 a. On 17 May 1996 Child 1's General Practitioner, Dr Barrow, wrote to Professor Walker-Smith referring Child 1 and indicating that Child 1 had been diagnosed as autistic and that his parents' concern was that his MMR vaccination might be responsible for his autism,
Admitted and found proved

- b. Dr Barrow's referral letter made no reference to any gastrointestinal symptoms,
Found proved on the basis that as a matter of fact Dr Barrow's letter makes no mention of any gastrointestinal symptoms, although the Panel notes that there is a passing reference of gastrointestinal symptoms in one of the several enclosures.

- c. Prior to his referral to Professor Walker-Smith Child 1's developmental delay had been noted, he had been seen by Dr Hauck, Consultant Psychiatrist, ~~but not~~ and previously a formal diagnosis of his condition had been reached,
(amended) Admitted and found proved

- d. On 21 July 1996 Child 1 was admitted to hospital under Professor Walker-Smith's clinical care,
Admitted and found proved

- e. Child 1's admission clerking note recorded that he had been referred for work-up of the possible relationship between autism/measles/IBD,
Admitted and found proved

f. Between 21 July 1996 and his discharge on 26 July 1996 Child 1 underwent an attempt at colonoscopy (which failed due to gross faecal loading), a clearance of his bowel and a colonoscopy, an MRI scan of his brain, an EEG and a variety of blood and urine tests,
Admitted and found proved

g. On 23 October 1996 Child 1 was re-admitted as an inpatient,
Admitted and found proved

h. Between 23 October 1996 and his discharge on 25 October 1996, Child 1 underwent a barium meal and follow-through, a limited neurological assessment by Dr Harvey and a lumbar puncture;
Admitted and found proved

- '11. a You caused Child 1 to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research,
Found proved
In reaching its decision the Panel is satisfied that it was your contact with Mrs 1 which initiated Dr Barrow's referral of Child 1 to Professor Walker-Smith on 17 May 1996. Professor Walker-Smith, after his assessment of Child 1 on 19 June 1996, concluded in his letter to Dr Barrow that Child 1 had the features of "toddler's diarrhoea" and planned to see Child 1 again in three months' time. However, Child 1 was admitted to hospital one month later. There were no apparent clinical reasons for this change in plan.

Child 1 underwent a colonoscopy, MRI scan of his brain, an EEG and a variety of blood and urine tests. These were some of the investigations listed in the programme of the project. He was further admitted on 23 October 1996 for further investigations regarding the "etiology of the autism", again for no obvious clinical gastro-intestinal reasons. During this admission, Child 1 underwent a barium meal and follow-through and a lumbar puncture. These were also the investigations listed in the programme of the project. The Panel has concluded that Child 1 underwent a programme of investigations for research purposes and for which there was no Ethics Committee approval.

- b. The programme of investigations carried out on Child 1 was part of the ~~research study~~ *project* referred to at paragraphs 5.b. and 5.c. above,
(Amended) Found proved.
In reaching its decision, the Panel is satisfied that the programme of investigations carried out on Child 1, and the reasons recorded in the clinical notes for those investigations, follow closely the project protocol referred to at paragraphs 5.b. and 5.c. In this

respect, the Panel has had regard to the letter dated 21 June 1996 from Professor Walker-Smith to Dr Barrow (Child 1's GP) which states: "As part of Dr Wakefield's and mine interest in the relationship between immunisation and chronic inflammatory bowel disease, I have arranged for routine blood tests to be done for screening for C-reactive protein, etc." It has also taken account of the letter from Dr Casson to you, dated 8 August 1996, asking when the child should be reviewed by you and if there were any other procedures that should be performed. In addition, the Panel has taken into account the discharge summary dated 9 August 1996 which states "Child 1 was admitted for further investigations into his autism and specifically to look into a possible association between his neurological condition and any gastro-intestinal disorders." On the basis of the investigations carried out, the Panel has concluded that these were part of the project.

c. ~~The research study was carried out on~~ Child 1 *was investigated under the project* without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(Amended) Found proved

The Panel is satisfied that there was no relevant Ethics Committee approval at the time when these investigations were carried out.

i. ~~contrary to the conditions of approval for Project 172-96~~ Child 1 had been enrolled into the project ~~research study~~ before 18 December 1996,

(amended) Found proved on the basis that the investigations on Child 1 were carried out in July 1996 and October 1996.

ii. ~~he did not qualify for the research study project~~ as he failed to meet the inclusion criteria set out at paragraph 5.c.i. above,

(Amended) Found proved on the basis that the medical records show that Child 1 had been vaccinated with MMR.

iii. ~~he did not qualify for the research study project~~ as he failed to meet the inclusion criteria set out at paragraph 5.c.ii. above,

(Amended) Found proved on the basis that Child 1 was admitted with an established diagnosis of autism.

d. ~~Contrary to the conditions of ethical approval for Project 172-96~~ you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 1's clinical notes,

Found not proved

The Panel accepts that at the time of Child 1's admissions to the Royal Free Hospital in July and October 1996, you could not have known about the conditions of ethical approval, which had been set out in a letter dated 7 January 1997 from the Ethics Committee

to Professor Walker-Smith, acknowledged by him on 9 January 1997, and copied to you on the same date.

e. By reason of the matters referred to at paragraphs 11.c. and 11.d. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 6.g. above,
Found proved in relation to 11. c. on the basis of 6.g.(ii)

f. Your conduct as set out above was contrary to the clinical interests of Child 1;
Found proved in the light of the Panel's findings at 11.a., 11.b., 11.c., and 11. e.

Child 3

'12. a. On 19 February 1996 Child 3's General Practitioner, Dr Shantha, referred Child 3 to Professor Walker-Smith indicating that Child 3 had behavioural problems of an autistic nature, severe constipation and learning difficulties all associated by his parents with his MMR vaccination,
Admitted and found proved

b. Child 3 was admitted to hospital on or about 8 September 1996 under Professor Walker-Smith's clinical care,
Admitted and found proved

c. Between 8 September 1996 and his discharge on 13 September 1996, Child 3 underwent a colonoscopy, barium meal and follow-through, an MRI scan of his brain, a lumbar puncture, an EEG and a variety of blood and urine tests,
Admitted and found proved

d. Of the tests set out in 12. c. above, the results from the lumbar puncture were normal;
Admitted and found proved

'13. a. You caused Child 3 to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research,
Found proved
In reaching its decision that you caused Child 3 to undergo a programme of investigations, the Panel has taken into account your evidence that you had initial contact with the parents of Child 3, which led to his referral to Professor Walker-Smith. The Panel has also taken into account Child 3's Royal Free Hospital records, including the letter dated 4 April 1996 from Professor Walker-Smith to you, in which he states that he has not yet booked Child 3 for a colonoscopy as he is waiting for "full details of the

investigative protocol” to be worked out. The letter dated 18 July 1996 from Professor Walker-Smith to you states: “we are arranging for [Child 3’s] admission for colonoscopy on Sunday, the 8th September, followed by your intensive investigations”. The Panel has concluded on the basis of this correspondence, that the programme of investigations that Child 3 underwent was for research purposes and there was no Ethics Committee approval for such research.

b. The programme of investigations carried out on Child 3 was part of the ~~research study~~ *project* referred to at paragraphs 5.b. and 5.c. above,

(Amended) Found proved.

In reaching its decision, the Panel is satisfied that the programme of investigations carried out on Child 3, and the reasons recorded in the clinical notes for those investigations, follow closely the project protocol referred to at paragraphs 5.b. and 5.c.

In addition to the reasons set out at 13. a., the Panel has taken into account the letter dated 16 May 1996 from Professor Walker-Smith to the paediatric neurologist which states: “I am actually passing on [your] letter to my colleague Dr Andy Wakefield, who is the inspiration of our work linking MMR, autistic behaviour and Crohn’s disease and I am asking him to write to you to fill you in on our proposed study...”.

The Panel has also borne in mind Dr Casson’s discharge summary to Child 3’s GP dated 4 October 1996 which states: “Child 3 was admitted for investigation of possible bowel disease and a possible association of this with his autism..”.

c. ~~The research study was carried out on~~ Child 3 *was investigated under the project* without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(Amended) Found proved

The Panel is satisfied that there was no relevant Ethics Committee approval at the time when these investigations were carried out.

i. contrary to the conditions of approval for Project 172-96 Child 3 had been enrolled into the ~~research study~~ *project* before 18 December 1996,

(Amended) Found proved

Child 3 was admitted for investigation at Royal Free on 8 September 1996.

ii. he did not qualify for the ~~research study~~ *project* as he failed to meet the inclusion criteria set out at paragraph 5.c.i. above,

(Amended) Found proved
Child 3 had been vaccinated with MMR.

iii. he did not qualify for the ~~research study~~ *project* as he failed to meet the inclusion criteria set out at paragraph 5.c.ii. above,

(Amended) Found proved
The Panel has taken into account the fact that Child 3 had a diagnosis of autism spectrum disorder.

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 3's clinical notes,

Found not proved

The Panel accepts that at the time of Child 3's admission to the Royal Free Hospital in September 1996, you could not have known about conditions of ethical approval, which had been set out in a letter dated 7 January 1997 from the Ethics Committee to Professor Walker-Smith, acknowledged by him on 9 January 1997, and copied to you on the same date.

e. You caused Child 3 to undergo a lumbar puncture,
Found proved on the basis that the lumbar puncture was an integral part of the programme of investigations for Project 172-96, for which you were a Responsible Consultant.

i. without ensuring that he was first assessed by a clinician with the requisite neurological or psychiatric expertise to determine whether such an investigation was clinically indicated,
Found not proved.

The Panel is not satisfied that this allegation has been proved to the requisite standard.

ii. which was not clinically indicated,

Found proved

The Panel has taken into account the fact that there is no evidence in Child 3's clinical notes to indicate that a lumbar puncture was required. Experts on both sides, Professor Rutter and Dr Thomas both considered that such a test was not clinically indicated.

f. Your actions as set out at paragraph 13.e. were contrary to your representations to the Ethics Committee that the procedures were clinically indicated,

Found proved in relation to 13eii.

In coming to this decision the Panel has noted the application you presented to the Ethics Committee entitled: "A new paediatric syndrome: enteritis and disintegrative disorder following

measles/rubella vaccination” in which you state: “all of the procedures ... are clinically indicated”.

g. By reason of the matters referred to at paragraphs 13.c., ~~13.d.~~, 13.e. and 13.f. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 6.g. above,
(amended) Found proved in relation to 13.c, 13.e(ii) and 13.f.

h. Your conduct as set out above was contrary to the clinical interests of Child 3;
Found proved. In reaching its decision, the Panel has had regard to its findings above.

Child 4

- ‘14. a. On 1 July 1996 Child 4’s General Practitioner, Dr Tapsfield, wrote to you referring Child 4 for assessment regarding his possible autism and his bowel problems,
Admitted and found proved
- b. On 4 July 1996 you wrote to Professor Walker-Smith passing on the referral of Child 4 whom you stated “*sounds like a good candidate for our forthcoming study*”,
Admitted and found proved
- c. Prior to Dr Tapsfield writing to you Child 4 had been diagnosed in 1992 by Dr O’Brien, Consultant Psychiatrist, as being developmentally delayed with prominent autistic tendencies,
Admitted and found proved
- d. On 29 September 1996 Child 4 was admitted to hospital under Professor Walker-Smith’s clinical care,
Admitted and found proved
- e. Child 4’s admission clerking note stated that he had been “*admitted for study of disintegrative disorder/colitis/MMR*”,
Admitted and found proved
- f. Between 29 September 1996 and his discharge on 4 October 1996 Child 4 underwent a colonoscopy, an attempt at barium meal and follow-through, an MRI scan of his brain, an EEG, other clinical neurophysiological investigations (namely an EP), and a variety of blood and urine tests,
Admitted and found proved
- g. Of the tests set out in 14.f. above,

i. on 30 September 1996 you signed a request form for an EEG and EP to be undertaken on Child 4, stating that the reason for the request/relevant history was “*disintegrative disorder and enteritis myelopathy*”,

Admitted and found proved

ii. the clinical neurophysiology results of the visual EP indicated that the investigator did not have latency values from control subjects but guessed at a normal response;

Admitted and found proved

‘15. a. You caused Child 4 to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research,

Found proved

In reaching its decision that you caused Child 4 to undergo the investigations, the Panel has taken into account that prior to his referral to the Royal Free Hospital on 1 July 1996, you had contact with the parents of Child 4 by letter dated 12 June 1996, and by telephone. In addition the Panel noted that you also had a telephone conversation with Child 4’s GP prior to his referral.

The Panel also had regard to a letter dated 4 July 1996 from you to Professor Walker-Smith, stating, “...(Child 4) sounds like a good candidate for our forthcoming study.”

Furthermore the Panel has had regard to a letter from Dr Casson to the parents of Child 4 which states, “...to confirm that [Child 4] is to be admitted...for colonoscopy...Any further investigations required will be decided on another occasion following consultation with Dr Wakefield.” The admission notes make it clear that Child 4 was admitted without a prior out-patient appointment and without any clinical assessment of him having taken place.

The Panel has concluded on the basis of this evidence that the programme of investigations that Child 4 underwent was for research purposes, for which there was no Ethics Committee approval.

b. The programme of investigations carried out on Child 4 was part of the ~~research study~~ *project* referred to at paragraphs 5.b. and 5.c. above,

(Amended) Found proved

In reaching its decision, the Panel finds that the programme of investigations carried out on Child 4, and the reasons recorded in the clinical records for those investigations, follow closely the project protocol referred to at paragraphs 5.b. and 5.c. The

admission clerking notes state “Admitted for study of disintegrative disorder/colitis/MMR.”

c. ~~The research study was carried out on~~ Child 4 *was investigated under the project* without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(amended) Found proved

The Panel is satisfied that there was no relevant Ethics Committee approval at the time when these investigations were carried out.

i. contrary to the conditions of approval for Project 172-96 Child 4 had been enrolled into the ~~research study project~~ before 18 December 1996,

(Amended) Found proved on the basis that Child 4 was admitted for investigations on 29 September 1996.

ii. he did not qualify for the ~~research study project~~ as he failed to meet the inclusion criteria set out at paragraph 5.c.ii. above,

(amended) Found proved on the basis that Child 4 was not diagnosed with disintegrative disorder.

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 4's clinical notes,

Found not proved

The Panel accepts that at the time of Child 4's admission on 29 September 1996, you could not have known about conditions of ethical approval, which had been set out in a letter dated 7 January 1997 from the Ethics Committee to Professor Walker-Smith, acknowledged by him on 9 January 1997, and copied to you on the same date.

e. By reason of the matters referred to at paragraphs 15.c. and ~~15.d.~~ you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 6.g. above,

(amended) Found proved

f. You ordered that the investigations set out at paragraph 14.g.i. above be carried out on Child 4,

Found proved

The Panel is satisfied that by signing the forms you ordered the investigations; it does not accept your explanation that your role was purely administrative.

i. without having the requisite paediatric qualifications to do so,

Found proved, as is evident by your CV.

ii. in contravention of the limitations on your Honorary Consultant appointment as set out at paragraph 2 above,

Found proved on the basis of the wording of your job description and your letter of employment (contract).

g. You stated that one of the reasons for ordering an EEG and an EP was that Child 4 had disintegrative disorder when there was no such diagnosis,

Found proved on the basis of the information on the request form.

h. You exposed Child 4 to an unnecessary neurophysiology investigation in that there were no control values available thereby rendering the investigation un-interpretable,

Found proved

The Panel is satisfied that in signing and sending the form to the Department of Clinical Neurophysiology, you exposed Child 4 to an unnecessary test.

i. Your conduct as set out above was contrary to the clinical interests of Child 4;

Found proved on the basis of the above findings.

Child 6

'16. a. On 9 August 1996 Child 6's General Practitioner, Dr Nalletamby, wrote to you following a previous discussion that you had had with him on the telephone. Dr Nalletamby stated that Child 6 had autism syndrome, and also bowel disorder, and that Child 6's mother was interested in entering him into your trial,
Admitted and found proved

b. On 11 September 1996 Professor Walker-Smith wrote to Dr Nalletamby stating that you had asked him to see Child 6 as he was the Paediatric Gastroenterologist associated with you in your study on autism and bowel disorder,
Admitted and found proved

c. On 2 October 1996 Child 6 attended an outpatient consultation with Professor Walker-Smith following which he wrote to Dr Nalletamby advising that Child 6 was to come in for a colonoscopy and to enter your programme of investigation of children with autistic problems,
Admitted and found proved

d. Child 6 was admitted to hospital on or about 27 October 1996 under Professor Walker-Smith's clinical care,
Admitted and found proved

e. Between his admission and his discharge on or about

1 November 1996 Child 6 underwent a colonoscopy, an MRI scan of his brain, a lumbar puncture, an EEG and other neurophysiological investigations;

Admitted and found proved

f. On or about 1 November 1996 Child 6 was seen by Dr Berelowitz who concluded that the most likely diagnosis was Asperger's Syndrome.

Admitted and found proved

'17. a. You caused Child 6 to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research,

Found proved.

In reaching this decision that you caused Child 6 to undergo the investigations, the Panel has taken into account the telephone conversation you had with Child 6's mother in March 1996 and your subsequent telephone conversation with the child's GP, the gist of which concerned your research hypothesis. The Panel has also noted the letter dated 11 September 1996 from Professor Walker-Smith to the GP which states: "I have been asked by Dr Wakefield to see Child 6 as I am the Paediatric Gastroenterologist associated with Dr Wakefield in our study on autism and bowel disorder." Taking these factors into account, the Panel has concluded that the programme of investigations that Child 6 underwent was for research purposes, for which there was no Ethics Committee approval.

b. The programme of investigations carried out on Child 6 was part of the ~~research study~~ *project* referred to at paragraphs 5.b. and 5.c. above,

(Amended) Found proved

In reaching its decision, the Panel finds that the programme of investigations carried out on Child 6, and the reasons recorded in the clinical records for those investigations, follows closely the project protocol referred to at paragraphs 5.b. and 5.c.

c. ~~The research study project was carried out on~~ Child 6 was *investigated under the project* without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(Amended) Found proved

The Panel is satisfied that there was no relevant Ethics Committee approval at the time when these investigations were carried out.

i. contrary to the conditions of approval for Project 172-96 Child 6 had been enrolled into the ~~research study~~ *project* before 18 December 1996,

(Amended) Found proved

Child 6 had been admitted for investigations on or about 27 October 1996.

ii. he did not qualify for the ~~research study~~ *project* as he failed to meet the inclusion criteria set out at paragraph 5.c.i. above,

(Amended) Found proved

Child 6 had been vaccinated with MMR.

iii. he did not qualify for the ~~research study~~ *project* as he failed to meet the inclusion criteria set out in paragraph 5(c)(ii) above,

(Amended) Found proved

Child 6 had been diagnosed with Asperger's Syndrome.

d. By reason of the matters referred to at paragraph 17.c. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 6.g. above,

Found proved

e. Your conduct as set out above was contrary to the clinical interests of Child 6;

Found not proved

The Panel found that, despite this child being subject to a programme of investigations rather than specific ones tailored to his needs, there was insufficient evidence to make a finding that the investigations were contrary to his clinical interests.

Child 9

'18. a. On or prior to 11 September 1996 you supplied Professor Walker-Smith with Child 9's name enabling him to contact Child 9's paediatrician, Dr Clifford Spratt,

Admitted and found proved

b. Thereafter, on 11 September 1996 Professor Walker-Smith wrote to Dr Spratt enclosing a copy of the ~~research protocol~~ *Proposed clinical and scientific study* and asking Dr Spratt whether he thought it was appropriate to investigate Child 9 in the protocol,

(amended) Found proved

The Panel is satisfied that the allegation, as amended, reflects accurately the meaning of the letter from Professor Walker-Smith to Dr Spratt.

c. On 25 September 1996 Dr Spratt wrote to Professor Walker-Smith indicating he would be pleased to take Professor Walker-Smith's advice about the proposed referral to your service,

Admitted and found proved

d. Dr Spratt's letter made no reference to Child 9 suffering from gastrointestinal symptoms,

Admitted and found proved

e. Prior to his referral to Professor Walker-Smith Child 9's developmental delay had been ~~provisionally~~ attributed to a form of autism in ~~1995~~ 1994 by Southampton University General Hospital autism service but this ~~provisional~~ diagnosis was not accepted by his parents ~~nor subsequently confirmed~~,

(amended) Admitted and found proved

f. Child 9 was admitted to hospital on 17 November 1996 under Professor Walker-Smith's clinical care,

Admitted and found proved

g. Between 17 November 1996 and his discharge on 22 November 1996, Child 9 underwent a colonoscopy, a barium meal and follow-through, and blood and urine tests. His parents refused to allow him to have a lumbar puncture which he was judged most unlikely to tolerate without sedation,

Admitted and found proved to the words 'urine tests'.

Found not proved from the words "His parents" onwards. The Panel is not satisfied to the requisite standard that this allegation has been made out.

h. On 9 December 1996 Child 9 was readmitted and underwent an MRI scan of his brain, an EEG and a lumbar puncture, all of which were undertaken under general anaesthetic,

Admitted and found proved

i. The results from the lumbar puncture were normal;

Admitted and found proved

'19. a. You caused Child 9 to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research,

Found proved

In reaching its decision that you caused Child 9 to undergo the programme of investigations, the Panel is satisfied that you were directly involved with the admission of Child 9 for the programme of investigations. By your own evidence, Mrs 9 contacted you, which initiated Child 9's referral to Professor Walker-Smith in November 1996. The Panel notes the letter dated 11 September 1996 from Professor Walker-Smith to Dr Spratt, Child 9's Consultant Paediatrician, with which he sent a copy of, "Dr Wakefield's detailed proposal". In his reply to that letter, dated 25 September 1996, Dr Spratt states; "I would of course be very pleased to have your opinion of Child 9's distressing case history, and to take your advice about his proposed referral to Dr

Wakefield's service." In these circumstances the Panel is satisfied that the programme of investigations that Child 9 underwent was for research purposes, for which there was no Ethics Committee approval.

b. The programme of investigations carried out on Child 9 was part of the ~~research study~~ *project* referred to at paragraphs 5.b. and 5.c. above.

(Amended) Found proved

In reaching its decision, the Panel finds that the programme of investigations carried out on Child 9, and the reasons recorded in the clinical notes for those investigations, follow closely the project protocol referred to at paragraphs 5.b. and 5.c. The Panel has also taken into account the letter dated 9 September 1996 from a research colleague, John Linnell, to Professor Walker-Smith, which states: "...it was agreed that he should, if possible, be included in our first 10 cases". In addition, the Panel has noted that Child 9, having been admitted to the Royal Free Hospital on 17 November 1996, was re-admitted on 9 December 1996 to complete the programme of investigations.

c. ~~The research study was carried out on~~ Child 9 *was investigated under the project* without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(Amended) Found proved

The Panel is satisfied that there was no relevant Ethics Committee approval at the time when these investigations were carried out.

i. contrary to the conditions of approval for Project 172-96 Child 9 had been enrolled into the ~~research study~~ *project* before 18 December 1996,

(Amended) Found proved

Child 9 was admitted for investigations on 17 November 1996 and 9 December 1996.

ii. he did not qualify for the ~~research study~~ *project* as he failed to meet the inclusion criteria set out at paragraph 5.c.i. above,

(Amended) Found proved on the basis that Child 9 had been vaccinated with MMR

iii. he did not qualify for the ~~research study~~ *project* as he failed to meet the inclusion criteria set out at paragraph 5.c.ii. above,

(Amended) Found proved on the basis that Child 9 had a form of autism.

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 9's clinical notes,

Found not proved

The Panel accepts that at the time of Child 9's admission in November 1996, you could not have known about conditions of ethical approval, which had been set out in a letter dated 7 January 1997 from the Ethics Committee to Professor Walker-Smith, acknowledged by him on 9 January 1997, and copied to you on the same date.

- e. You caused Child 9 to undergo a lumbar puncture,

Found proved.

The lumbar puncture was an integral part of programme of investigations for Project 172-96, for which you were a Responsible Consultant.

- i. without ensuring that he was first assessed by a clinician with the requisite neurological or psychiatric expertise to determine whether such an investigation was clinically indicated,

Found not proved. The Panel is not satisfied that this has been proved to the requisite standard.

- ii. which was not clinically indicated,

Found proved

In reaching its decision, the Panel has taken into account its finding at the stem of 19.e. and the fact that there was no evidence that there had been a further neurological deterioration in Child 9's condition.

- f. Your actions as set out at paragraph 19.e. were contrary to your representations to the Ethics Committee that the procedures were clinically indicated,

Found proved in relation to 19.e.ii.

- g. By reason of the matters referred to at paragraphs 19.c., 19.d., 19.e. and 19.f. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 6.g. above,

Found proved in relation to 19.c, 19. e.ii. and 19.f.

- h. Your conduct as set out above was contrary to the clinical interests of Child 9;

Found proved on the basis of the above findings.

Child 5

- '20. a. On or about 30 September 1996 you telephoned Child 5's General Practitioner's surgery and spoke to Dr Letham, a partner in the practice, who made a note of the call recording that you had made a very lengthy and convincing case for Child 5 to be referred to Professor Walker-Smith,
Admitted and found proved

b. On 1 October 1996 Child 5's General Practitioner, Dr Shillam, wrote to Professor Walker-Smith stating that Child 5's parents had been in contact with you and had asked Dr Shillam to refer Child 5 to him in relation to the study into the association between autism and childhood bowel problems,

Admitted and found proved

c. Dr Shillam's referral letter gave details of Child 5's developmental delay with classical features of autism, and stated that Child 5's parents were concerned about an association between the MMR vaccine, childhood enteritis and possible brain damage, but made no reference to any gastrointestinal symptoms,

Admitted and found proved

d. Prior to his referral to Professor Walker-Smith, in January 1992 Dr Williams, a Clinical Psychologist for the West Berkshire Health Authority, concluded that it was very likely that Child 5 was suffering from autism,

Admitted and found proved

e. Child 5 was admitted to hospital on or about 1 December 1996 under Professor Walker-Smith's clinical care,

Admitted and found proved

f. Between 1 December 1996 and his discharge on 6 December 1996 Child 5 underwent a colonoscopy, a barium meal and follow-through, an MRI scan of his brain, a neurological assessment by Dr Harvey, a lumbar puncture (although no results were obtained), an EEG, a variety of blood and urine tests,

Admitted and found proved

g. On 2 December 1996 you signed the request form for the EEG, referred to at 20.f. above, to be undertaken on Child 5 stating that the reason for the request/relevant history was "*disintegrative disorder and autism*",

Admitted and found proved

h. On 3 December 1996 Child 5 was seen by Dr Berelowitz who concluded that the likely diagnosis was a developmental disorder, such as autism, but that chromosomal studies needed to be done,

Admitted and found proved

i. On 15 January 1997 Child 5 was readmitted and underwent a repeat barium meal and follow-through under sedation, because of a previous suspected stricture, and a repeat lumbar puncture;

Admitted and found proved

- ‘21. a. You caused Child 5 to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research,
Found proved.
In reaching its decision that you caused Child 5 to undergo a programme of investigations, the Panel has taken into account your initial contact with Child 5’s parents and with Child 5’s General Practitioner, which precipitated his referral to Professor Walker-Smith on 1 October 1996. This referral letter states that Child 5 is being referred to Professor Walker-Smith “regarding your current study into association between autism and childhood bowel problems”. The Panel has concluded that the programme of investigations that Child 5 underwent was for research purposes, for which there was no Ethics Committee approval.
- b. The programme of investigations carried out on Child 5 was part of the ~~research study~~ *project* referred to at paragraphs 5.b. and 5.c. above,
(Amended) Found proved
The Panel finds that the programme of investigations carried out on Child 5, and the reasons recorded in the clinical notes for those investigations, follow closely the project protocol referred to at paragraphs 5.b. and 5c.
- c. ~~The research study was carried out on~~ Child 5 *was investigated under the project* without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,
(Amended) Found proved
The Panel is satisfied that there was no relevant Ethics Committee approval at the time when these investigations were carried out.
- i. ~~contrary to the conditions of approval for Project 172-96~~ Child 5 had been enrolled into the ~~research study~~ *project* before 18 December 1996,
(amended) Found proved.
The first admission of Child 5 took place before 18 December 1996.
- ii. ~~he did not qualify for the project~~ *research study* as he failed to meet the inclusion criteria set out at paragraph 5.c.i. above,
(amended) Found proved.
Child 5 had been vaccinated with MMR
- iii. ~~he did not qualify for the research study project~~ as he failed to meet the inclusion criteria set out at paragraph 5.c.ii. above,
(amended) Found proved.

Professor Walker-Smith's letter dated 12 November 1996 to the child's GP, copied to you, confirmed that Child 5 was referred "with autism and disturbed behaviour".

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 5's clinical notes,
Found proved in relation to the further investigations that Child 5 underwent during his second admission on or around 15 January 1997 under Project 172-96.

e. By reason of the matters referred to at paragraphs 21.c. and 21.d. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 6.g. above,
Found proved

f. You ordered that the investigation set out at paragraph 20.g. above be carried out on Child 5,
Found proved
The Panel is satisfied that by signing the forms you ordered the investigations; it does not accept your explanation of your role that it was purely administrative.

- i. without having the requisite paediatric qualifications to do so,
Found proved, as is evident by your CV.
- ii. in contravention of the limitations on your Honorary Consultant appointment as set out at paragraph 2. above,
Found proved on the basis of the wording of your job description and your letter of employment (contract).

g. You stated that one of the reasons for ordering an EEG was that Child 5 had disintegrative disorder when there was no such diagnosis,
Found proved.
The Panel is persuaded by the EEG request form dated 2 December 1996 and signed by you giving the diagnosis of disintegrative disorder and autism whereas Professor Walker Smith's letter to the GP dated 12 November 1996 and copied to you, confirms that Child 5 was referred with the diagnosis of "autism and disturbed behaviour."

h. Your conduct as set out above was contrary to the clinical interests of Child 5;
Found proved. In reaching this decision, the Panel has taken into account the above findings.

Child 12

'22. a. On 19 July 1996 you wrote to Child 12's mother,

- i. thanking her for her letter regarding her son,
Admitted and found proved
 - ii. telling her to seek a referral to Professor Walker-Smith,
Admitted and found proved
 - iii. asking that she provide you with the General Practitioner's phone number,
Admitted and found proved

- b. On or about 20 July 1996 you telephoned Child 12's General Practitioner, Dr Stuart, who noted in Child 12's medical records: "*call from Dr Wakefield – needs colonoscopy B12 absorption tests. History of measles vaccination reaction*",
Admitted and found proved

- c. On 23 September 1996 Dr Stuart wrote a letter addressed to Professor Walker-Smith but marked for your attention referring Child 12,
Admitted and found proved

- d. Dr Stuart's referral letter stated Child 12 had seen Dr Ing, a Consultant Child Psychiatrist, who had said that Child 12 may well have Asperger's Syndrome,
Admitted and found proved

- e. On 21 October 1996 Professor Walker-Smith wrote to you stating that,
Admitted and found proved
 - i. Child 12 really had features of autism but had rather minimal gastrointestinal symptoms,
Admitted and found proved
 - ii. he felt it was not right to proceed with the intensive programme until you had ethical committee approval and it was clear that the parents wished you to proceed,
Admitted and found proved

- f. On 25 November 1996 Professor Walker-Smith wrote to Child 12's mother stating that he thought that it would be appropriate to arrange for Child 12 to come in for a colonoscopy,
Admitted and found proved

- g. Child 12 was admitted to hospital on 5 January 1997 under Professor Walker-Smith's clinical care,
Admitted and found proved

- h. Child 12's admission clerking note, dated 6 January 1997, indicated that he was being admitted for investigation of autism and bowel problems,

Admitted and found proved

i. Between 6 January 1997 and his discharge on 10 January 1997 Child 12 underwent a colonoscopy, a barium meal and follow-through, an MRI scan of his brain, a lumbar puncture (on 9 January 1997), an EEG and other neurophysiological tests, and a variety of blood and urine tests,

Admitted and found proved

j. Of the tests set out in 22.i. above,

i. You signed the request form, dated on or about 6 January 1997, for the EEG and for other neurophysiological investigations,

Admitted and found proved

ii. the results of the lumbar puncture were normal,

Admitted and found proved

k. On 9 January 1997 Dr Harvey visited Child 12 on the ward but he was unable to undertake a neurological examination because Child 12 was asleep,

Admitted and found proved

l. On 10 January 1997 Child 12 was interviewed by Dr Berelowitz who concluded that Child 12 had language delay, possible Attention Deficit Disorder and possible features of Asperger's Syndrome;

Admitted and found proved

'23. a. You caused Child 12 to undergo a programme of investigations as part of the ~~research study~~ *project* referred to at paragraphs 5.b. and 5.c. above,

(Amended) Found proved

In reaching its decision that you caused Child 12 to undergo a programme of investigations, the Panel is satisfied that you were actively involved in the referral process of Child 12 in that you were in written and telephone contact with Mrs 12. In particular, the Panel has taken into account your letter dated 19 July 1996 to Mrs 12, in which you invite her to call you and also that you would like her to seek a referral from Child 12's GP to Professor Walker-Smith "for investigation." In addition, the Panel has had regard to your telephone conversation on or about 20 July 1996 with Child 12's GP, supported by his note of 30 July 1996 which states; "Call from [you] – needs colonoscopy. B12 absorption tests." The Panel has also taken into account the evidence given by Mrs 12 and the GP that they understood Child 12 would be undergoing a programme to investigate the possible connection between MMR vaccine, bowel problems and autism.

Additionally, the Panel has taken into account Professor Walker-Smith's letter to you, dated 21 October 1996, in which he states "I did not feel it right in fact to proceed with our intensive programme at the moment until we have had ethical committee approval."

On the basis of all of this evidence, the Panel has concluded that the programme of investigations that Child 12 underwent was for research purposes.

b. ~~The research study project was carried out on Child 12 was investigated under the project~~ without the approval of the Ethics Committee in that he did not qualify for the ~~research study project~~ as he failed to meet the inclusion criteria set out at,

(Amended) Found proved

- i. paragraph 5.c.i. above,
Found proved on the basis that Child 12 had been vaccinated with MMR
- ii. paragraph 5.c.ii. above,
Found proved
Child 12 had not been diagnosed with disintegrative disorder

c. Contrary to the conditions of ethical approval for Project 172-96 you failed to ensure that a copy of the consent form and information sheet was included in Child 12's clinical notes,

Found not proved

The Panel accepts that at the time of Child 12's admission on 5 January 1997, you could not have known about conditions of ethical approval, which were set out in a letter dated 7 January 1997 from the Ethics Committee to Professor Walker-Smith, acknowledged by him on 9 January 1997, and copied to you on the same date.

d. You caused Child 12 to undergo a lumbar puncture,

Found proved

The Panel is satisfied that the lumbar puncture was an integral part of programme of investigations for Project 172-96, for which you were a Responsible Consultant.

i. without ensuring that he was first assessed by a clinician with the requisite neurological or psychiatric expertise to determine whether such an investigation was clinically indicated,
Found not proved on the basis that the Panel is not satisfied that this allegation has been made out to the requisite standard.

ii. which was not clinically indicated,

Found proved on the basis of Professor Walker-Smith's ward round notes of 6 January 1997 which states: "not to have MRI or LP"

e. Your actions as set out at paragraph 23.d. were contrary to your representations to the Ethics Committee that the procedures were clinically indicated,

Found proved in relation to 23.d.ii. on the basis that the lumbar puncture was not clinically indicated.

f. By reason of the matters referred to at paragraphs 23.b., ~~23.c.~~, 23.d. and 23.e. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 6.g. above,

(amended) Found proved

g. You ordered that the investigations set out at paragraph 22.j.i. be carried out on Child 12,

Found proved

The Panel is satisfied that by signing the forms you ordered the investigations; it does not accept your explanation of your role as purely administrative.

i. without having the requisite paediatric qualifications to do so,

Found proved, as is evident by your CV.

ii. in contravention of the limitations on your Honorary Consultant appointment as set out at paragraph 2. above,
Found proved on the basis of the wording of your job description and your letter of employment (contract).

h. Your conduct as set out above was contrary to the clinical interests of Child 12;

Found proved on the basis of the above findings.

Child 8

'24. a. On 3 October 1996 Child 8's General Practitioner, Dr Jelley, wrote to you,

Admitted and found proved

i. referring Child 8 to your investigation programme into the possible effects of vaccine damage and her ongoing GI tract symptoms,

Admitted and found proved

ii. reiterating that there had been significant concerns about Child 8's development prior to her MMR vaccination but that she supported Child 8's mother's request for further information,

Admitted and found proved

b. On 9 October 1996 you wrote to Professor Walker-Smith saying that you had requested a letter of referral to him and confirming the referral,

Admitted and found proved

c. Child 8 was admitted to hospital on 19 January 1997 under Professor Walker-Smith's clinical care,

Admitted and found proved

d. Between 19 January 1997 and her discharge on or about 25 January 1997 Child 8 underwent a colonoscopy, a barium meal and follow-through, an MRI scan of her brain, a variety of blood and urine tests and an interview with Dr Berelowitz,

Admitted and found proved

e. Dr Berelowitz concluded that Child 8 may have post vaccination encephalitis and that an autistic spectrum diagnosis was not merited;

Admitted and found proved

'25. a. You caused Child 8 to undergo a programme of investigations as part of the ~~research study project~~ referred to at paragraphs 5.b. and 5.c. above,

(Amended) Found proved

In reaching its decision that you caused Child 8 to undergo the programme of investigations, the Panel has taken into account the contact you had with Child 8's mother, which precipitated Child 8's GP referral letter dated 3 October 1996 to you. That letter states: "Child 8's mother has been in to see me and said that you needed a referral letter from me in order to accept Child 8 into your investigation programme. I gather this is a specific area of expertise relating to the possible effects of vaccine damage and her ongoing GI tract symptoms".

The Panel has also borne in mind that Child 8 was admitted to the Royal Free Hospital on 19 January 1997, without prior outpatient assessment. In addition, the Panel has taken into account the endoscopy clerking note dated 20 January 1997, which state: "Plan: Dr Wakefield protocol", and the discharge summary dated 27 November 1997 from Dr Casson to the GP, which states "Child 8 was admitted ... for further investigation of possible association between developmental delay, gastrointestinal symptoms and vaccination".

b. ~~The research study project was carried out on~~ Child 8 was *investigated under the project* without the approval of the Ethics

Committee in that she did not qualify for the ~~research study~~ *project* as she failed to meet the inclusion criteria set out at,

(Amended)

- i. paragraph 5.c.i. above,
Found proved on the basis that Child 8 had been vaccinated with MMR
- ii. paragraph 5.c.ii. above,
Found proved on the basis that Child 8 had not been diagnosed with disintegrative disorder by any of the clinicians who had seen her prior to her admission to the Royal Free Hospital.

c. Contrary to the conditions of ethical approval for Project 172-96 you failed to ensure that a copy of the consent form and information sheet was included in Child 8's clinical notes,

Found proved.

In reaching its decision, the Panel has taken into account that Professor Walker-Smith sent you a copy of the letter from the Ethics Committee setting out conditions, and his confirmation of acceptance of that letter on 9 January 1997.

d. By reason of the matters referred to at paragraph 25.b. and 25.c. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 6.g. above,

Found proved

e. Your conduct as set out above was contrary to the clinical interests of Child 8;

Found proved on the basis of the above findings.

Child 7

'26. a. On or about 5 December 1996 Child 7's General Practitioner, Dr Nalletamby, wrote to Professor Walker-Smith referring Child 7 and stating that he,

Admitted and found proved

i. probably did not have autism but he did have convulsions which Dr Nalletamby believed might make him eligible for your study,

Found not proved to the requisite standard on the basis that as the letter is addressed to Professor Walker-Smith, and not copied to you, the words "your study" may not have included you.

ii. suffered from bowel problems similar to his brother [Child 6] who had recently been investigated,

Admitted and found proved

b. Child 7 was admitted to hospital on 26 January 1997 under Professor Walker-Smith's clinical care,
Admitted and found proved

c. Child 7's admission clerking note recorded that he had been admitted for colonoscopy and investigations as part of the Disintegrative Disorder/Colitis study,
Admitted and found proved

d. Between 26 January 1997 and his discharge on February 1997 Child 7 underwent a colonoscopy, a barium meal and follow-through, an MRI scan of the brain, a lumbar puncture, an EEG and other neurophysiological investigations, blood and urine tests,
Admitted and found proved

e. You signed a request form, dated 27 January 1997, for the EEG and other neurophysiological investigations referred to at 26.d. above to be undertaken on Child 7 and stated that the reason for the request/relevant history was "*disintegrative disorder and inflammatory bowel disease*";
Admitted and found proved

'27. a. You caused Child 7 to undergo a programme of investigations as part of the ~~research study~~ *project* referred to at paragraphs 5.b. and 5.c. above,
(Amended) Found not proved
Although the Panel is satisfied that you became involved in the programme of investigation of Child 7, it is not satisfied to the requisite standard that you were involved in the original referral of Child 7 to the Royal Free Hospital.

b. ~~The research study was carried out on~~ Child 7 was investigated under the project without the approval of the Ethics Committee in that he did not qualify for the ~~research study~~ *project* as he failed to meet the inclusion criteria set out at,
(Amended)

i. paragraph 5.c.i. above,
Found proved on the basis that Child 7 had been vaccinated with MMR

ii. paragraph 5.c.ii. above,
Found proved on the basis that Child 7 had not been diagnosed with disintegrative disorder.

c. Contrary to the conditions of ethical approval for Project 172-96 you failed to ensure that a copy of the consent form and information sheet was included in Child 7's clinical notes,
Found proved.

In reaching its decision, the Panel has taken into account that Professor Walker-Smith sent you a copy of the letter from the Ethics Committee setting out conditions, and his confirmation of acceptance of that letter on 9 January 1997.

d. By reason of the matters referred to at paragraphs 27.b. and 27.c. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 6.g. above,
Found proved

e. You ordered that the investigations set out at paragraph 26.e. above be carried out on Child 7,
Found proved.

The Panel is satisfied that by signing the forms, you ordered the investigations. It does not accept your explanation of your role that it was purely administrative.

i. without having the requisite paediatric qualifications to do so,

Found proved, as is evident by your CV.

ii. in contravention of the limitations on your Honorary Consultant appointment as set out at paragraph 2. above,
Found proved on the basis of the wording of your job description and your letter of employment (contract).

f. You stated that one of the reasons for ordering an EEG and other neurophysiological investigations was that Child 7 had disintegrative disorder when there was no such diagnosis,
Found proved in view of your admission at 26.e.

g. Your conduct as set out above was contrary to the clinical interests of Child 7;
Found proved in view of the finding that you ordered the neurophysiological investigations without having requisite paediatric qualifications and writing an incorrect diagnosis on the investigation form.

Child 10

'28. a. On 14 October 1996 Child 10's General Practitioner, Dr Hopkins, wrote to Professor Walker-Smith referring Child 10 and stating that,
Admitted and found proved

i. Child 10 had a history of loss of acquired skills which appeared to follow a measles-type illness,
Admitted and found proved

ii. he had previously been given the MMR and his measles antibody was significantly raised,
Admitted and found proved

iii. no actual diagnosis had been given for Child 10's condition but the most recent report referred to severe speech and language disorder with some autistic features,
Admitted and found proved

b. Dr Hopkins' referral letter made no reference to gastrointestinal symptoms,
Admitted and found proved

c. Child 10 was admitted to hospital on 16 February 1997 under Professor Walker-Smith's clinical care,
Admitted and found proved

d. Child 10's admission clerking note recorded that he had been admitted for investigation of disintegrative disorder/measles/IBD,
Admitted and found proved

e. Between 16 February 1997 and his discharge on 19 February 1997 Child 10 underwent a colonoscopy, a lumbar puncture (on 17 February 1997), and a variety of blood and urine tests,
Admitted and found proved

f. The results from the lumbar puncture were normal,
Admitted and found proved

g. On 18 February 1997 Dr Berelowitz saw Child 10's father and concluded that Child 10 did not meet the criteria for either autism or disintegrative disorder and the most likely diagnosis was an encephalitic episode;
Admitted and found proved

'29. a. You caused Child 10 to undergo a programme of investigations as part of the ~~research study project~~ referred to at paragraphs 5.b. and 5.c.,

(amended) Found not proved

Although the Panel is satisfied that you became involved in the programme of investigation of Child 10, it is not satisfied to the requisite standard that you were involved in the original referral of this child to the Royal Free Hospital.

b. ~~The research study project was carried out on~~ Child 10 was *investigated under the project* without the approval of the Ethics Committee in that he did not qualify for the ~~research study project~~ as he failed to meet the inclusion criteria set out at,
(amended)

- i. paragraph 5.c.i. above,
Found proved on the basis that Child 10 had been vaccinated with MMR
 - ii. paragraph 5.c.ii. above,
Found proved on the basis that Child 10 had not been diagnosed with disintegrative disorder
- c. Contrary to the conditions of ethical approval for Project 172-96 you failed to ensure that a copy of the consent form and information sheet was included in Child 10's clinical notes,
Found proved.
In reaching its decision, the Panel has taken into account that Professor Walker-Smith sent you a copy of the letter from the Ethics Committee setting out conditions, and his confirmation of acceptance of that letter on 9 January 1997.
- d. You caused Child 10 to undergo a lumbar puncture,
Found not proved on the basis that the Panel is not satisfied that this allegation has been made out to the requisite standard.
- i. without ensuring that he was first assessed by a clinician with the requisite neurological or psychiatric expertise to determine whether such an investigation was clinically indicated,
Found not proved
 - ii. which was not clinically indicated,
Found not proved
- e. Your actions as set out at paragraph 29.d. were contrary to your representations to the Ethics Committee that the procedures were clinically indicated,
Found not proved on the basis that paragraph 29.d. is found not proved
- f. By reason of the matters referred to at paragraphs 29.b., 29.c., 29.d. and 29.e. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 6.g. above,
(amended) Found proved
- g. Your conduct as set out above was contrary to the clinical interests of Child 10;
Found not proved. The Panel found that, despite this child being subject to a programme of investigations rather than specific ones tailored to his needs, there was insufficient evidence to make a finding that you caused them or that the investigations were contrary to his clinical interests.

The Lancet Paper

- '30. a. The investigations on the children whose individual circumstances are set out above were subsequently written up anonymised by numbers in a scientific paper entitled "*Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis and Pervasive Developmental Disorder in Children*" which was published in the Lancet Journal Vol. 351 dated 28 February 1998 ("the Lancet paper"), **Admitted and found proved with the exception of the word 'scientific'.**
Found proved in its entirety. In reaching its decision, the Panel has taken into account the terminology you used in your evidence when describing the paper as "a standard format for the presentation of a scientific paper" (Day66p4)
- Furthermore, the application to the Ethics Committee for project 172-96 describes you as "senior scientific investigator".**
- b. The number of each child herein corresponds with the number of that child in the Lancet paper and Child 11 in the Lancet paper was a private patient from the USA;
Admitted and found proved
- '31. a. The Lancet paper purported to identify associated gastrointestinal disease and developmental regression in a group of previously normal children which was generally associated in time with possible environmental triggers which were identified by their parents in eight cases with the child's MMR vaccination,
Admitted and found proved
- b. You knew or ought to have known that your reporting in the Lancet paper of a temporal link between the syndrome you described and the MMR vaccination,
Admitted and found proved
- i. had major public health implications,
Admitted and found proved
- ii. would attract intense public and media interest,
Admitted and found proved
- c. In the circumstances set out at paragraph 31.b. above, and as one of the senior authors of the Lancet paper, you,
- i. knew or ought to have known the importance of accurately and honestly describing the patient population,
Admitted and found proved
- ii. had a duty to ensure that the factual information in the paper and provided by you in response to queries about it was true and accurate,

Found proved

In reaching its decision, the Panel has taken into account the guidance from the Lancet, published in October 1997, which states “he or she [authors of the paper] must share responsibility for what is published.” The Panel is satisfied that, as one of the senior authors of the Lancet paper, you had a duty to ensure that the factual information contained in the paper was true and accurate. In his evidence, Professor Rutter also referred to the importance of accuracy in scientific papers.

In evidence, you accepted that when providing information in response to queries about the contents of the paper you had a duty to ensure that such information was true and accurate.

iii. had a duty to disclose to the Editor of the Lancet any disclosable interest including matters which could legitimately give rise to a perception that you had a conflict of interest;

Found proved

The Panel is satisfied that the concept of a conflict of interest, and the extension of this to the perception of a conflict of interest, was known in the scientific community in 1997. At that time the Lancet and other organisations had published guidance on the requirement for authors for recognising and declaring financial and other conflicts of interests, as well as the importance of declaring “potential”, “perceived” or “apparent” conflicts of interest. The Panel therefore rejects the proposition put forward by your Counsel that third party perceived conflicts of interest did not fall within the relevant definition at the time.

- ‘32. a. You failed to state in the Lancet paper that the children whose referral and histories you described were part of a research study project, the purpose of which was to investigate a postulated new syndrome comprising gastrointestinal symptoms and disintegrative disorder following vaccination,
(amended)) Found proved on the basis that the children who were described in the paper were admitted under a programme of investigations for Project 172-96 for research purposes.
- b. Your conduct as set out at paragraph 32.a. was,
- i. dishonest,
Found proved
 - ii. irresponsible,
Found proved
 - iii. resulted in a misleading description of the patient population in the Lancet paper;

Found proved

In reaching its decision, the Panel notes that the project reported in the Lancet paper was established with the purpose to investigate a postulated new syndrome and yet the Lancet paper did not describe this fact at all. Because you drafted and wrote the final version of the paper, and omitted correct information about the purpose of the study or the patient population, the Panel is satisfied that your conduct was irresponsible and dishonest.

The Panel is satisfied that your conduct at paragraph 32.a would be considered by ordinary standards of reasonable and honest people to be dishonest.

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

Admitted and found proved

- b. You knew or ought to have known that such a description implied,

- i. a routine referral to the gastroenterology department in relation to symptoms which included gastrointestinal symptoms,

Found proved

- ii. a routine process in which the investigators had played no active part;

Found proved

In reaching its decisions, the Panel has taken into account the article in the Lancet (volume 350, October 4, 1997) "Writing for the Lancet", which states, "...it is a general reader whom you are trying to reach". The Panel is satisfied that a general reader would interpret the wording in 33.a. to mean that the children had been referred to the gastroenterology department with gastrointestinal symptoms, and that the investigators had played no active part in the referral process.

- '34. a. Contrary to paragraph 33.b.i., the referrals of,
- i. Child 1 as set out at paragraphs 10.a. and 10.b.,
Found proved
- ii. Child 9 as set out at paragraphs 18.a. to 18.d.,

- iii. **Found proved**
Child 5 as set out at paragraphs 20.a. to 20.c.,
Found proved
- iv. Child 10 as set out at paragraphs 28.a. and 28.b.,
Found proved

did not constitute routine referrals to the gastroenterology department in relation to intestinal symptoms as the referring doctors referred the children for investigation of the role played by the measles vaccination or the MMR vaccination into their developmental disorders and did not report any history of gastrointestinal symptoms,

Found proved

Having regard to its findings in relation to Child 1, 9, 5 and 10, namely that these children were admitted to undergo a programme of investigations for research purposes, and that they all lacked a history of gastrointestinal symptoms, the Panel is satisfied that these referrals did not constitute routine referrals to the gastroenterology department.

- b. Contrary to paragraph 33.b.ii., the referrals of,
 - i. Child 2 as set out at paragraphs 8.a. to 8.e.,
Found proved
 - ii. Child 9 as set out at paragraphs 18.a. to 18.c.,
Found proved
 - iii. Child 5 as set out at paragraphs 20.a. and 20.b.,
Found proved
 - iv. Child 12 as set out at paragraphs 22.a. to 22.c.,
Found proved

included active involvement in the referral process by you,
Found proved on the basis of your admissions and the Panel's findings.

- c. The description of the referral process in the Lancet paper was therefore,
 - i. irresponsible,
Found proved
 - ii. misleading,
Found proved
 - iii. contrary to your duty to ensure that the information in the paper was accurate;
Found proved

In reaching its decision, the Panel concluded that your description of the referral process as "routine", when it was not, was irresponsible and misleading and contrary to your duty as a senior author.

- ‘35. a. In a letter to the Lancet volume 351 dated 2 May 1998, in response to the suggestion of previous correspondents that there was biased selection of patients in the Lancet article, you stated that the children had all been referred through the normal channels (e.g. from general practitioner, child psychiatrist or community paediatrician) on the merits of their symptoms,
Admitted and found proved
- b. In the circumstances set out in paragraphs 32.a., 34.a. and 34.b. this statement was,
- i. dishonest,
Found proved.
 - ii. irresponsible,
Found proved
 - iii. contrary to your duty to ensure that the information provided by you was accurate;
Found proved
The Panel is satisfied that you had such a duty, as set out in paragraph 31.c.ii.

The Panel is persuaded by all the correspondence in the Lancet Journal volume 351 dated 2 May 1998 regarding a suggestion by correspondents to the Lancet that there was a biased selection of patients in the Lancet Paper of 28 February 1998, of which you were one of the senior authors.

The Panel has found that your statement as set out in paragraph 35.a. does not respond fully and accurately to the queries made by correspondents to the Lancet.

The Panel is satisfied that the statement you made would be considered by ordinary standards of reasonable and honest people to be dishonest. Additionally, you knew that this statement omitted necessary and relevant information, such as the active role you played in the referral process, and the fact that the referral letters in four cases made no mention of any gastrointestinal symptoms and the fact that the investigations had been carried out under Project 172-96 for research purposes.

Therefore, the Panel is satisfied that your conduct in this regard was dishonest and irresponsible.

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

including the twelve children in the Lancet paper and you stated that all patients reviewed so far had come through General Practitioners or paediatricians by “the standard route”,

Admitted and found proved

b. In the circumstances set out in paragraphs 32.a., 34.a. and 34.b. this statement was,

- i. dishonest,
Found proved
- ii. irresponsible,
Found proved
- iii. contrary to your duty to ensure that the information provided by you was accurate;
Found proved
The Panel is satisfied that you had such a duty, as set out in paragraph 31.c.ii.

The Panel has taken into account that this was an important scientific meeting to consider the implications of your published research and the major public health implications arising from it. The Panel has found that your responses to the questions raised at this meeting were inaccurate.

The Panel is satisfied that you knew that your response to the questions was factually wrong. The statement you made would be considered by ordinary standards of reasonable and honest people to be dishonest. The Panel is satisfied that your conduct in this regard was dishonest and irresponsible.

‘37. a. The Lancet paper stated that the investigations reported in it were approved by the Ethical Practices Committee of the Royal Free Hospital NHS Trust,

Found proved

The Panel noted the statement written under the heading “Ethical approval and consent” in the Lancet paper published in February 1998.

b. In fact, you did not have ethical approval for the investigations in the circumstances set out in paragraphs 5. to 29. above,

(amended) Found proved

The Panel has accepted that paragraphs 5 to 29 have been found proved on the basis that this was Project 172-96. Therefore the Panel is sure that you did not have ethical approval for the investigations as set out in these paragraphs.

c. The statement you made in the Lancet paper with regard to ethical approval was therefore,

- i. dishonest,
Found not proved
- ii. irresponsible,
Found proved
- iii. contrary to your duty to ensure that the information provided by you was accurate;
Found proved
Your Counsel accepted on your behalf that you had such a duty (closing submissions section 12 p288). Given the findings in head of charge 37, the Panel is sure that you have failed in your duty in this respect and therefore your conduct was irresponsible.

However, the Panel is not certain that you intended to deceive by inserting that statement in the Lancet Paper. Therefore the Panel is not satisfied that this meets all the criteria required to prove the allegation of dishonesty.

- '38. a. On or before 5 June 1997 you instructed agents to file with the UK Patent Office a patent application with the short title "*Pharmaceutical Composition for Treatment of IBD and RBD*", naming the applicants as the Royal Free Hospital School of Medicine and Neuroimmuno Therapeutics Research Foundation ("the Patent"),
Admitted and found proved
- b. The invention which was the subject of the patent, and of which you were one of the inventors, related to a new vaccine for the elimination of MMR and measles virus and to a pharmaceutical or therapeutic composition for the treatment of IBD (Inflammatory Bowel Disease); particularly Crohn's Disease and Ulcerative Colitis and regressive behavioural disease (RBD);
Admitted and found proved

- '39. a. Your,
- i. involvement in the MMR litigation,
 - ii. receipt of funding for part of Project 172-96 from the Legal Aid Board,
 - iii. involvement in the Patent,

constituted a disclosable interest which included matters which could legitimately give rise to a perception of a conflict of interest in relation to your role as a co-author of the Lancet paper which you did not disclose to the Editor of The Lancet,
Found proved

In reaching its decision, the Panel has taken into account your admissions and its findings at paragraph 31c. The Panel is satisfied that the matters set out at 39.a. above each constituted a disclosable interest and could have given rise to a perception of a conflict of interest.

- b. Your conduct as set out at,
 - i. paragraph 39.a.i.,
 - ii. paragraph 39.a.ii.,
 - iii. paragraph 39.a.iii.,

was contrary to your duties as a senior author of the Lancet paper;

Found proved. Having regard to its findings at paragraph 31.c., the Panel is satisfied that your conduct in failing to disclose your involvement in the MMR litigation, your receipt of funding for part of Project 172-96 from the Legal Aid Board and your involvement in the Patent, constituted disclosable interests. Your failure to disclose these to the Editor of The Lancet was contrary to your duties as a senior author of the Lancet paper.

Transfer Factor

- '40. a. In or about December 1997 you started Child 10 on a substance called Transfer Factor,

Found not proved

The Panel has not seen or heard any evidence to prove to the requisite standard that you personally started Child 10 on this substance.

- b. On 2 February 1998 you submitted an application to the Ethics Committee,

Admitted and found proved

- i. seeking approval for a trial entitled "*A preliminary open-label study of the effect of oral measles virus-specific dialyzable lymphocyte extract transfer factor (DLE-TFmv) in children with autistic enteropathy*",

Admitted and found proved

- ii. naming Professor Walker-Smith as one of the Principal Clinical Investigators and you as Principal Scientific Investigator,

Admitted and found proved

- c. The application referred to at paragraph 40.b. above was allocated reference 22-98 ("Project 22-98"),

Admitted and found proved

d. At or around the same time as the events set out at paragraphs 40.a. and 40.b., you were involved in a proposal to set up a company called Immunospecifics Biotechnologies Ltd to specialise in the production, formulation and sale of Transfer Factor,
(amended) Admitted and found proved with the exception of '40.a.'

e. On 26 February 1998 you wrote to the Finance Officer at the Royal Free Hospital School of Medicine informing him that the proposed CEO of the company was the father of Child 10 ("Mr 10"),
Admitted and found proved

f. A proposal, dated 4 March 1998 and drafted by Mr 10, was submitted to the Royal Free Hospital School of Medicine in relation to the proposed company,
Admitted and found proved

i. seeking funding for a clinical trial of Transfer Factor in the treatment of Inflammatory Bowel Disease, and Pervasive Developmental Disorder, and for research into using Transfer Factor as an alternative measles specific vaccine,
Admitted and found proved with the exception of the words 'an alternative'

Found proved in respect of the words "an alternative" on the basis of the proposal referred to above in 40.f. where it states, "The company will also investigate the potential of Transfer Factors as vaccine alternatives."

ii. stating that Mr 10 was to be the Managing Director of the company,
Admitted and found proved

iii. stating that you were to be the Research Director,
Admitted and found proved

iv. proposing that the equity in the company would be split between a number of parties including Mr 10 and yourself,
Admitted and found proved

g. Between July and November 1998 you and Professor Walker-Smith undertook research into the safety of Transfer Factor which you submitted to the Ethics Committee,
Admitted and found proved

h. On 18 December 1998 the Ethics Committee wrote to Professor Walker-Smith stating that Project 22-98 had been approved at a meeting on 16 December 1998;
Admitted and found proved

'41. a. You inappropriately caused Child 10 to be administered Transfer Factor,

Found proved. The Panel is persuaded that Child 10 was administered Transfer Factor by the weekly diary card completed by his mother, submitted to the Royal Free hospital in January 1998 which states, “over Christmas and New Year we felt very optimistic about the apparent effect of Transfer Factor...is it possible that the dose now needs to be increased?”. The Panel concluded that you caused the child to be administered with Transfer Factor on the basis of the letter of 23 July 1997 that you and Professor Walker-Smith wrote to the Dispensary Manager. You informed her that “we would like to start Child 10 ...on measles specific Transfer Factor and we are prepared to take full responsibility for the outcome of this treatment. The supplies of the drug are presently in our hands (Dr Wakefield)” Further, you sought permission from the Medical Advisory Committee by letter dated 9 September 1997 for Child 10 to be administered Transfer Factor on a named patient basis as is evidenced by the approval letter sent to you by its chairman, Dr Lloyd in a letter dated 15 September 1997.

- i. for experimental reasons,

Found proved

In reaching its decision the Panel is satisfied that in December 1997 you were preparing an application to seek approval from the Ethics Committee for a trial entitled: “A preliminary open-label study of the effect of oral measles virus-specific dialyzable lymphocyte extract transfer factor (DLE-TF mv) in children with autistic enteropathy.”

The Panel noted that Child 10’s deterioration was not assessed by any clinician prior to being administered Transfer Factor. Therefore the Panel has concluded that Child 10 was given Transfer Factor for experimental reasons.

- ii. prior to obtaining information as to the safety of prescribing Transfer Factor to children,

Found not proved

The Panel has taken into account the letter dated 23 July 1997 to the Dispensary Manager from you and Professor Walker-Smith in which you refer to about 300 peer reviewed scientific publications on the use of Transfer Factor and state that this substance was safe.

- iii. prior to obtaining ethical approval for a clinical trial of Transfer Factor,

Found not proved

The Panel has noted the letter dated 15 September 1997 from Dr Lloyd, giving you Chairman’s approval for the use of Transfer Factor to Child 10. The Panel is

therefore satisfied that obtaining ethical approval for a clinical trial for this child was not relevant in December 1997.

- iv. without,
 - a. recording *or causing to be recorded* the fact of or dose of the prescription in Child 10's medical records,
(amended) Found proved
 - b. informing Child 10's General Practitioner *or causing him to be informed* that Child 10 had been prescribed it,
(amended) Found proved

In reaching its decisions in relation to 41.a.iv.a. and b, the Panel has taken into account the letter dated 23 July 1997 to Dispensary Manager from you and Professor Walker-Smith which states: "we are prepared to take full responsibility for the outcome of this treatment."

The Panel is satisfied that you had a duty to ensure that the treatment was recorded properly in Child 10's medical records, or to have arranged for someone else to have done so. The Panel considers this was important, given your role in causing Child 10 to be administered Transfer Factor.

Furthermore, an essential requirement of a doctor is to share information with colleagues in the ways that best serve patients' interests. The Panel has noted the evidence that Child 10's GP did not have any knowledge of any prescription of Transfer Factor other than that contained in a letter from the community paediatrician. The Panel is satisfied that you did not inform the GP or arrange for someone else to do so.

- c. recording *or causing to be recorded* in Child 10's medical records the fact and nature of any discussion as to the risks and benefits of the prescription with Child 10's parents,
(amended) Found not proved
The Panel noted that there is no evidence relating to any such discussion with the parents and therefore you could not have recorded it.
- v. without having the requisite paediatric qualifications,
Found proved, as is evident from your CV.

- vi. in contravention of the limitations on your Honorary Consultant appointment as set out at paragraph 2. above,
Found not proved
The Panel is satisfied that causing Child 10 to be administered Transfer Factor for experimental reasons did not contravene the remit of your contract.
- b. Your actions as set out above were,
 - i. contrary to the clinical interests of Child 10,
Found proved on the basis of its findings at 41.a.i, 41.a.iv.a, 41.a. iv.b and 41.a.v.
 - ii. an abuse of your position of trust as a medical practitioner;
Found proved on the basis of its findings at 41.a.i, 41.a.iv.a, 41.a.iv.b and 41.a.v.

The Birthday Party

- '42. a. On a date unknown prior to 20 March 1999 at your son's birthday party you,
 - i. ~~took~~ *caused blood to be taken* from a group of children to use for research purposes,
(amended) Found proved
The Panel considers that the amendment is necessary to reflect the state of the evidence.
 - ii. paid those children who gave blood £5 each for doing so,
Found proved
The Panel is satisfied by your own evidence (Day 55p41) that you paid the children "as a reward at the end of the party the children who had given blood all received £5"
- b. On 20 March 1999 you gave a presentation to the MIND Institute, in California, USA in the course of which you,
Admitted and found proved to the words 'California, USA'
 - i. described the incident referred to in 42.a. above in humorous terms,
Found proved
 - ii. expressed an intention to obtain research samples in similar circumstances in the future;
Found proved
The Panel is satisfied that this has been found proved in its entirety, having viewed the video.
- '43. a. **Your conduct as set out in paragraph 42.a. above was unethical**
in that,

i. you did not have ethics committee approval for your actions,

Found proved

The Panel does not accept your explanation that you did not consider this action to be unethical or that Ethics Committee approval was required.

ii. you took *caused* blood to be taken from children in an inappropriate social setting,

(amended) Found proved

The Panel considers that the amendment was necessary to reflect the state of the evidence.

iii. you offered financial inducement to children in order to obtain blood samples,

Found not proved

The Panel accepts that the children were not persuaded to give blood by being offered money first.

iv. you showed a callous disregard for the distress and pain that you knew or ought to have known the children involved might suffer,

Found proved

The Panel is satisfied by your evidence that the children were “paid for their discomfort”(day 67p23), which it concluded was evidence of a callous disregard.

v. in the circumstances you abused your position of trust as a medical practitioner,

Found proved on the basis of the above findings.

b. Your conduct set out in paragraph 42.b. was such as to bring the medical profession into disrepute;

Found proved on the basis of the above findings.

Having made the above findings of fact, the Panel went on to consider whether those facts found proved or admitted, were insufficient to amount to a finding of serious professional misconduct. The Panel concluded that these findings, which include those of dishonesty and misleading conduct, would not be insufficient to support a finding of serious professional misconduct.

In the next session, commencing 7 April 2010, the Panel, under Rule 28, will hear evidence to be adduced and submissions from prosecution counsel then Dr Wakefield’s own counsel as to whether the facts as found proved do amount to serious professional misconduct, and if so, what sanction, if any, should be imposed on his registration.

B. Professor John Angus WALKER-SMITH

The Panel will inquire into the following allegation against John Angus Walker-Smith, MB BS 1960 University of Sydney SR:

“That being registered under the Medical Act 1983,

- ‘1. At all material times you were,
 - a. A UK registered medical practitioner,
Admitted and found proved
 - b. Professor of Paediatric Gastroenterology employed by the Royal Free School of Medicine with an honorary clinical contract with the Royal Free Hampstead NHS Trust;
Admitted and found proved

Research and Ethics Committee Approval

‘2. On or about 16 September 1996 an application was submitted to the Ethical Practices Sub-Committee of the Royal Free Hampstead NHS Trust (“the Ethics Committee”),
Admitted and found proved

- a. Naming you, Dr Wakefield and Professor Murch as the responsible consultants,
Admitted and found proved
- b. Seeking approval for a ~~research-study~~ project involving 25 children entitled “A new paediatric syndrome: enteritis and disintegrative disorder following measles/rubella vaccination”,
(amended) Found proved. The Panel is satisfied this reflects the wording in the application.
- c. Describing a ~~study~~-project which entailed a programme of investigations, including invasive gastrointestinal and neurological tests, to be carried out on children who had,
(amended) Found proved
 - i. been vaccinated with the measles or measles/rubella vaccine, and
Found proved
 - ii. *manifested* disintegrative disorder, and
(amended) Found proved
 - iii. symptoms and signs of intestinal disease or dysfunction namely pain, bloating, alternating constipation and diarrhoea, steatorrhoea and failure to thrive,
Found proved
In reaching its decision in relation to the entirety of 2c the Panel is satisfied on the basis of the wording in the application document.

- d. Indicating that all the procedures you proposed to undertake were part of normal patient care and clinically indicated,
Admitted and found proved
- e. Attaching an explanation of the proposed scientific and clinical study, a timetable of investigations, a handout of information for parents and a sample consent form;
Admitted and found proved
- ‘3. a. The application referred to at paragraph 2. above was allocated reference 172-96 (“Project 172-96”),
Admitted and found proved
- b. The Chairman of the Ethics Committee, on behalf of the Committee, raised with you and ~~Dr Wakefield~~ reservations about ~~concerns as to~~ the intensive regime that children who took part in the study would have to undergo,
(amended) Found proved
The Panel was satisfied that the letter dated 15 October 1996 raising reservations was sent to you and forwarded by you to Dr Wakefield and Professor Murch for comment.
- c. In a letter dated 11 November 1996 you informed the Chairman of the Ethics Committee that the children would have the investigations even if there were no trial and five had already been investigated on a clinical need basis,
Admitted and found proved
- d. On the basis of the information provided in the application documentation and in your letter of 11 November 1996, the Ethics Committee granted ethical approval for Project 172-96 on 18 December 1996 subject to conditions, as set out in a letter dated 7 January 1997, including,
Admitted and found proved
- i. only patients enrolled after 18 December 1996 would be considered to be in the trial,
Admitted and found proved
- ii. the Ethics Committee was to be informed of and approve any proposed amendments to your initial application which had a bearing on the treatment or investigation of patients or volunteers,
Admitted and found proved
- iii. a copy of the consent form and the information sheet was to be lodged in the clinical notes of each patient,
Admitted and found proved
- e. In a letter dated 9 January 1997 you confirmed your acceptance of these conditions,
Admitted and found proved

f. Between 16 September 1996 and 15 July 1998 no further applications were made to the Ethics Committee for approval in connection with Project 172-96 nor was the Committee informed of any amendments to your initial application, save as a set out in Dr Wakefield's letter to the Chairman of the Ethics Committee dated 3 February 1997.

Admitted and found proved

g. As a named Responsible Consultant you had a duty to ensure that,

i. the information in support of your application to the Ethics Committee was true and accurate,

Found proved

ii. only children who met the stated inclusion criteria for the ~~research study~~ Project 172-96 were admitted to the study,

(amended) Found proved

iii. you complied with the conditions attached by the Ethics Committee to any approval given,

Admitted and found proved

iv. the children whom you admitted under the protocol were treated in accordance with the terms of the approval given by the Ethics Committee;

Admitted and found proved

Notwithstanding that yours was a shared rather than a sole responsibility and you could not be held responsible for factors outside your knowledge and control, the Panel is satisfied that this was within the parameters of duties of a named responsible consultant.

Child 2

'4. a. On 29 June 1995 Child 2 was referred to you, whilst you were at St Bartholomew's Hospital, by Dr Wozencroft, a Consultant in Child Psychiatry, who stated that Child 2's condition fell within the diagnostic category of Autistic Spectrum Disorder,

Admitted and found proved

b. Prior to his referral to you Child 2 had a history of gastrointestinal symptoms,

Admitted and found proved

c. On 1 August 1995 Child 2 attended an outpatient consultation with you at St Bartholomew's Hospital following which you concluded that there was no evidence of Crohn's disease or chronic inflammatory bowel disease,

Admitted and found proved

d. On 13 September 1995 you wrote to Child 2's General Practitioner, Dr Cartmel, stating that inflammatory bowel disease was extremely unlikely and you had not arranged to see Child 2 again,
Admitted and found proved

e. On 16 May 1996 you wrote to Child 2's mother asking to see Child 2 again and stating that you and Dr Wakefield had a plan for investigations,
Found proved

The Panel was satisfied on the basis of the letter dated 16 May 1996 to Child 2's mother, that you had discussed with Dr Wakefield a plan for investigations and had arranged an outpatient's appointment for the child.

f. On 21 June 1996 Child 2 attended an outpatient consultation with you at the Royal Free Hospital and you,
Admitted and found proved

i. noted that he was on an exclusion diet and developed diarrhoea when he had certain foods,

Admitted and found proved

ii. arranged for him to undergo blood tests which subsequently demonstrated that the indices of inflammation were normal,

Admitted and found proved

g. On 24 June 1996 you wrote to Dr Wakefield stating that Child 2 was the most appropriate child to begin your programme,
Admitted and found proved

h. On 28 June 1996 you wrote to Dr Cartmel stating that,

i. Crohn's disease was unlikely but Dr Wakefield's view was that there might be some kind of other inflammation of relevance to Child 2's illness,

Admitted and found proved

ii. you and Dr Wakefield now had a programme for investigating children who had an association with autism and a possible reaction to immunisation,

Admitted and found proved

iii. you were arranging for Child 2 to be admitted for investigation,

Admitted and found proved

i. On 3 July 1996 Dr Hunter, a Consultant Physician in the Department of Gastroenterology at Addenbrooke's Hospital, wrote to you stating that Child 2 was being treated with probiotics and an

exclusion diet and that Child 2's mother had reported that his guts were greatly improved with this treatment,
Admitted and found proved

j. Child 2 was admitted to hospital on or about 1 September 1996 under your clinical care,

Admitted and found proved

The Panel was satisfied that, notwithstanding your partial absence during the admission dates, as documented in Royal Free Hospital notes, this child was admitted under your care.

k. Child 2's admission clerking note recorded that he had,

i. been admitted for investigation of the possible association between gastrointestinal disease/autism/measles,
Admitted and found proved

ii. a history of intermittent diarrhoea and abdominal pain since 20 months,
Admitted and found proved

iii. been started on an exclusion diet in April 1996, which seemed to have improved his abdominal pain,
Admitted and found proved

l. Between 1 September 1996 and his discharge on or about 9 September 1996 Child 2 underwent a colonoscopy, a barium meal and follow-through, an MRI scan of his brain, a lumbar puncture, a Schilling test, an EEG and other neurophysiological investigations, and a variety of blood and urine tests,
Admitted and found proved

m. Save that Child 2's haemoglobin was slightly low, the blood tests demonstrated that the inflammatory indices in the blood were normal,
Found proved
Given that the normal range is 11.5, the Panel was satisfied that the haemoglobin was slightly low.

n. Dr Berelowitz, Consultant Paediatric Psychiatrist, and Dr Harvey, a Consultant Neurologist, assessed Child 2 after he had undergone the lumbar puncture referred to at 4.l. above;
Admitted and found proved

'5. a. You subjected Child 2 to a programme of investigations for research purposes without having Ethics Committee approval for such research,
Found proved
The Panel was satisfied that you admitted the child under your care after discussion with Dr Wakefield, and re-assessing the

child on 21 June 1996. You also sent the child's mother a copy of the protocol for investigations and arranged the investigations. You wrote to Child 2's GP on 28 June 1996, stating "I think Crohn's disease is unlikely. Dr Wakefield has the view that there may be some kind of other inflammation which may be a relevant factor in Child 2's illness and we now have a programme for investigating children who have autism and a possible reaction to immunisation." The Panel has concluded, on the basis of the medical records, that the programme of investigations that Child 2 underwent was for research purposes for which there was no ethical approval.

b. The programme of investigations carried out on Child 2 was part of the ~~research study~~ project referred to at paragraphs 2.b. and 2.c. above,

(amended) Found proved

The Panel found that the programme of investigations carried out on Child 2, and the reasons for the investigations, follow closely the project protocol referred to at paragraphs 2b and 2c. In coming to that view, the Panel had regard to the letter signed by you on 28 June 1996 to Dr Wakefield [Child 2 RFHR 161], where you state that Child 2 is "the most appropriate child to begin our programme." The medical records further indicate that at least four paired biopsies were taken at colonoscopy, which the Panel concludes was in accordance with the investigations described in the project.

c. Child 2 was investigated under the project ~~The research study was carried out on Child 2~~ without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(amended) Found proved

The Panel is satisfied that there was no relevant Ethics committee approval at the time when these investigations were carried out.

i. contrary to the conditions of approval for Project 172-96 Child 2 had been enrolled into the ~~research study~~ project before 18 December 1996,

(amended) Found proved

Child 2 was admitted for investigations in September 1996.

ii. he did not qualify for the ~~research study~~ project as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,

(amended) Found proved

Child 2 had been vaccinated with MMR.

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 2's clinical notes,

Found not proved

The Panel accepts that at the time of Child 2's admission in September 1996, you could not have known about the conditions of ethical approval, which were set out in a letter dated 7 January 1997 to you from the Ethics Committee, acknowledged by you on 9 January 1997.

e. You caused Child 2 to undergo a,

i. colonoscopy,

Found proved

ii. barium meal and follow-through,

Found proved

which was not clinically indicated,

Found proved

The Panel accepted your own evidence that the child's condition was improving at this stage and therefore these investigations were not clinically indicated.

f. Your actions as set out at paragraph 5.e. were contrary to your representations to the Ethics Committee that the investigations were clinically indicated,

Found proved

g. By reason of the matters referred to at paragraphs 5.c., ~~5.d.~~, 5.e. and 5.f. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,

(amended) Found proved

h. You caused Child 2 to undergo a lumbar puncture without ensuring that he was first assessed by a clinician with the requisite neurological or psychiatric expertise to determine whether such an investigation was clinically indicated,

Found not proved

The Panel considered that you, as the senior paediatrician, did not need Child 2 to be assessed by another clinician and that you could make the decision for the lumbar puncture to be undertaken.

i. Your conduct as set out above was contrary to the clinical interests of Child 2;

Found proved.

Child 1

'6. a. On 17 May 1996 Child 1's General Practitioner, Dr Barrow, wrote to you referring Child 1 and indicating that he had been

diagnosed as autistic and his parents' concern was that his MMR vaccination might be responsible for his autism,
Admitted and found proved

b. Dr Barrow's referral letter made no reference to any gastrointestinal symptoms,
Admitted and found proved

c. Prior to his referral to you Child 1's developmental delay had been noted, he had been seen by Dr Hauck, Consultant Psychiatrist, ~~but had no~~ *and previously* a formal diagnosis for his condition *had been reached*,

(amended) Admitted and found proved

d. On 19 June 1996 you saw Child 1 in your outpatients clinic and noted he had undigested food in his stools, with blood occasionally in his stools,

Admitted and found proved

e. On 21 June 1996 you wrote to Dr Barrow indicating that,

i. you had arranged for routine blood tests to measure for C-reactive protein, etc as part of your and Mr Wakefield's interest in the relationship between immunisation and chronic inflammatory bowel disease,
Admitted and found proved

ii. the diarrhoea that Child 1 had, had features of Toddlers diarrhoea,
Admitted and found proved

iii. you would see Child 1 in three months' time,
Admitted and found proved

iv. if Child 1's mother then felt *that it was* appropriate you ~~would~~ could consider *performing* endoscopy and further assessments *neurologically and psychologically* of his autism to explore the *possible link with between* measles immunisation, *bowel inflammation and autism*

(amended) Admitted and found proved

f. On or about 25 June 1996 Child 1's blood test results showed normal inflammatory indices,

Admitted and found proved

g. On 21 July 1996 Child 1 was admitted to hospital under your clinical care,

Admitted and found proved to the word 'hospital'

The Panel was satisfied that, notwithstanding your absence at the time, as documented in Royal Free Hospital notes, this child was admitted under your care.

- h. Child 1's admission clerking note recorded that he,
- i. had been referred for work-up of the possible relationship between autism/measles/IBD,
Admitted and found proved
 - ii. had a history of watery diarrhoea, without blood or mucous, and undigested food,
Admitted and found proved
 - iii. now had no bowel control, no blood, possibly occasional mucous; the stools were not offensive but occasionally pale,
Admitted and found proved
- i. On 22 July 1996 an attempt was made at colonoscopy which failed due to gross faecal loading,
Admitted and found proved
- j. Child 1 underwent a clearance of his bowel and a colonoscopy was carried out on 25 July 1996. The caecum was reached although accumulated faecal material made it impossible to go further; no abnormality was noted *on macroscopic observation*,
(amended) Admitted and found proved
- k. Between 21 July 1996 and his discharge on 26 July 1996 Child 1 also underwent an MRI scan of his brain, an EEG and a variety of blood and urine tests,
Admitted and found proved
- l. The blood tests referred to at 6.k. demonstrated normal inflammatory indices,
Admitted and found proved
- m. On 23 October 1996 Child 1 was re-admitted as an inpatient under your clinical care,
Admitted and found proved to the word 'in-patient'
The Panel was satisfied that, as documented in Royal Free Hospital notes, this child was admitted under your care.
- n. Between 23 October 1996 and his discharge on 25 October 1996, Child 1 underwent an abdominal x-ray, a barium meal and follow-through, a limited neurological assessment by Dr Harvey and a lumbar puncture,
Admitted and found proved
- o. Of the tests set out in 6.n. above,
- i. the abdominal x-ray showed faecal loading throughout,
Admitted and found proved
 - ii. barium meal and follow-through was normal;
Admitted and found proved

7. a. You subjected Child 1 to a programme of investigations for research purposes without having Ethics Committee approval for such research,

Found proved

The Panel was satisfied that you saw this patient, that you expedited his admission and that there was no Ethics Committee approval for these investigations in July or October 1996.

Child 1 underwent a colonoscopy, MRI scan of his brain, an EEG and a variety of blood and urine tests. These were some of the investigations listed in the programme of the project. He was again admitted in October 1996 for further investigations regarding the “etiology of the autism”, again for no obvious clinical gastro-intestinal reasons. During this admission Child 1 underwent a barium meal and follow-through and a lumbar puncture which were also investigations listed in the project. The Panel concluded that Child 1 underwent these for research purposes for which there was no Ethics Committee approval.

- b. The programme of investigations carried out on Child 1 was part of the ~~research study~~ project referred to at paragraphs 2.b. and 2.c. above,

Found proved.

The Panel had regard to the letter dated 21 June 1996 from you to Child 1’s GP which states “As part of Dr Wakefield’s and mine interest in the relationship between immunisation and chronic inflammatory bowel disease, I have arranged for routine blood tests to be done for screening for C-reactive protein, etc.” The panel also took into account the discharge summary dated 9 August 1996 that states “child 1 was admitted for further investigations into his autism and specifically to look into a possible association between his neurological condition and any gastro-intestinal disorders.” On the basis of the investigations carried out, the Panel has concluded these were part of the project.

- c. ~~The research study was carried out on~~ Child 1 *was investigated under the project* without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(amended) Found proved

- i. contrary to the conditions of approval for Project 172-96 Child 1 had been enrolled into the project ~~research study~~ before 18 December 1996,

(amended) Found proved on the basis that the investigations on Child 1 were carried out in July and October 1996.

ii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,

(amended) Found proved on the basis that the medical records show that Child 1 had been vaccinated with MMR.

iii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.ii.above,

(amended) Found proved on the basis that Child 1 was admitted with an established diagnosis of autism.

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 1's clinical notes,

Found not proved.

The Panel accepts that at the time of Child 1's admissions to the Royal Free hospital in July and October 1996, you could not have known about the conditions for ethical approval, which were subsequently set out in a letter to you dated 7 January 1997 from the Ethics Committee, acknowledged by you on 9 January 1997 and copied to Dr Wakefield on the same date.

e. You caused Child 1 to undergo an attempt at colonoscopy when such an investigation was not clinically indicated,

Found proved

The Panel was satisfied that you considered that the child had the features of toddler's diarrhoea and therefore a colonoscopy would not be clinically indicated.

f. You caused Child 1 to undergo a colonoscopy and a barium meal and follow-through although,

Found proved

i. the first attempt at colonoscopy suggested that his loose stools were more consistent with overflow secondary to constipation than with diarrhoea,

Found not proved. The Panel concluded that you were not present and would not have known the results of the first attempt.

ii. such investigations were not clinically indicated,

Found proved, for the reasons set out above.

g. Your actions as set out at paragraphs 7.e. and 7.f ii. were contrary to your representations to the Ethics Committee that the investigations were clinically indicated,

(amended) Found proved. The Panel was satisfied that the representations to the Ethics Committee included Child 1 and that the investigations were not clinically indicated.

h. By reason of the matters referred to at paragraphs 7.c., ~~7.d.~~, 7.e., 7.fii. and 7.g. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,

(amended) Found proved, for the reasons set out above.

i. Your reliance on the views of Child 1's mother in making the decision to undertake a colonoscopy was inappropriate,

Found proved.

The Panel was satisfied on the basis of your letter to his GP dated 21 June 1996, where you stated "...if (child 1's mother) feels that is appropriate we could consider performing endoscopy and further assessments..." The Panel concluded that your reliance on her views that there was a link between autism and immunisation and bowel inflammation was inappropriate.

j. Your conduct as set out above was contrary to the clinical interests of Child 1;

Found proved.

Child 3

'8. a. On 19 February 1996 Child 3's General Practitioner, Dr Shantha, referred Child 3 to you indicating that Child 3 had behavioural problems of an autistic nature, severe constipation and learning difficulties all associated by his parents with his MMR vaccination,

Admitted and found proved

b. On 3 April 1996 you,

i. saw Child 3 in your outpatients clinic,

Admitted and found proved

ii. noted that Child 3 had developed constipation from the age of about 6 months,

Admitted and found proved

iii. screened Child 3 with routine blood tests,

Admitted and found proved

iv. planned to consider in due course whether it was appropriate to perform a colonoscopy,

Admitted and found proved

c. On receiving the results of Child 3's blood tests you concluded that he had no evidence of bowel inflammation but on the basis of

Dr Wakefield's opinion that subtle changes in inflammation may be present you arranged for Child 3's admission to hospital for intensive investigation,

Found proved

The Panel is persuaded by the letters written by you at the time, to Child 3's paediatric neurologist, his school doctor and his GP, that you did conclude there was no evidence of bowel inflammation on routine blood results but nevertheless you decided to admit Child 3. In particular, the Panel noted the wording of the letter dated 18 July 1996 to the paediatric neurologist: "...the initial blood screens for bowel inflammation were negative, however Dr Wakefield is of the opinion that subtle changes in relation to inflammation may be present...and we have arranged (Child 3's) admission".

d. Child 3 was admitted to hospital on or about 8 September 1996 under your clinical care with the plan he should undergo colonoscopy and any further investigations decided on following consultation with Dr Wakefield,

Admitted and found proved to 'colonoscopy'

The Panel noted the admission details from the Royal Free hospital documentation including the patient episode summary. Found not proved from the words "and any" to "Dr Wakefield". The Panel considered that although there was correspondence suggestive that Dr Wakefield would be consulted such as the letter by Dr Casson dated 28 August 1996, there is no conclusive evidence to suggest this was seen by you.

e. Between 8 September 1996 and his discharge on 13 September 1996, Child 3 underwent a colonoscopy, barium meal and follow-through, an MRI scan of his brain, a lumbar puncture, an EEG and a variety of blood and urine tests,

Admitted and found proved

f. Of the tests set out in 8.e. above, the results from the lumbar puncture were normal and the blood tests demonstrated normal inflammatory indices;

Admitted and found proved

'9. a. You subjected Child 3 to a programme of investigations for research purposes without having Ethics Committee approval for such research,

Found proved

In reaching its decision that you subjected this child to the programme of investigations, the Panel is persuaded by Child 3's Royal Free Hospital records, in particular the letter dated 4 April 1996 from you to Dr Wakefield in which you state that you have not yet booked Child 3 for a colonoscopy as you are waiting for the "full details of the investigative protocol" to be worked out. It

also noted your letter dated 18 July 1996 to Dr Wakefield which states, “we are arranging for (Child 3’s) admission for colonoscopy on Sunday 8 September, followed by your intensive investigations.” The Panel concluded on this basis that the programme of investigations that Child 3 underwent was for research purposes and that there was no Ethics Committee approval for such research.

b. The programme of investigations carried out on Child 3 was part of the project ~~research study~~ referred to at paragraphs 2.b. and 2.c. above,

(amended) Found proved

The Panel is satisfied that the programme of investigations carried out on Child 3, and the reasons recorded in the clinical notes for those investigations, follow closely the project protocol referred to at paragraph 2.b and 2.c. In addition, the Panel took into account the letter dated 16 May 1996 from you to the paediatric neurologist which states, “I am actually passing on [your] letter to my colleague, Dr Andy Wakefield, who is the inspiration of our work linking MMR, autistic behaviour and Crohns Disease and I am asking him to write to you to fill you in on our proposed study...”.

c. ~~The research study was carried out on Child 3~~ *was investigated under the project* without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(amended) Found proved

The Panel is satisfied that there was no relevant Ethics Committee approval at the time when these investigations were carried out.

i. contrary to the conditions of approval for Project 172-96 Child 3 had been enrolled into the project ~~research study~~ before 18 December 1996,

(amended) Found proved

Child 3 was admitted for investigation at the Royal Free Hospital on 8 September 1996.

ii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,

(amended) Found proved

Child 3 had been vaccinated with MMR.

iii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above,

(amended) Found proved

The Panel has taken into account that Child 3 had a diagnosis of autism spectrum disorder.

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 3's clinical notes,

Found not proved.

The Panel accepts that at the time of Child 3's admission to the Royal Free Hospital in September 1996, you could not have known of the conditions of ethical approval which were set out in a letter dated 7 January 1997.

e. You caused Child 3 to undergo a,

i. colonoscopy,

Found proved. The Panel notes the handwritten note on the letter of 18 July 1996 where Dr Casson records he has discussed the undertaking of a colonoscopy with you and Dr Murch.

ii. barium meal and follow-through,

Found proved.

The letter dated 18 July 1996 from you to Dr Wakefield where you state Child 3 will undergo colonoscopy "followed by your intensive investigations", together with the clinical notes of this Child persuaded the Panel that he had undergone the barium meal and follow-through and because he was under your clinical care, you had caused it. which was not clinically indicated,

Found proved

Experts on both sides, Professor Booth and Dr Miller, agreed that a colonoscopy (and therefore the barium meal and follow through) would not be clinically indicated at this stage.

f. You caused Child 3 to undergo a lumbar puncture,

Found proved.

The Panel is satisfied that the clinical notes including the discharge summary show that this procedure was undertaken and that you caused it to be done.

i. without ensuring that he was first assessed by a clinician with the requisite neurological or psychiatric expertise to determine whether such an investigation was clinically indicated,

Found not proved.

The Panel considered that you, as the senior paediatrician, did not need Child 3 to be assessed by another clinician and that you could make the decision for the lumbar puncture to be undertaken.

ii. which was not clinically indicated,

Found proved

The Panel has taken into account that there is no evidence in Child 3's clinical notes to indicate that a lumbar puncture was required. Professor Rutter and Dr Thomas, experts on

both sides, considered that such a test was not clinically indicated.

g. Your actions as set out at paragraphs 9.e. and 9.fii. were contrary to your representations to the Ethics Committee that the investigations were clinically indicated,
(amended) Found proved.

h. By reason of the matters referred to at paragraphs 9.c., ~~9.d.~~, 9.e., 9.fii. and 9.g. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,
(amended) Found proved, for the reasons set out above.

i. Your conduct as set out above was contrary to the clinical interests of Child 3;
Found proved. The Panel had regard to its findings above.

Child 4

'10. a. On 1 July 1996 Child 4's General Practitioner, Dr Tapsfield, wrote to Dr Wakefield referring Child 4 regarding his possible autism and his bowel problems,
Admitted and found proved

b. On 4 July 1996 Dr Wakefield passed on the referral of Child 4 whom he said "*sounds like a good candidate for our forthcoming study*",
Admitted and found proved

c. Prior to his referral to you Child 4,

i. was developmentally delayed with prominent autistic tendencies as diagnosed by Dr O'Brien Consultant Psychiatrist in 1992,
Admitted and found proved

ii. had a history of diarrhoea and 2 episodes of gastrointestinal infections with giardia in 1993 and shigella in 1994,
Admitted and found proved

d. On 28 August 1996 your registrar (clinical lecturer) Dr Casson wrote to Child 4's parents stating that Child 4 was to be admitted to hospital for colonoscopy and any further investigations would be decided following consultation with Dr Wakefield,
Amended to read: 'On 28 August 1996 Dr Casson, Honorary Senior Registrar and Lecturer in the Department of Gastroenterology, wrote to Child 4's parents stating that Child 4 was to be admitted to hospital for

colonoscopy and any further investigations would be decided following consultation with Dr Wakefield,

Admitted as amended and found proved

e. On 29 September 1996 Child 4 was admitted to hospital under your clinical care,

Admitted and found proved to the word 'hospital'

The Panel is satisfied that, as documented in the patient episode summary in the Royal Free Hospital notes, the child was admitted under your care.

f. Child 4's admission clerking note,

i. stated that he had been "*admitted for study of disintegrative disorder/colitis/MMR*",

Admitted and found proved

ii. indicated with respect to his diarrhoea, that he was presently well most of the time, that if he got exacerbation it seemed to be related to new foods, that his bowels opened once or twice a day, normal, no straining, abdominal pain resolved,

Admitted and found proved

g. Between 29 September 1996 and his discharge on 4 October 1996 Child 4 underwent a colonoscopy, an attempt at barium meal and follow-through, an MRI scan of his brain, an EEG, other clinical neurophysiological investigations, and a variety of blood and urine tests,

Admitted and found proved

h. Of the tests set out in 10.g. above,

i. colonoscopy revealed mild granularity of the rectum, *with slight disturbance of vascular pattern ("neovascularisation")*, a normal colon but the ileum showed marked lymphoid nodular hyperplasia,

(amended) Admitted and found proved

ii. the histology on the bowel mucosa was noted in the clinical records on 4 October 1996 to have been assessed at the weekly clinical histology meeting as showing dense lymphoid pattern ~~of the ileum~~, no acute inflammation *and* normal architecture *in the ileum, prominent lymphoid follicles and* no active inflammation *in the colon, and* no granulomas,

(amended) Admitted and found proved

iii. barium meal and follow-through could not be performed,

Admitted and found proved

iv. blood tests including inflammatory indices were normal,

Admitted and found proved

i. On 16 October 1996 your registrar Dr Casson sent a discharge summary setting out the histological findings as in 10.h.ii. above,
Amended to read: On 16 October 1996 Dr Casson, Honorary Senior Registrar and Lecturer in the Department of Gastroenterology, sent a discharge summary setting out the histological findings as in 10.h.ii. above,

Admitted as amended and found proved

j. On 20 March 1997 you wrote to Dr Tapsfield stating that in the light of the histological finding of colitis Child 4 should undergo a therapeutic trial of mesalazine or salazopyrin which should be discontinued if there was no effect on gastrointestinal symptoms or behaviour in a month;

Admitted and found proved

'11. a. You subjected Child 4 to a programme of investigations for research purposes without having Ethics Committee approval for such research,

Found not proved

The Panel has noted Dr Wakefield's letter to you dated 4 July 1996, stating, "Child 4 sounds like a good candidate for our forthcoming study" and the hospital admission clerking note which states, "...admitted for study of disintegrative disorder/colitis/MMR". Child 4 was admitted for research purposes for which there was no Ethics Committee approval at that time. However, the Panel accepted your evidence that you did not see this patient until 3 October 1996 on a ward round and so there is insufficient evidence that you had selected this child or subjected him to the investigations.

b. The programme of investigations carried out on Child 4 was part of the project ~~research study~~ referred to at paragraphs 2.b. and 2.c. above,

(amended) Found proved

The Panel found this as a matter of fact notwithstanding that you did not subject the child to the investigations.

c. ~~The research study was carried out on~~ *Child 4 was investigated under the project* without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(amended) Found proved. The Panel is satisfied there was no relevant Ethics Committee approval at the time when these investigations were carried out.

i. contrary to the conditions of approval for Project 172-96 Child 4 had been enrolled into the project ~~research study~~ before 18 December 1996,

(amended) Found proved as Child 4 was admitted in September 1996.

ii. he did not qualify for the project ~~the research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above,

(amended) Found proved because the child was not diagnosed with disintegrative disorder.

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 4's clinical notes,

Found not proved. The Panel has accepted you were not responsible for the admission of the child on 29 September 1996 and in any event could not have known of the conditions set out by the Ethics Committee in its letter to you of 7 January 1997.

e. You caused Child 4 to undergo a colonoscopy which was not clinically indicated,

Found not proved

The Panel concluded that you did not see the child before your ward round of 3 October 1996 and therefore could not be held responsible for the child undergoing this procedure.

f. Your actions as set out at paragraph 11.e. were contrary to your representations to the Ethics Committee that the investigations were clinically indicated,

Found not proved

g. By reason of the matters referred to at paragraphs 11.c., 11.d., 11.e. and 11.f. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,

Found proved in relation to 11c. The Panel concluded that as a Responsible Consultant you had a duty to ensure adequate research governance. Whilst the Panel accepts that you could not be held responsible for factors outwith your knowledge, nevertheless you had joint responsibility for overseeing the overall process governing the project.

h. You did not assess Child 4's symptoms or cause them to be assessed by a senior member of the paediatric gastroenterology team prior to admitting him to hospital,

Found not proved to the requisite standard.

i. You failed to carry out markers of inflammation on Child 4 to assess the need for colonoscopy,

Found not proved (the child's colonoscopy was on 30 September and you did not see him until 3 October).

j. You diagnosed Child 4 as suffering from colitis, and consequently prescribed treatment, without recording any explanation in his medical records for the basis of such a diagnosis given that it was contrary to the histology meeting assessment on 4 October 1996,
Found proved.

The Panel accepted your own evidence that you should have “made the provenance of that clearer as to why that was” - Day 78p29)

k. Your conduct as set out above was contrary to the clinical interests of Child 4;

Found not proved

Child 6

‘12. a. On 9 August 1996 Child 6’s General Practitioner, Dr Nalletamby, wrote to Dr Wakefield stating that Child 6 had autism syndrome, and also bowel disorder, and that Child 6’s mother was interested in entering him into Dr Wakefield’s trial,

Admitted and found proved

b. On 11 September 1996 you wrote to Dr Nalletamby stating that you had been asked by Dr Wakefield to see Child 6 as you were the Paediatric Gastroenterologist associated with Dr Wakefield in your study on autism and bowel disorder,

Admitted and found proved

c. On 2 October 1996 Child 6 attended an outpatient consultation with you following which you wrote to Dr Nalletamby advising that Child 6 was to come in for a colonoscopy and to enter your programme of investigation of children with autistic problems,

Admitted and found proved

d. Child 6 was admitted to hospital on or about 27 October 1996 under your clinical care,

Admitted and found proved to “October 1996”

Found proved on the basis of the patient episode summary contained within the Royal Free Hospital notes.

e. Between his admission and his discharge on or about 1 November 1996 Child 6 underwent a colonoscopy, an MRI scan of his brain, a lumbar puncture, an EEG and other neurophysiological investigations;

Admitted and found proved

f. On or about 1 November 1996 Child 6 was seen by Dr Berelowitz who concluded that the most likely diagnosis was Asperger’s Syndrome.

Admitted and found proved

- ‘13. a. You subjected Child 6 to a programme of investigations for research purposes without having Ethics Committee approval for such research,
Found proved. In reaching its decision that you subjected Child 6 to a programme of investigations, the Panel is satisfied by the evidence of the medical records, in particular the letter from you to the child’s GP dated 4 October 1996 wherein you state, “I am arranging for him to come in to have a colonoscopy and entering our programme of investigation of children with autistic problems.” The Panel has concluded that the programme of investigations that this child underwent was for research purposes for which there was no ethical approval.
- b. The programme of investigations carried out on Child 6 was part of the project ~~research study~~ referred to at paragraphs 2.b. and 2.c. above,
(amended) Found proved. The Panel found that the programme of investigations carried out on Child 6 and the reasons as set out in the correspondence for those investigations, follow closely the project protocol referred to at paragraphs 2.b and 2.c.
- c. ~~The research study was carried out on~~ Child 6 was investigated under the project without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,
(amended) Found proved. The Panel is satisfied there was no relevant Ethics Committee approval at the time when these investigations were carried out.
- i. contrary to the conditions of approval for Project 172-96 Child 6 had been enrolled into the project ~~research study~~ before 18 December 1996,
(amended) Found proved. The Panel notes this child was admitted on or about 27 October 1996.
- ii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,
(amended) Found proved. This child was vaccinated with MMR.
- iii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out in paragraph 2(c) (ii) above, **Found proved. This child had a diagnosis of Aspergers’ Syndrome.**
- d. By reason of the matters referred to at paragraph 13.c. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,
Found proved.

e. Your conduct as set out above was contrary to the clinical interests of Child 6;

Found not proved. The Panel found that, despite this child being subject to a programme of investigations rather than specific ones tailored to his needs, there was insufficient evidence to make a finding that the investigations were contrary to his clinical interests.

Child 9

'14. a. On 11 September 1996 you wrote to Dr Spratt Consultant Paediatrician at the General Hospital, St Helier, Jersey enclosing a copy of a document entitled "Proposed Clinical and Scientific Study" ~~the research protocol and,~~

(amended) Found proved

i. indicating that you had heard from Dr Wakefield about Child 9 whose parents were keen for him to be investigated,

Admitted and found proved

ii. asking Dr Spratt whether he thought it was appropriate to investigate Child 9 in the protocol,

Admitted and found proved

b. On 25 September 1996 Dr Spratt wrote to you indicating he would be pleased to take your advice about the proposed referral to Dr Wakefield's service,

Admitted and found proved

c. Dr Spratt's letter made no reference to Child 9 suffering from gastrointestinal symptoms,

Admitted and found proved

d. Prior to his referral to you,

i. Child 9's developmental delay had been provisionally attributed to a form of autism in 1994 ~~1995~~ by Southampton University General Hospital autism service but this provisional diagnosis was not accepted by his parents nor subsequently confirmed,

(amended) Admitted, but found proved on the basis that the developmental delay had been attributed to a form of autism in 1994 by Southampton General Hospital autism service but this diagnosis was not accepted by his parents. The Panel noted the assessment form dated 13 April (1995) which stated, "...9 is showing a number of autistic features...our observations indicated he was autistic...."

The Panel concluded the date of 1995 on the report was inaccurate and that 1994 was the date of his second assessment, based on the sequence of events documented.

The Panel received legal advice from the Legal Assessor on how to approach this head of charge which was emailed to the parties on 25 November 2009, who responded with written submissions, accepting his advice.

ii. there are no notes relating to any significant gastrointestinal symptoms in Child 9's medical records,

Found not proved

e. On 8 November 1996,

i. you saw Child 9 in outpatients clinic and noted that he passed one loose stool a day which seemed to be a pattern since the age of two and that he had screaming attacks, which you queried were attributable to abdominal pain,

Admitted and found proved

ii. you wrote to Dr Spratt that you had seen several children with autism and gastrointestinal symptoms, that all on investigation proved to have bowel inflammation, that the parents were keen for investigation and that you were arranging for Child 9 to be admitted for colonoscopy, barium meal and follow-through and repeat lumbar puncture,

Admitted and found proved

f. Child 9 was admitted to hospital on 17 November 1996 under your clinical care,

Admitted and found proved

The Panel concluded, on the basis of the clinical notes of the Royal Free Hospital that this child was admitted under your clinical care.

g. Between 17 November 1996 and his discharge on 22 November 1996, Child 9 underwent a colonoscopy, a barium meal and follow-through, and blood and urine tests. His parents refused to allow him to have a lumbar puncture which he was judged most unlikely to tolerate without sedation,

Found proved to the words "urine tests". Found not proved in respect of the rest of the allegation because the Panel could not be satisfied to the requisite standard.

h. On 9 December 1996 Child 9 was readmitted and underwent an MRI scan of his brain, an EEG and a lumbar puncture, all of which were undertaken under general anaesthetic,

Admitted and found proved

i. Of the tests set out in 14.g. and 14.h. above,

i. endoscopy revealed no abnormality up to the terminal ileum except for a small area at the hepatic flexure which was

slightly erythematous. There was a marked increase in the size and number of lymphoid nodules,

Admitted and found proved

ii. the histology report on the bowel mucosa indicated prominent lymphoid follicles but no histological abnormality,

Admitted and found proved

iii. the barium meal was reported as normal in the clinical records,

Admitted and found proved

iv. a full blood count including inflammatory indices was normal,

Admitted and found proved

v. the results from the lumbar puncture were normal,

Admitted and found proved

j. You wrote to Dr Spratt on 31 December 1996 stating that,

i. histologically there was an increase in chronic inflammatory cells throughout the colon with a moderate increase in intra-epithelial lymphocytes,

Admitted and found proved

ii. the diagnosis for Child 9 was indeterminate colitis with lymphoid nodular hyperplasia,

Admitted and found proved

iii. a therapeutic trial of mesalazine might be worthwhile,

Admitted and found proved

iv. you wondered if he had *seen* any other similar cases in

Jersey,

(amended) Admitted and found proved

k. Child 9 was treated with mesalazine initially and subsequently, on your advice, sulphasalazine was substituted;

Admitted and found proved

‘15. a. You subjected Child 9 to a programme of investigations for research purposes without having Ethics Committee approval for such research,

Found proved

In reaching this decision that you subjected the child to the programme of investigations, the Panel is persuaded by the evidence, in particular your letter dated 11 September 1996 to the local consultant paediatrician, Dr Spratt, in which you enclosed, “Dr Wakefield’s detailed proposal” and state that Child 9’s parents are keen “for us to investigate the child in our protocol” and that, if Dr Spratt felt it appropriate, you would be happy to see Child 9. Having seen the child in outpatients, you wrote to Dr Spratt on 8 November 1996, stating, “We have now seen several children with autism and gastrointestinal symptoms...I...have arranged for him to have a colonoscopy...we will then endeavour to follow this with

**barium meal and follow through...and repeat lumbar puncture.”
The Panel is satisfied that the programme of investigations that
Child 9 underwent was for research purposes, for which there was
no Ethics Committee approval.**

b. The programme of investigations carried out on Child 9 was part of the project ~~research study~~ referred to at paragraphs 2.b. and 2.c. above,

(amended) Found proved.

The Panel concluded that the programme of investigations carried out on Child 9, and the reasons recorded for those investigations, follow closely the project protocol referred to at paragraphs 2.b and 2.c. The Panel has also taken into account the letter dated 9 September 1996 from a research colleague, John Linnell to you, which states “..it was agreed that he should, if possible, be included in our first ten cases.” In addition the Panel has noted that Child 9, having been discharged from the Royal Free in November 1996 with normal results on the investigations to date, was re-admitted on 9 December 1996 for completion of the programme of investigations.

c. ~~The research study was carried out on~~ Child 9 was investigated under the project without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(amended) Found proved. The Panel is satisfied that there was no relevant Ethics Committee approval at the time when these investigations were carried out.

i. contrary to the conditions of approval for Project 172-96 Child 9 had been enrolled into the project ~~research study~~ before 18 December 1996,

Found proved. The child was admitted on 17 November and 9 December 1996.

ii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,

Found proved. This child had MMR vaccination.

iii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above,

Found proved on the basis that this child had a form of autism.

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 9's clinical notes,

Found not proved. The Panel accepts that at the time of Child 9's admission you could not have known about the conditions of

ethical approval which were set out in a letter to you from the Ethics Committee on 7 January 1997.

- e. You caused Child 9 to undergo a,
 - i. colonoscopy,
Found proved.
 - ii. barium meal and follow-through,
Found proved.
which was not clinically indicated,
Found proved. The Panel is persuaded by the evidence in the clinical notes and also accepted the evidence of both experts called by the GMC and Defence, who agreed they would not have undertaken these procedures and therefore they were not clinically indicated at this stage.

- f. You caused Child 9 to undergo a lumbar puncture,
Found proved on the basis of your letter dated 8 November 1996 to the local consultant paediatrician, informing him that your plan included a repeat lumbar puncture.
 - i. without ensuring that he was first assessed by a clinician with the requisite neurological or psychiatric expertise to determine whether such an investigation was clinically indicated,
Found not proved. The Panel considered that you, as the senior paediatrician, did not need to have this child assessed by another clinician and that you could make the decision for another lumbar puncture to be undertaken.
 - ii. which was not clinically indicated,
Found proved. The Panel is satisfied that there had been no evidence of recent further neurological deterioration to warrant a repeat lumbar puncture.

- g. Your actions as set out at paragraphs 15.e. and 15.f. were contrary to your representations to the Ethics Committee that the investigations were clinically indicated,
Found proved.

- h. By reason of the matters referred to at paragraphs 15.c., ~~15.d.,~~ 15.e., 15.f. and 15.g. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,
Found proved

- i. You failed to carry out markers of inflammation on Child 9 to assess the need for colonoscopy,
Found not proved. The Panel accept that the markers were not essential.

j. You failed to record any explanation in Child 9's medical records as to the discrepancy between the histological description (and consequent diagnosis and treatment) provided to Dr Spratt on 31 December 1996 and Child 9's clinical histology report,
Found proved. The Panel concluded that you had a duty to record the discrepancy and that you failed, which you accepted as highly unsatisfactory (Day 93p15). You also stated in your own evidence to the Panel (Day81p11) that you "should have recorded the provenance of these observations".

k. Your conduct as set out above was contrary to the clinical interests of Child 9;
Found proved on the basis of the above findings.

Child 5

'16. a. On 1 October 1996 Child 5's General Practitioner, Dr Shillam, wrote to you stating that Child 5's parents had been in contact with Dr Wakefield and had asked Dr Shillam to refer Child 5 to you in relation to your study into the association between autism and childhood bowel problems,

Admitted and found proved

b. Dr Shillam's referral letter gave details of Child 5's developmental delay with classical features of autism, and stated that Child 5's parents were concerned about an association between the MMR vaccine, Childhood enteritis and possible brain damage, but made no reference to any gastrointestinal symptoms,

Admitted and found proved

c. Prior to his referral to you,

i. in January 1992 Dr Williams, a Clinical Psychologist for the West Berkshire Health Authority, concluded that it was very likely that Child 5 was suffering from autism,

Admitted and found proved

ii. there are no notes relating to any significant gastrointestinal symptoms in Child 5's medical records,

Found proved. The Panel noted that although there were minor GI symptoms recorded, they were not considered to be significant.

d. On 8 November 1996 Child 5 attended an outpatient consultation with you. You elicited a history of episodes of diarrhoea once a month and episodes of abdominal pain. You did not undertake any blood tests to check Child 5's inflammatory markers,

Admitted and found proved

e. Child 5 was admitted to hospital on or about 1 December 1996 under your clinical care,

Admitted and found proved

The Panel concluded that admission was arranged by you after referral by the child's GP, and he was assessed in the outpatients clinic by you. The Panel noted the nursing care plan dated 1 December 1996 and the discharge notification dated 6 December 1996 within the Royal Free notes both name you as the consultant in charge of this child.

f. Child 5's admission clerking note indicated that he had intermittent diarrhoea and abdominal pain but there was no blood or mucus in his stool,

Admitted and found proved

g. Between 1 December 1996 and his discharge on 6 December 1996 Child 5 underwent a colonoscopy, a barium meal and follow-through, an MRI scan of his brain, a neurological assessment by Dr Harvey, a lumbar puncture (although no results were obtained), an EEG and a variety of blood and urine tests,

Admitted and found proved except "lumbar puncture (although no results were obtained)"

Found not proved in relation to the words "lumbar puncture (although no results were obtained)". The Panel was not satisfied that a lumbar puncture was undertaken at this time.

h. On 3 December 1996 Child 5 was seen by Dr Berelowitz who concluded that the likely diagnosis was a developmental disorder, such as autism, but that chromosomal studies needed to be done,

Admitted and found proved

i. The blood tests set out at 16.g. above demonstrated that the inflammatory markers in the blood were normal,

Admitted and found proved

j. On 15 January 1997 Child 5 was readmitted and underwent a repeat barium meal and follow-through under sedation, because of a previous suspected stricture, and a repeat lumbar puncture;

Admitted and found proved except the word "repeat"

Found not proved in respect of the word "repeat" relating to the lumbar puncture.

'17. a. You subjected Child 5 to a programme of investigations for research purposes without having Ethics Committee approval for such research,

Found proved. In reaching its decision that you subjected Child 5 to a programme of investigations, the Panel is persuaded by the letter dated 1 October 1996 to you, from his GP, stating "this ...child's parents have been in contact with Dr Wakefield and have

asked me to refer him to yourself regarding your current study into association between autism and childhood bowel problems” and your decision to admit, copied to Dr Wakefield as detailed in your response dated 12 November 1996, “...I saw him in the clinic...I am arranging for him to come in for a colonoscopy.” The Panel has concluded that the programme of investigations that Child 5 underwent was for research purposes, for which there was no Ethics Committee approval.

b. The programme of investigations carried out on Child 5 was part of the ~~project research study~~ referred to at paragraphs 2.b. and 2.c. above,

(amended) Found proved. The Panel finds that the programme of investigations carried out on Child 5, and the reasons recorded in the clinical notes for those investigations, follow closely the project protocol referred to at 2.b and 2.c.

c. ~~The research study was carried out on Child 5~~ *was investigated under the project* without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(amended) Found proved. The Panel is satisfied that there was no other relevant Ethics Committee approval at the time when these investigations were carried out.

i. contrary to the conditions of approval for Project 172-96 Child 5 had been enrolled into the *project research study* before 18 December 1996,

(amended) Found proved. Child 5 was first admitted to the Royal Free before 18 December 1996.

ii. he did not qualify for the *project research study* as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,

(amended) Found proved. Child 5 had been vaccinated with MMR.

iii. he did not qualify for the *project research study* as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above,

(amended) Found proved. Your letter to the child’s GP dated 12 November 1996 confirmed this child was referred with “autism and disturbed behaviour”.

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 5’s clinical notes,

Found proved in relation to the further investigations undertaken during this child’s second admission around 15 January, which was after the letter of the Ethics Committee setting out the conditions dated 7 January 1997.

e. You caused Child 5 to undergo a,

i. colonoscopy,

Found proved.

ii. barium meal and follow-through,

Found proved.

which was not clinically indicated,

Found proved. The Panel concluded there were no significant GI signs and symptoms to justify colonoscopy and BMFT at that time.

f. Your actions as set out at paragraph 17.e. were contrary to your representations to the Ethics Committee that the investigations were clinically indicated,

Found proved. The Panel noted your assurance to the Ethics Committee in your letter dated 11 November 1996, that “I can confirm that children would have these investigations even if there were no trial”.

g. By reason of the matters referred to at paragraphs 17.c., 17.d., 17.e. and 17.f. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,

Found proved.

h. You failed to carry out markers of inflammation on Child 5 to assess the need for colonoscopy,

Found not proved. The Panel accepts that the inflammatory markers were not essential.

i. Your conduct as set out above was contrary to the clinical interests of Child 5;

Found proved on the basis of the above findings.

Child 12

‘18. a. On 23 September 1996 Child 12’s General Practitioner, Dr Stuart, wrote a letter to you referring Child 12 and stating,

i. Child 12 had had bowel problems for sometime but he did not present to her surgery until March 1996, when his mother attended to discuss his soiling habit, and at that time his abdomen was normal with an empty rectum,

Admitted and found proved

ii. Child 12 had seen Dr Ing, a Consultant Child Psychiatrist, who had said that Child 12 may well have Asperger’s Syndrome,

Admitted and found proved

b. On 18 October 1996 Child 12 attended an outpatient consultation with you during which you elicited a history of Child 12 soiling, not having diarrhoea and having variable abdominal pain,
Admitted and found proved

c. You arranged for Child 12 to undergo a blood test on 18 October 1996 which demonstrated that the indices of inflammation were normal save for a ~~marginally~~ *slightly* raised C-reactive protein,
(amended) Admitted and found proved

d. You concluded that,

i. Child 12 had minimal gastrointestinal symptoms,
Found proved

Based on the letters you wrote dated 21 October 1996 to Dr Wakefield and the child's GP, stating that the child has "rather minimal GI symptoms" and "relatively minor GI symptoms", the Panel is satisfied that that you had concluded the child had minimal GI symptoms.

ii. you felt it was not right to proceed with the intensive programme until you had ethical committee approval and it was clear that the parents wished you to proceed,

Found proved

The Panel is satisfied that the wording of your letter dated 21 October 1996 to Dr Wakefield stating "I did not feel it right in fact to proceed with our intensive programme at the moment until we have had ethical committee approval and it is clear that the parents wish us to proceed" shows this was your conclusion at the time.

e. On 25 November 1996 you wrote to Child 12's mother stating that one of the blood tests was slightly abnormal and that as she was keen for you to proceed with investigation you thought that it would be appropriate to arrange for Child 12 to come in for a colonoscopy,
Admitted and found proved

f. Child 12 was admitted to hospital on 5 January 1997 under your clinical care,

Admitted and found proved to "5 January 1997"

Found proved. The Panel is satisfied that, as documented in the patient episode summary contained in the Royal Free Hospital notes, the child was admitted under your care.

g. Child 12's admission clerking note, dated 6 January 1997, indicated that,

i. he was being admitted for investigation of autism and bowel problems,

Admitted and found proved

ii. he had been clean by the age of three and he started soiling sometime later,

Admitted and found proved

iii. he was currently soiling eight times a day,

Admitted and found proved

iv. the stools were loose, pale and very smelly,

Admitted and found proved

v. he had abdominal pain about once a week,

Admitted and found proved

h. Between 6 January 1997 and his discharge on 10 January 1997, Child 12 underwent a colonoscopy, a barium meal and follow-through, an MRI scan of his brain, a lumbar puncture (on 9 January 1997), an EEG and other neurophysiological tests, and a variety of blood and urine tests,

Admitted and found proved

i. Of the tests set out in 18.h. above,

i. appearances at colonoscopy were described as almost normal to the caecum and minor changes in the rectum and caecum (slight changes in vascularity and prominent lymphoid follicles); the ileo-caecal valve could not be identified,

Admitted and found proved

ii. the histology report on the colonic biopsies was normal,

Found proved

The Panel is satisfied that the histology report of 17 January 1997 states “normal series”

iii. the barium meal and follow-through demonstrated lymphonodular hyperplasia of the terminal ileum,

Admitted and found proved

iv. the results from the lumbar puncture were normal,

Admitted and found proved

v. the inflammatory indices in the blood were normal,

Admitted and found proved

j. On 9 January 1997 Dr Harvey visited Child 12 on the ward but he was unable to undertake a neurological examination because Child 12 was asleep,

Admitted and found proved

k. On 10 January 1997 Child 12 was interviewed by Dr Berelowitz who concluded that Child 12 had language delay, possible Attention Deficit Disorder and possible features of Asperger’s Syndrome,

Admitted and found proved

l. On 22 January 1997 a Discharge Summary was sent by

Dr Casson to Dr Stuart stating that it was conceivable that many of Child 12's problems were associated with a degree of constipation and therefore treatment with paraffin was recommended,

Admitted and found proved

m. On 25 April 1997 you wrote to Dr Stuart stating that you had found evidence of lymphoid nodular hyperplasia and non-specific colitis in Child 12 and recommending that he be treated with anti-inflammatory therapy, namely olsalazine,

Admitted and found proved

n. On 30 May 1997 Child 12 attended the outpatient clinic where he underwent an abdominal x-ray which demonstrated marked faecal loading. He was reviewed by Dr Casson who, following discussion with you, wrote to Dr Stuart reiterating that Child 12 should be treated with olsalazine and that treatment for his constipation should be withheld;

Admitted and found proved, up to "olsalazine"

Found not proved (from the words "and that treatment.."). The panel considered that Dr Casson's words in his letter, "We should hold fire on treating his constipation" was not tantamount to withholding treatment.

'19. a. You subjected Child 12 to a programme of investigations as part of the project ~~research study~~ referred to at paragraphs 2.b. and 2.c. above,

(amended) Found proved. In reaching its decision that you subjected this child to a programme of investigations, the Panel is satisfied with the evidence contained within the letter from Mrs 12 to you of 20 October 1996, where she makes it plain she had seen the "proposed clinical and scientific study" and that she is "happy for [Child 12] to be referred on to Dr Wakefield's study project", and your response to her dated 25 November 1996, in which you state that as she is keen to proceed with investigation, you will arrange it, and "the children are usually admitted for the course of a week and various other aspects of the protocol are undertaken". The Panel also noted your letter dated 21 October 1996 to Dr Wakefield in which you state "I did not feel it right in fact to proceed with our intensive programme at the moment until we have had ethical committee approval and it is clear that the parents wish us to proceed."

b. The project ~~research study~~ was carried out on Child 12 without the approval of the Ethics Committee in that he did not qualify for the research study as he failed to meet the inclusion criteria set out at,

(amended)

i. paragraph 2.c.i. above,

Found proved. The child had been vaccinated with MMR

ii. paragraph 2.c.ii. above,

Found proved. This child was not diagnosed with disintegrative disorder.

c. Contrary to the conditions of ethical approval for Project 172-96 you failed to ensure that a copy of the consent form and information sheet was included in Child 12's clinical notes,

Found not proved. The Panel accepts that at the time of this child's admission on 5 January 1997, you could not have known about conditions of ethical approval which were set out in a letter from the Ethics Committee to you dated 7 January 1997.

d. You caused Child 12 to undergo a,

i. colonoscopy,

Found proved.

ii. barium meal and follow-through,

Found proved.

which was not clinically indicated,

Found proved. The Panel is satisfied that the slightly raised CRP, in conjunction with the overall clinical picture, did not warrant a colonoscopy or barium meal and follow through.

e. You caused Child 12 to undergo a lumbar puncture,

Found not proved. Notwithstanding that you caused Child 12 to undergo the programme of investigations, the Panel accepts that on your ward round of 6 January 1997, you stated that the child should not undergo a lumbar puncture.

i. without ensuring that he was first assessed by a clinician with the requisite neurological or psychiatric expertise to determine whether such an investigation was clinically indicated,

Found not proved

ii. which was not clinically indicated,

Found not proved

f. Your actions as set out at paragraphs 19.d. and ~~19.e.~~ were contrary to your representations to the Ethics Committee that the investigations were clinically indicated,

(amended) Found proved. The Panel noted your assurance to the Ethics Committee in your letter dated 11 November 1996, that "I can confirm that children would have these investigations even if there were no trial".

g. By reason of the matters referred to at paragraphs 19.b., ~~19.c., 19.d., 19.e.~~ and 19.f. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,

(amended) Found proved

h. You failed to record in Child 12's medical records your reasons for concluding that Child 12 had evidence of non-specific colitis, and consequently prescribing treatment, when the clinical histology report had indicated no abnormalities and no active inflammation,
Found proved. The Panel accepted your own evidence that there was a lack of provenance in the records.

i. Although Child 12 was suffering from constipation you advised that treatment with laxatives be withheld,
Found not proved for the reasons set out in 18n, above.

j. Your conduct as set out above was contrary to the clinical interests of Child 12;
Found proved on the basis of the above findings.

Child 8

'20. a. On 3 October 1996 Child 8's General Practitioner, Dr Jelley, wrote to Dr Wakefield,
Found proved. The Panel has seen the letter referred to in the Royal Free Hospital notes.

i. referring Child 8 to his investigation programme into the possible effects of vaccine damage and her ongoing GI tract symptoms,

Admitted and found proved up to "programme"
Found proved in its entirety on the basis that the wording reflects the letter.

ii. reiterating that there had been significant concerns about Child 8's development prior to her MMR vaccination but that she supported Child 8's mother's request for further information,
Found proved. The evidence is contained in the letter.

b. On 9 October 1996 Dr Wakefield wrote to you saying he had requested a letter of referral to you and confirming the referral,
Admitted and found proved

c. On 3 December 1996 you wrote to Child 8's mother indicating that you had heard that she would like the investigations to go ahead and that you had arranged for Child 8's admission for colonoscopy and other investigations during the week,
Admitted and found proved

d. Child 8 was admitted to hospital on 19 January 1997 under your clinical care,
Admitted and found proved
The Panel is satisfied on the evidence of the patient episode summary contained within the Royal Free hospital notes.

e. Child 8's admission clerking note indicated that she had had a diarrhoeal illness and febrile convulsions leading to an admission to hospital about 2 weeks after her MMR vaccination, and subsequent diarrhoea which continued for more than one year with 5-6 loose stools a day until her mother tried Evening Primrose Oil in November and her diarrhoea got better,

Admitted and found proved

f. Between 19 January 1997 and her discharge on or about 25 January 1997 Child 8 underwent a colonoscopy, a barium meal and follow-through, an MRI scan of her brain, a variety of blood and urine tests and an interview with Dr Berelowitz,

Admitted and found proved

g. Of the tests set out in 20.f. above,

i. appearances at colonoscopy were described as normal except for mild increase in lymph node tissue in the terminal ileum,

Admitted and found proved

ii. the histology report concluded that there was minimal inflammatory change possibly the result of operative artefact,

Admitted and found proved

iii. barium meal and follow-through appeared normal,

Admitted and found proved

iv. all inflammatory indices were normal,

Admitted and found proved

v. Dr Berelowitz informed you that he wondered if she had post vaccination encephalitis and he did not think autistic spectrum diagnosis was merited,

Admitted and found proved

h. On 27 November 1997 Dr Casson wrote a Discharge Summary to Dr Jelley detailing the results of the investigations and stating that they were not indicative of marked ongoing inflammation,

Admitted and found proved

i. On 15 January 1998 Dr Wakefield wrote to you indicating that Child 8's mother had contacted him to say that Child 8's gastrointestinal symptoms were particularly severe and suggesting she was an ideal candidate for mesalazine,

Admitted and found proved

j. On 14 April 1998 you wrote to Dr Jelley suggesting that Child 8 should have a therapeutic trial of anti-inflammatory therapy, namely Pentasa (a mesalazine preparation containing 5-ASA);

Admitted and found proved

- ‘21. a. You subjected Child 8 to a programme of investigations as part of the project ~~research study~~ referred to at paragraphs 2.b. and 2.c. above,
Found proved. In reaching its decision that you subjected this child to the programme of investigations, the Panel noted that no clinician at the Royal Free had seen the child at outpatients prior to her admission. Your letter to Child 8’s mother, dated 3 December 1996 stated, “I have had documentation concerning Child 8 and I have heard that you would like us to go ahead with the investigations...I have arranged for (her) to be admitted...the colonoscopy will be the next day...other investigations will be arranged during the week.”
- b. ~~The research study was carried out on~~ Child 8 *was investigated under the project* without the approval of the Ethics Committee in that she did not qualify for the ~~research study project~~ as she failed to meet the inclusion criteria set out at,
(amended)
- i. paragraph 2.c.i. above,
Found proved. This child had been vaccinated with MMR vaccine.
- ii. paragraph 2.c.ii. above,
Found proved. This child had not manifested disintegrative disorder.
- c. Contrary to the conditions of ethical approval for Project 172-96 you failed to ensure that a copy of the consent form and information sheet was included in Child 8’s clinical notes,
Found proved. The Panel is satisfied that you had received the letter dated 7 January 1997 from the Ethics Committee and had confirmed your acceptance of the conditions in your letter dated 9 January 1997.
- d. You caused Child 8 to undergo a,
- i. colonoscopy,
Found proved.
- ii. barium meal and follow-through,
Found proved.
- which was not clinically indicated,
Found proved. The Panel considered that there were minimal GI symptoms to warrant a colonoscopy at that stage. It also noted your own evidence (Day 94p32) that if a colonoscopy was not clinically indicated, “then the barium meal and follow through is not”.
- e. Your actions as set out at paragraph 21.d. were contrary to your representations to the Ethics Committee that the investigations were clinically indicated,

Found proved. The Panel noted your assurance to the Ethics Committee in your letter dated 11 November 1996, that “I can confirm that children would have these investigations even if there were no trial”.

f. By reason of the matters referred to at paragraphs 21.b., 21.c., 21.d. and 21.e. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,

Found proved.

g. You did not assess Child 8’s symptoms or cause them to be assessed by a senior member of the paediatric gastroenterology team prior to admitting her to hospital,

Found proved. Your letter to her mother dated 3 December 1996 confirms you only had documentation concerning the child prior to arranging her admission.

h. You failed to carry out markers of inflammation on Child 8 to assess the need for colonoscopy,

Found not proved. The Panel accepts that inflammatory markers are not essential.

i. You prescribed anti-inflammatory therapy to Child 8 without recording in her medical records your reasons for such therapy when the clinical histology report did not indicate a need for it,

Found proved. The Panel accepts your own evidence that there was a lack of provenance in the records.

j. Your conduct as set out above was contrary to the clinical interests of Child 8;

Found proved on the basis of the above findings.

Child 7

‘22. a. On or about 5 December 1996 Child 7’s General Practitioner, Dr Nalletamby, wrote to you referring Child 7 and stating that he,

i. probably did not have autism but he did have convulsions which Dr Nalletamby believed might make him eligible for your study,

Admitted and found proved

ii. suffered from bowel problems similar to his brother [Child 6] who you had recently investigated,

Admitted and found proved

b. On 15 January 1997 Child 7 attended an outpatient consultation with you during which you elicited a history of intermittent episodes of passage of blood associated with constipation and alternating

diarrhoea with mucous. You did not undertake an abdominal x-ray to confirm whether or not constipation was the primary cause of Child 7's symptoms,

Admitted and found proved

c. Thereafter you wrote to Dr Nalletamby advising that it would be appropriate for Child 7 to be investigated by colonoscopy,

Admitted and found proved

d. Child 7 was admitted to hospital on 26 January 1997 under your clinical care,

Admitted and found proved

The Panel has noted the admission details on the patient episode summary within the Royal Free notes showing this child was admitted under your care from 26 January 1997-1 February 1997.

e. Child 7's admission clerking note recorded that,

i. he had been admitted for colonoscopy and investigations as part of the Disintegrative Disorder/Colitis study,

Admitted and found proved

ii. he had a history of severe constipation with blood and mucous alternating with diarrhoea without blood,

Admitted and found proved

f. Between 26 January 1997 and his discharge on 1 February 1997 Child 7 underwent a colonoscopy, a barium meal and follow-through, an MRI scan of the brain, a lumbar puncture, an EEG and other neurophysiological investigations, blood and urine tests,

Admitted and found proved

g. Of the tests set out at 22.f. above,

Admitted and found proved

i. colonoscopy was reported as showing slight evidence of vascular abnormality in the rectum and sigmoid but otherwise essentially normal. The terminal ileum demonstrated a marked degree of lymphonodular hyperplasia,

Admitted and found proved

ii. the histology report was normal,

Admitted and found proved

iii. on barium meal and follow-through the small bowel appeared normal and small filling defects were seen in the terminal ileum consistent with lymphoid nodular hyperplasia,

Admitted and found proved

iv. the inflammatory indices in the blood demonstrated minor abnormalities,

Admitted and found proved with the exception of the word "minor".

Found not proved in relation to the word “minor”. The Panel accepts that a drop in haemoglobin from 10.6 to 9.4 within 2 days (28 January 1997 and 30 January 1997) was not minor, as detailed on the lab record in the Royal Free notes.

h. On 16 April 1997 Child 7 attended an outpatient consultation with you following which you wrote to Dr Nalletamby advising that Child 7 had lymphoid nodular hyperplasia but no evidence of inflammation in his distal bowel *although he continued to have symptoms, which were chiefly behavioural*. You prescribed anti-inflammatory therapy, namely olsalazine;
(amended) Admitted and found proved

‘23. a. You subjected Child 7 to a programme of investigations as part of the ~~project research study~~ referred to at paragraphs 2.b. and 2.c. above,

(amended) Found proved. The Panel is persuaded by the evidence, in particular your letter dated 17 January 1997 to the child’s GP, and copied to Dr Wakefield, which states “he will be having other investigations as part of the protocol”, together with the admission clerking notes in the Royal Free Hospital notes, which record that the child is undergoing “colonoscopy and investigations as part of the disintegrative disorder/colitis study” and under the heading “Plan” it states “autism protocol”.

b. ~~The research study was carried out on~~ Child 7 was investigated under the project without the approval of the Ethics Committee in that he did not qualify for the ~~project research study~~ as he failed to meet the inclusion criteria set out at,

(amended) Found proved for the reasons cited above.

i. paragraph 2.c.i. above,

Found proved. This child had MMR vaccination.

ii. paragraph 2.c.ii. above,

Found proved. This child was not diagnosed with disintegrative disorder.

c. Contrary to the conditions of ethical approval for Project 172-96 you failed to ensure that a copy of the consent form and information sheet was included in Child 7’s clinical notes,

Found proved. The Panel is satisfied that you had received the letter from the Ethics Committee dated 7 January 1997 setting out the conditions and you confirmed your acceptance of those conditions in your letter of 9 January 1997.

d. By reason of the matters referred to at paragraphs 23.b. and 23.c. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,
Found proved.

e. You failed to carry out an abdominal x-ray on Child 7 in order to assess the need for colonoscopy before that procedure was carried out,

Found not proved. The Panel concluded it was not essential to carry this out after the abdomen had been examined.

f. You prescribed anti-inflammatory agents to Child 7 when there was no clinical indication to do so,

Found not proved. The Panel accepted they were prescribed as part of a therapeutic trial.

g. Your conduct as set out above was contrary to the clinical interests of Child 7;

Found not proved. The Panel concluded that although this child was admitted to the hospital and subjected to investigations as part of the project, there is evidence that the investigations were clinically indicated and were therefore in Child 7's clinical interests.

Child 10

'24. a. On 14 October 1996 Child 10's General Practitioner, Dr Hopkins, wrote to you referring Child 10 and stating that,
Admitted and found proved

i. he had a history of loss of acquired skills which appeared to follow a measles-type illness,

Admitted and found proved

ii. he had previously been given the MMR and his measles antibody was significantly raised,

Admitted and found proved

iii. no actual diagnosis had been given for his condition but the most recent report referred to severe speech and language disorder with some autistic features,

Admitted and found proved

b. Dr Hopkins' referral letter made no reference to gastrointestinal symptoms,

Admitted and found proved

c. Prior to his referral to you there are no notes suggesting any significant history of gastrointestinal symptoms in Child 10's medical records,

Admitted and found proved

d. On 8 November 1996 Child 10 attended an outpatient consultation with you. You elicited a history of intermittent episodes of watery diarrhoea and episodes of screaming when Child 10 clutched his abdomen, which could have been related to abdominal pain. You

did not undertake any blood tests to check Child 10's inflammatory markers,

Admitted and found proved

e. Child 10 was admitted to hospital on 16 February 1997 under your clinical care,

Admitted and found proved

The Panel notes the patient episode summary contained within the Royal Free Hospital documentation which indicates this child was admitted under your care.

f. Child 10's admission clerking note recorded,

i. that he had been admitted for investigation of disintegrative disorder/measles/IBD,

Admitted and found proved

ii. a history of Child 10 pulling his knees up, clutching his abdomen and screaming but that his symptoms seemed to improve when dairy products were removed from his diet,

Admitted and found proved

iii. that he had variable bowel habit with occasionally watery and occasionally dry stools; he occasionally had to strain at stool; there was no blood or mucous,

Admitted and found proved

g. Between 16 February 1997 and his discharge on 19 February 1997 Child 10 underwent a colonoscopy, a lumbar puncture (on 17 February 1997), and a variety of blood and urine tests,

Admitted and found proved

h. Of the tests set out in 24.g. above,

Admitted and found proved

i. the results from the lumbar puncture were normal,

Admitted and found proved

ii. inflammatory indices in the blood were normal,

Admitted and found proved

i. On 18 February 1997 Dr Berelowitz saw Child 10's father and concluded that Child 10 did not meet the criteria for either autism or disintegrative disorder and the most likely diagnosis was an encephalitic episode;

Admitted and found proved

'25. a. You subjected Child 10 to a programme of investigations designed to further the project ~~research study~~ referred to at paragraphs 2.b. and 2.c. above,

(amended) Found proved. In reaching its decision that you subjected Child 10 to a programme of investigations, the Panel is

persuaded by the admission clerking note contained within the Royal Free Hospital records which states, “admitted for Ix (investigations) of disintegrative disorder/measles/IBD” together with the letter from the local paediatrician to you dated 6 February 1997, wherein he states “ ...look forward to the outcome of the research in due course” and the letter dated 20 February 1997 of Dr Berelowitz to you - “...mother would not wish to participate in a research interview.”

b. ~~The research study was carried out on Child 10 was investigated under the project~~ without the approval of the Ethics Committee in that he did not qualify for the ~~research study project~~ as he failed to meet the inclusion criteria set out at,

(amended)

i. paragraph 2.c.i. above,

Found proved. The child had been vaccinated with MMR.

ii. paragraph 2.c.ii. above,

Found proved. The child did not manifest disintegrative disorder.

c. Contrary to the conditions of ethical approval for Project 172-96 you failed to ensure that a copy of the consent form and information sheet was included in Child 10’s clinical notes,

Found proved. The Panel is satisfied that you had received the letter dated 7 January 1997 from the Ethics Committee and had confirmed your acceptance of the conditions in your letter dated 9 January 1997.

d. You caused Child 10 to undergo a colonoscopy which was not clinically indicated,

Found not proved. The Panel concluded that there was insufficient evidence to support this head of charge to the requisite standard.

e. You caused Child 10 to undergo a lumbar puncture,

Found proved on the basis that you subjected this child to a programme of investigations and that the LP was part of that programme. The Panel has also noted the parental consent taken on the day of the child’s admission and the results of the LP.

i. without ensuring that he was first assessed by a clinician with the requisite neurological or psychiatric expertise to determine whether such an investigation was clinically indicated,
Found not proved. The Panel concluded that you as a senior paediatrician did not need to have this child to be assessed by another clinician and could make a decision for a lumbar puncture.

ii. which was not clinically indicated,

Found not proved. The Panel accepted the expert evidence of Dr Thomas that it was clinically indicated and that he would have undertaken it because there was no firm diagnosis in respect of this child.

f. Your actions as set out at paragraphs 25.d. and 25.e. were contrary to your representations to the Ethics Committee that the investigations were clinically indicated,
Found not proved.

g. By reason of the matters referred to at paragraphs 25.b., 25.c., ~~25.d., 25.e. and 25.f.~~ you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,
(amended) Found proved.

h. You failed to carry out markers of inflammation on Child 10 to assess the need for colonoscopy,
Found not proved. The Panel accepts that the inflammatory markers were not essential.

i. Your conduct as set out above was contrary to the clinical interests of Child 10;
Found not proved. The Panel concluded that despite this child being subject to a programme of investigations, there is insufficient evidence to make a finding that the investigations were contrary to the child's clinical interests.

Transfer Factor

'26. a. In or about December 1997 you started Child 10 on a substance called Transfer Factor,
Found not proved. The Panel accepted your evidence that you did not, and has seen no evidence to support this allegation.

b. On 2 February 1998 Dr Wakefield submitted an application to the Ethics Committee,

i. seeking approval for a trial entitled "*A preliminary open-label study of the effect of oral measles virus-specific dialyzable lymphocyte extract transfer factor (DLE-TFmv) in children with autistic enteropathy*",

Admitted and found proved. The Panel noted that the Legal Assessor and Panel Secretary confirmed this admission with your legal representatives whilst *in camera* (2 December 2009)

ii. naming you as one of the Principal Clinical Investigators and Dr Wakefield as Principal Scientific Investigator,
Admitted and found proved

c. The application referred to at paragraph 26.b. above was allocated reference 22-98 ("Project 22-98"),

Admitted and found proved

d. Between July and November 1998 you and Dr Wakefield undertook research into the safety of Transfer Factor, which you submitted to the Ethics Committee,

Admitted and found proved

e. On 18 December 1998 the Ethics Committee wrote to you stating that Project 22-98 had been approved at a meeting on 16 December 1998;

Admitted and found proved

'27. a. You inappropriately caused Child 10 to be administered Transfer Factor,

Found proved. The Panel is persuaded that Child 10 was administered Transfer Factor by the weekly diary card completed by his mother, submitted to the Royal Free Hospital in January 1998 which states, "over Christmas and New Year we felt very optimistic about the apparent effect of Transfer Factor...is it possible that the dose now needs to be increased?". The Panel concluded that you caused the child to be administered with Transfer Factor on the basis of the letter of 23 July 1997 that you and Dr Wakefield wrote to the Dispensary Manager. You informed her that "we would like to start Child 10 ...on measles-specific Transfer Factor and we are prepared to take full responsibility for the outcome of this treatment. The supplies of the drug are presently in our hands (Dr Wakefield)." Further, Dr Wakefield sought permission from the Medical Advisory Committee by letter dated 9 September 1997 for Child 10 to be administered Transfer Factor on a named patient basis as is evidenced by the approval letter dated 15 September 1997 sent to him and copied to you, by its chairman, Dr Lloyd.

i. for experimental reasons,

Found proved. The Panel is persuaded that this was experimental treatment and not given for clinical reasons, because you had not seen or assessed the child before causing him to be administered with the unlicensed drug and you stated "we do not know whether the treatment will work" in your letter to the Dispensary manager of the pharmacy, dated 23 July 1997, jointly signed by you and Dr Wakefield. You also state within that letter, "we are prepared to take full responsibility for the outcome of the treatment".

ii. prior to obtaining information as to the safety of prescribing Transfer Factor to children,

Found not proved. The Panel has noted the letter dated 23 July 1997 to the Dispensary manager from you and Dr Wakefield, in

which you refer to about 300 peer-reviewed scientific publications on the use of TF and state that this substance was safe.

- iii. prior to obtaining ethical approval for a clinical trial of Transfer Factor, **Found not proved. The Panel has taken into account the letter dated 15 September 1997 from Dr Lloyd to Dr Wakefield and copied to you, giving Chairman's approval for the use of Transfer Factor to Child 10 on a named patient basis. The Panel is therefore satisfied that obtaining ethical approval for a clinical trial for this child was not relevant in December 1997.**

iv. without,

a. recording the fact of or dose of the prescription in Child 10's medical records,

Found proved. Despite the application form to the Ethics Committee signed by you on 30 January 1998, stating "Anecdotally we have started one child...on an approved compassionate basis. ..he has tolerated therapy for one month so far", the Panel noted that there is no evidence of any notes nor a recording of this child being seen.

b. informing Child 10's General Practitioner that Child 10 had been prescribed it,

Found proved. The Panel concluded an essential requirement of a doctor is to share information with colleagues in the ways that best serve patients' interests. The child's GP did not have knowledge of any prescription of TF other than that contained in a letter from a consultant community paediatrician. You did not inform the GP nor did you arrange for someone else to do so.

c. recording in Child 10's medical records the fact and nature of any discussion as to the risks and benefits of the prescription with Child 10's parents,

Found not proved. The Panel noted your evidence that after this child was discharged from hospital on 19 February 1997, you did not see the child again and therefore had no opportunity for discussion with the parents of Child 10 concerning the prescription and could not have recorded it.

b. Your actions as set out above were,

i. irresponsible,

Found proved.

ii. contrary to the clinical interests of Child 10;

Found proved.

The Panel concluded that these charges are proved on the basis of the findings at 27.a.i, 27. a.iv.a., 27a.iv.b.

The Lancet Paper

- '28. a. The investigations on the children whose individual circumstances are set out above were subsequently written up anonymised by numbers in a scientific paper entitled "*Ileal lymphoid-nodular hyperplasia, non-specific colitis and pervasive developmental disorder in children*" which was published in the Lancet journal vol.351 dated 28 February 1998 ("The Lancet paper"),
Admitted and found proved
- b. The number of each Child herein corresponds with the number of that Child in the Lancet paper and Child 11 in the Lancet paper was a private patient from the USA;
Admitted and found proved
- '29. a. The Lancet paper purported to identify associated gastrointestinal disease and developmental regression in a group of previously normal children which was generally associated in time with possible environmental triggers which were identified by their parents in eight cases with the Child's MMR vaccination,
Admitted and found proved
- b. You knew or ought to have known that your reporting in the Lancet paper of a temporal link between the syndrome you described and the MMR vaccination,
- i. had major public health implications,
Found proved. The Panel took into account the circumstances at the time. The Pulse article in which Dr Wakefield had voiced concerns about MMR, appeared in print in August 1997. You wrote to the Department of Child Health as early as 4 August 1997 in response to Professor Taylor's concerns about the Pulse article. You stated "like you I am very concerned at any weakening of MMR uptake in the community", then, "However, in these autistic children...there seems to be strong presumptive evidence of an MMR link." You had a meeting with the Department of Health in September, which JABS and others attended. These events should have alerted you to there being major public health implications of any link reported. The Lancet paper was submitted in late 1997 and published in early 1998.

The Panel also noted that the proposed scientific and clinical study, submitted as part of the application to the Ethics Committee in September 1996, states at p12 that "our ability to confirm or exclude the role of measles or

measles/rubella vaccine also has major implications for public health.”

ii. would attract intense public and media interest,
Found proved. In the same letter to Professor Taylor where you were responding to his being “incandescent about the recent unfortunate publicity concerning Andy Wakefield” following the Pulse article, you state that you will say nothing to the media and also “We have a rapacious press and media in this country which I will eschew completely”. The Panel concluded that even before its publication, you were aware of the intense public and media interest the Lancet paper would attract.

c. In the circumstances set out at paragraph 29.b. above, and as one of the senior authors of the Lancet paper, you,
Found proved. You are described on the Lancet paper as a senior clinical investigator and listed as its last author which the Panel has accepted traditionally denotes seniority.

i. knew or ought to have known the importance of accurately and honestly describing the patient population,
Found proved.

ii. had a duty to ensure that the factual information in the paper and provided by you in response to queries about it was true and accurate;
Found proved.

In reaching its decision, the Panel has taken into account the guidance from the Lancet, published in October 1997, which states “he or she [authors of the paper] must share responsibility for what is published.” The Panel is satisfied that, given that you were one of the senior authors of the Lancet paper, you had a duty to ensure that the factual information contained in the paper was true and accurate. In his evidence, Professor Rutter also referred to the importance of accuracy in scientific papers.

‘30. a. You failed to state in the Lancet paper that the children whose referral and histories you described were part of a project, ~~research~~ study the purpose of which was to investigate a postulated new syndrome comprising gastrointestinal symptoms and disintegrative disorder following vaccination,
(amended) Found proved on the basis that the children who were described in the paper were admitted under a programme of investigations under Project 172-96 for research purposes.

b. Your conduct as set out at paragraph 30.a. was,

i. dishonest,

Found not proved. The Panel concluded that your actions were not premeditated and you did not intend to be deliberately dishonest. It noted that you did not write or see the final draft of the paper and considered that you had been naïve in your lack of thoroughness regarding the paper submitted to the Lancet.

ii. irresponsible,

Found proved. The Panel considered that you as a senior author should have checked the validity or otherwise of the paper. You said you were given the second draft but did not see the final one. The Panel concluded that your conduct as a senior clinician and senior author was irresponsible.

iii. resulted in a misleading description of the patient population in the Lancet paper;

Found proved.

- '31. a. The Lancet paper stated that the children who were the subject of the paper were "*consecutively referred to the department of paediatric gastroenterology with a history of a pervasive developmental disorder with loss of acquired skills and intestinal symptoms (diarrhoea, abdominal pain, bloating and food intolerance)*" and subsequently described them as a "*self-referred*" group,
Admitted and found proved

b. You knew or ought to have known that such a description implied,

i. a routine referral to the gastroenterology department in relation to symptoms which included gastrointestinal symptoms,
Found proved.

ii. a routine process in which the investigators had played no active part;
Found proved.

The Panel took into account the article in the Lancet (volume 350 October 4 1997) "Writing for the Lancet" – "it is a general reader whom you are trying to reach". The Panel is satisfied that a general reader would interpret the wording in 30a to mean that children were referred to the gastroenterology department with gastrointestinal symptoms and that the investigators had played no active part in that referral.

- '32. a. Contrary to paragraph 31.b.i., the referrals of,

i. Child 1 as set out at paragraphs 6.a. and 6.b.,
Found proved.

ii. Child 9 as set out at paragraphs 14.a. to 14.c.,
Found proved.

iii. Child 5 as set out at paragraphs 16.a. to 16.b.,
Found proved.

iv. Child 10 as set out at paragraphs 24.a. and 24.b.,
Found proved.

did not constitute routine referrals to the gastroenterology department in relation to intestinal symptoms as the referring doctors referred referring the children for investigation of the role played by the measles vaccination or the MMR vaccination into their developmental disorders and did not report any history of gastrointestinal symptoms, **(amended for grammatical purposes). Having regard to its findings in relation to Child 1, 9, 5 and 10, namely that these children were admitted to undergo a programme of investigations for research purposes, and that they all lacked a history of gastrointestinal symptoms, the Panel is satisfied that these referrals did not constitute routine referrals to the gastroenterology department.**

b. Contrary to paragraph 31.b.ii., the referrals of,

i. Child 2, as set out at paragraph 4.e.,
Found not proved. At the end of the first assessment of the child, you said you would be happy to see the child again should the need arise. The Panel accepted that you wrote to Child 2's mother on 16 May 1996, offering to see Child 2 again, in response to her telephone call saying that her child's symptoms had worsened.

ii. Child 9, as set out at paragraph 14.a.,
Found proved. The Panel is satisfied that your letter to Dr Spratt the paediatrician, asking if it was appropriate to investigate Child 9 in the protocol, was tantamount to an express invitation for the child to be seen by you.
involved your express invitation for the Child to be seen by you,

c. The description of the referral process in the Lancet paper was therefore,

i. irresponsible,
Found proved.

ii. misleading,
Found proved.

iii. contrary to your duty to ensure that the information in the paper was accurate;
Found proved.

In reaching its decision, the Panel concluded that your description of the referral process as "routine", when it was not, was irresponsible and misleading and contrary to your duty as a senior author.

- '33. a. In a response by you, published in the Lancet vol. 363, dated 6 March 2004, to a statement by the editors of the Lancet you stated, **Admitted and found proved**
- i. that no children were invited to participate in the study which was the subject of the Lancet paper, **Admitted and found proved**
 - ii. that to the best of your recollection you did not invite any children to participate in the study which was the subject of the Lancet paper, **Admitted and found proved**
- b. In the circumstances set out in paragraph 32.b., these statements were,
- i. dishonest, **Found not proved. The Panel concluded there was insufficient evidence to support the two-pronged test as set out in the Legal Assessor's advice, that dishonesty must be intentional and deliberate.**
 - ii. irresponsible, **Found proved in relation to Child 9 only. The Panel concluded that you had a duty to make sure the information you provided was accurate and it is satisfied that in not so doing, you were irresponsible.**
 - iii. contrary to your duty to ensure that the information provided by you was accurate; **Found proved in relation to 32bii (Child 9) only.**
- '34. a. The Lancet paper stated that the investigations reported in it were approved by the Ethical Practices Committee of the Royal Free Hospital NHS Trust, **(amended) Admitted and found proved with the exception of the word "the" before "investigations". The Panel accepted that the amended wording accurately reflects the Lancet paper.**
- b. In fact, you did not have ethical approval for the investigations in the circumstances set out in paragraphs 2. to 25. above, **Found proved. The Panel has accepted that paragraphs 2 to 25 have been found proved on the basis that this was Project 172-96. Therefore the Panel is sure that you did not have ethical approval for the investigations as set out in these paragraphs.**
- c. The statement you made in the Lancet paper with regard to ethical approval was therefore,
- i. dishonest, **Found not proved.**
 - ii. irresponsible,

Found proved.

iii. contrary to your duty to ensure that the information in the paper was accurate;

Found proved.

The Panel concluded you had a duty and that in failing in that duty you were irresponsible. However, the Panel could not be certain that you intended to deceive and therefore the criteria for proving dishonesty are not met.

Child JS

- '35. a. On 29 April 1996, following contact between Child JS' mother and Mr Wakefield, Child JS' Consultant Community Paediatrician, Dr Mills, wrote a letter to Dr Wakefield which was copied to you. Dr Mills stated that,
- i. Dr Wakefield had suggested to Child JS' mother that a referral to you may be appropriate and she had contacted Dr Mills asking if he would make the referral,
Admitted and found proved
 - ii. Child JS had had mild diarrhoea which had not really been a clinical problem,
Admitted and found proved
 - iii. there had been no problems with Child JS' growth or weight gain,
Admitted and found proved
- b. Prior to Dr Mills' letter Child JS had been diagnosed with atypical autism in February 1995,
Admitted and found proved
- c. On 6 November 1996 Dr Wakefield wrote to you stating that he,
Admitted and found proved
- i. wanted Child JS to be included in your study if you considered him suitable,
Admitted and found proved
 - ii. would be grateful if you would arrange to see Child JS as an outpatient to assess him for possible investigation in your trial,
Admitted and found proved
- d. On 7 November 1996 you wrote to Dr Mills stating that,
Admitted and found proved
- i. through Dr Wakefield you had been looking at a group of children with autistic symptoms related to the MMR vaccine and had found that a significant number had gastrointestinal symptoms,
Admitted and found proved

ii. when gastrointestinal symptoms had been present you had so far found endoscopic abnormalities in all five children you had investigated,

Admitted and found proved

iii. you would be happy to see Child JS' parents and indicate what investigations might be appropriate and then get Dr Mills' advice as to the right way to proceed,

Admitted and found proved

e. On 15 November 1996 Dr Mills wrote to you stating that as Child JS' main Consultant he did not think that your research programme was appropriate for Child JS at that time, although *this may change* and Child JS' family may disagree with his views,

(amended) Admitted and found proved

f. On 22 November 1996 you wrote to Dr Mills stating that you quite understood him feeling that it may not be appropriate for you to see Child JS at that time, although you would be happy to hear from him again should the position change,

Admitted and found proved

g. On 16 April 1997, following a conversation you had had with Dr Wakefield, he wrote to you,

Admitted and found proved

i. asking you to re-consider Child JS for admission and investigation,

Admitted and found proved

ii. stating that Child JS' behaviour had deteriorated,

Admitted and found proved

iii. stating that Child JS' mother was keen for Child JS to be investigated at your earliest convenience,

Admitted and found proved

h. On 23 April 1997 you wrote to Dr Mills enclosing a copy of your ~~research~~ protocol and stating that you would be grateful if Dr Mills would reconsider the issue of Child JS' referral to you,

(amended) Admitted and found proved as amended

i. On 12 May 1997 Dr Mills wrote to you,

Admitted and found proved

i. asking for details as to how your detailed gastroenterological investigations had helped children like Child JS who had a minimum of gastroenterological symptoms,

Admitted and found proved

ii. stating that he had a responsibility to ensure that Child JS had appropriate investigations,

Admitted and found proved

iii. indicating his concern about your contacts with Child JS' family,

Admitted and found proved

j. On 29 May 1997 you replied to Dr Mills stating that you were reacting to pressure from Child JS' parents,

Found proved. The Panel is persuaded by your letter which states "The pressure is coming from the parents...I am reacting to parental pressure".

k. On 5 July 1997 Child JS' mother wrote to Mr Wakefield asking if he could refer Child JS for investigation and that letter was passed on to you,

Admitted and found proved

l. On 30 July 1997, following you writing to Child JS' mother, Child JS attended an outpatient consultation with you and you noted that he,

Admitted and found proved

i. had episodes of diarrhoea from about the age of two years, however his stools were much better now and only occasionally loose,

Admitted and found proved

ii. normally passed two large stools per day and currently his episodes of diarrhoea were quite infrequent,

Admitted and found proved

iii. sometimes had pain on defecation,

Admitted and found proved

iv. had never passed blood but at the age of four years there was some anal pathology which apparently was diagnosed as piles from which he subsequently settled,

Admitted and found proved

v. was very well nourished,

Admitted and found proved

m. On 31 July 1997 you wrote to Child JS' General Practitioner, Dr Shore, and to Dr Mills enclosing copies of your ~~research~~ protocol and stating that,

(amended) Found proved on the basis of the letter wherein you state "I enclose details of our protocol..."

i. Child JS was within the autistic spectrum and he currently had some rather minor gastrointestinal symptoms,

Admitted and found proved

ii. there was considerable parental concern about the role of MMR,

Admitted and found proved

- iii. Child JS would be suitable to have investigation by colonoscopy and other investigation under the protocol,
Admitted and found proved
 - n. On 12 November 1997 Child JS was admitted as an inpatient under your clinical care,
Admitted and found proved
The Panel notes the patient episode summary contained within the Royal Free Hospital documentation.
 - o. A colonoscopy was carried out on Child JS under general anaesthetic on 14 November 1997,
Admitted and found proved
 - p. Between 12 November 1997 and his discharge on 14 November 1997 Child JS also underwent blood tests which demonstrated normal inflammatory indices;
Admitted and found proved
- '36. a. You subjected Child JS to a colonoscopy,
Found proved. The Panel noted the letter to the Deputy Contracts Manager of the Royal Free Hospital on 10 November 1997 where you stated that "it is essential that this child has a colonoscopy".
 - i. in reaction to parental pressure,
Found not proved. There was insufficient evidence to find that the colonoscopy was undertaken as a direct consequence of parental pressure and it accepts your evidence that it was not.
 - ii. without any proper consideration to your duty to treat him in accordance with his best interests,
Found proved. The Panel noted that the parents' concern was regarding the child's presenting with behavioural difficulties rather than GI symptoms because the child was at the time well-nourished and had improved bowel motions. A colonoscopy was undertaken without proper consideration of his current clinical presentation.
 - iii. for the purposes of yours and Dr Wakefield's research into a purported association between gastrointestinal symptoms, autistic symptoms and the MMR vaccine,
Found proved. The Panel noted the letter dated 6 November 1996 from Dr Wakefield to you, stating "this is a child I would like to be included in our study..." together with the letter dated 7 November 1996 from you to the community paediatrician stating, "Through Dr Wakefield we have been looking at a group of children with autistic symptoms related to MMR vaccine and have found that a significant number of children have had gastrointestinal symptoms." You wrote to the Deputy Contracts Manager of the Royal

Free Hospital on 10 November 1997, saying “I think it is essential this child does have a colonoscopy. This kind of service is just not available elsewhere for children with autism and for the special investigations which Dr Wakefield can offer” and the Panel also noted the admission note dated 13 November 1997 which notes an “elective admission for colonoscopy”.

iv. without first carrying out markers of inflammation on Child JS to assess the need for colonoscopy,
Found not proved. The Panel concluded that inflammatory markers were not essential for an assessment.

v. which was not clinically indicated,
Found proved. The Panel concluded that subjecting the child to a colonoscopy was not clinically indicated as his main presentation was behavioural difficulties and you accepted his GI symptoms were “rather minor” in your letter to the community paediatrician on 31 July 1997. In your evidence to the Panel you accepted that you did “lower the threshold” in relation to this child. (day96p15)

b. Your conduct as set out above was contrary to the clinical interests of Child JS;’

Found proved on the basis of the above findings.

Having made the above findings of fact, the Panel went on to consider whether those facts found proved or admitted, were insufficient to amount to a finding of serious professional misconduct. The Panel concluded that these findings, which include those of your irresponsible conduct and not acting in the child’s best clinical interests in several instances, would not be insufficient to support a finding of serious professional misconduct.

In the next session, commencing 7 April 2010, the Panel, under Rule 28, will hear evidence and submissions from prosecution counsel then Professor Walker-Smith’s own counsel as to whether the facts as found proved do amount to serious professional misconduct, and if so, what sanction, if any, should be imposed on his registration.

C. Professor Simon Harry MURCH

The Panel will inquire into the following allegation against Simon Harry Murch, MB BS 1980 Lond; MRCS Eng LRCP Lond 1980 SR:

“That, being registered under the Medical Act 1983,

- ‘1. At all material times you were a,
Admitted and found proved
 - a. UK registered medical practitioner,
Admitted and found proved
 - b. Senior Lecturer in Paediatric Gastroenterology employed by the Royal Free Hospital School of Medicine with an honorary consultant contract with the Royal Free Hampstead NHS Trust;
Admitted and found proved

Research and Ethics Committee Approval

‘2. On or about 16 September 1996 an application was submitted to the Ethical Practices Sub-Committee of the Royal Free Hampstead NHS Trust (“the Ethics Committee”),
Admitted and found proved

- a. Naming you, Professor Walker-Smith and Mr Wakefield as the responsible consultants,
Admitted and found proved
- b. Seeking approval for a project ~~research study~~ involving 25 children entitled “A new paediatric syndrome: enteritis and disintegrative disorder following measles/rubella vaccination”,
(amended) Found proved. The Panel is satisfied this reflects the wording in the application.
- c. Describing a project ~~study~~ which entailed a programme of investigations, including invasive gastrointestinal and neurological tests, to be carried out on children who had,
(amended) Found proved
 - i. been vaccinated with the measles or measles/rubella vaccine, and
Found proved
 - ii. *manifested* disintegrative disorder, and
(amended) Found proved
 - iii. symptoms and signs of intestinal disease or dysfunction namely pain, bloating, alternating constipation and diarrhoea, steatorrhoea and failure to thrive,
Found proved.
In reaching its decision on 2c, the panel is satisfied this in accordance with the wording on the application document.

- d. Indicating that all the procedures you proposed to undertake were part of normal patient care and clinically indicated,
Admitted and found proved
- e. Attaching an explanation of the proposed scientific and clinical study, a timetable of investigations, a handout of information for parents and a sample consent form;
Admitted and found proved
- ‘3. a. The application referred to at paragraph 2. above was allocated reference 172-96 (“Project 172-96”),
Admitted and found proved
- b. The Chairman of the Ethics Committee, on behalf of the Committee, raised with Professor Walker-Smith ~~and Mr Wakefield concerns- reservations about~~ the intensive regime that children who took part in the study would have to undergo,
(amended) Found proved. The Panel was satisfied that the letter dated 15 October 1996 raising reservations was sent to Professor Walker-Smith and forwarded by him to you and Dr Wakefield.
- c. In a letter dated 11 November 1996, and copied to you, Professor Walker-Smith informed the Chairman of the Ethics Committee that the children would have the investigations even if there were no trial and five had already been investigated on a clinical need basis,
Admitted and found proved
- d. On the basis of the information provided in the application documentation and in the letter of 11 November 1996, the Ethics Committee granted ethical approval for Project 172-96 on 18 December 1996 subject to conditions, as set out in a letter dated 7 January 1997, including,
Found proved
- i. only patients enrolled after 18 December 1996 would be considered to be in the trial,
Admitted and found proved
- ii. the Ethics Committee was to be informed of and approve any proposed amendments to your initial application which had a bearing on the treatment or investigation of patients or volunteers,
Admitted and found proved
- iii. a copy of the consent form and the information sheet was to be lodged in the clinical notes of each patient,
Admitted and found proved
- e. In a letter dated 9 January 1997 Professor Walker-Smith confirmed acceptance of these conditions,
Admitted and found proved

f. Between 16 September 1996 and 15 July 1998 no further applications were made to the Ethics Committee for approval in connection with Project 172-96 nor was the Committee informed of any amendments to your initial application, save as a set out in Dr Wakefield's letter to the Chairman of the Ethics Committee dated 3 February 1997.

Admitted and found proved

g. As a named Responsible Consultant you had a duty to ensure that,

i. the information in support of your application to the Ethics Committee was true and accurate,

Found proved.

ii. only children who met the stated inclusion criteria for the Project 172-96 ~~research study~~ were admitted to the study, **(amended) Found proved.**

iii. you were aware of and complied with the conditions attached by the Ethics Committee to any approval given, **Found proved.**

iv. the children whom you admitted under the protocol were treated in accordance with the terms of the approval given by the Ethics Committee;

Found proved.

The Panel concluded that notwithstanding that yours was a shared responsibility and that you could not be held responsible for factors outside your knowledge and control, the Panel is satisfied that this was within the parameters of duties of a named responsible consultant.

Child 2

'4. a. On 2 September 1996 you carried out a colonoscopy on Child 2, **Admitted and found proved**

b. The colonoscopy was one investigation in a programme of investigations carried out on Child 2 for research purposes, **Found proved.**

The Panel relied on the evidence of your colonoscopy report within the Royal Free notes, where you stated it "was performed in the further investigation of disintegrative disorder...". The Panel also relied on the letter from Dr Berelowitz dated 30 September 1996, to you where he stated, "I saw (Child 2) at the request of yourself and Andy Wakefield for the purposes of learning more about possible links between his presentation and measles vaccination and bowel disease..."

c. As the Consultant carrying out the colonoscopy procedure you had a responsibility to ensure that it was clinically indicated by

reference to Child 2's clinical history and presenting symptoms, as recorded in his medical records and set out below,

Found proved. The Panel was satisfied with your own evidence during your cross examination (Day 118 p1) that you had such a responsibility.

i. on 21 June 1996 Child 2, who had been diagnosed as suffering from autistic spectrum disorder, attended an outpatient consultation with Professor Walker-Smith who,

Admitted and found proved

a. had seen Child 2 previously at St Bartholomew's Hospital in August 1995 when he concluded that there was no evidence of Crohn's disease or chronic inflammatory bowel disease,

Admitted and found proved

b. on this occasion noted that Child 2 was on an exclusion diet and developed diarrhoea when he had certain foods,

Admitted and found proved

c. arranged for Child 2 to undergo blood tests which subsequently demonstrated that the indices of inflammation were normal,

Admitted and found proved to the words 'blood tests'. Found proved. The Panel was satisfied that the blood test reports by Professor Walker Smith on 21 June 1996 showed the indices to be within normal limits.

ii. Child 2 was admitted to the Royal Free Hospital on or about 1 September 1996 under Professor Walker-Smith's clinical care,

Admitted but found proved only to the words 'September 1996'. Found proved in its entirety on the basis of the Royal Free documentation.

iii. Child 2's admission clerking note recorded that he had,

a. been admitted for investigation of the possible association between gastrointestinal disease/autism/measles,

Admitted and found proved

b. a history of intermittent diarrhoea and abdominal pain,

Admitted and found proved with exception of the word 'intermittent'

Found not proved in relation to the word “intermittent” – the Panel accepted the evidence of the admission clerking note.

c. been started on an exclusion diet which seemed to have improved his abdominal pain,

Admitted and found proved

d. Between 1 September 1996 and his discharge on 9 September 1996, in addition to the colonoscopy referred to at 4.a. above, Child 2 also underwent a barium meal and follow-through, an MRI scan of his brain, a lumbar puncture, a Schilling test, an EEG and other neurophysiological investigations, and a variety of blood and urine tests;

Admitted and found proved

‘5. a. Child 2 underwent the programme of investigations for research purposes without there being Ethics Committee approval for such research,

Found proved. The Panel relied on the evidence of the admission clerking note and the colonoscopy report contained within the Royal Free notes, to conclude that the programme of investigations was for research purposes for which there was no ethical approval.

b. The programme of investigations carried out on Child 2 was part of the project ~~research study~~ referred to at paragraphs 2.b. and 2.c. above,

(amended) Found proved. The Panel is satisfied that the programme of investigations followed closely the project protocol referred to in paragraphs 2.b and 2.c.

c. ~~The research study was carried out on~~ Child 2 was investigated under the project without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(amended) Found proved. The Panel is satisfied that there was no relevant Ethics committee approval at the time when these investigations were carried out.

i. contrary to the conditions of approval for Project 172-96 Child 2 had been enrolled into the project ~~research study~~ before 18 December 1996,

(amended) Found proved. Child 2 was admitted for investigations in September 1996.

ii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,

(amended) Found proved. Child 2 had been vaccinated with MMR.

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 2's clinical notes,

Found not proved. The Panel accepts that you could not have known the conditions for ethical approval which were set out in a letter dated 7 January 1997 to Professor Walker Smith.

e. You carried out a colonoscopy on Child 2 which was not clinically indicated,

Found proved. The Panel relies on your colonoscopy report dated 2 September 1996 where you state that the investigation was performed in the further investigation of disintegrative disorder.

f. Your actions as set out at paragraph 5.e. were contrary to your representations to the Ethics Committee that the procedures were clinically indicated,

Found proved. In view of the Panel's findings on 5e and noting your admission in 2d, the Panel concluded that it was contrary to your representations.

g. By reason of the matters referred to at paragraphs 5.c., 5.d., 5.e. and 5.f. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,

(amended) Found proved. The Panel concluded that as a Responsible Consultant you had a duty to ensure adequate research governance. Whilst the Panel accepts you could not be held responsible for factors outwith your knowledge and expertise, nevertheless you had joint responsibility for overseeing the overall process governing the project.

h. Your conduct as set out above was contrary to the clinical interests of Child 2;

Found proved.

Child 1

'6. a. On 22 July 1996 you attempted to carry out a colonoscopy on Child 1 which failed due to gross faecal loading,
Admitted and found proved

b. Child 1 underwent a clearance of his bowel and on 25 July 1996 you carried out a colonoscopy on Child 1 during which the caecum was reached although accumulated faecal material made it impossible to go further; no abnormality was noted,
Admitted and found proved

c. The attempted colonoscopy, and subsequent colonoscopy, was one investigation in a programme of investigations carried out on Child 1 for research purposes,

Found proved. The Panel relied on your colonoscopy report dated 22 July 1996, wherein you stated the history as being “disintegrative disorder”. The Panel has further relied on Professor Walker-Smith’s letter to Child 1’s GP dated 21 June 1996, which you would have seen prior to undertaking the colonoscopy, which mentions “as part of Dr Wakefield’s and mine interest in the relationship between immunisation and chronic inflammatory bowel disease...”. The letter concludes “...to explore the possible link between measles immunisation bowel inflammation and autism.”

d. As the Consultant carrying out the colonoscopy procedure you had a responsibility to ensure that it was clinically indicated by reference to Child 1’s clinical history and presenting symptoms, as recorded in his medical records and set out below,

Found proved. The Panel was satisfied with your own evidence during your cross examination (Day 118 p1) that you had such a responsibility.

i. on 17 May 1996 Child 1’s General Practitioner referred Child 1 to Professor Walker-Smith indicating that Child 1 had been diagnosed as autistic and that his parents’ concern was that his MMR vaccination might be responsible for his autism,
Admitted and found proved

ii. on 19 June 1996 Professor Walker-Smith saw Child 1 in his outpatient clinic and noted Child 1 had undigested food in his stools, with blood occasionally in his stools,
Admitted and found proved

iii. on 21 June 1996 Professor Walker-Smith wrote to Dr Barrow indicating that,
Admitted and found proved

a. he had arranged for routine blood tests to be done,
Admitted and found proved

b. Child 1’s diarrhoea had features of Toddlers diarrhoea,
Admitted and found proved

c. he would see Child 1 in three months’ time,
Admitted and found proved

d. if Child 1’s mother then felt it appropriate he ~~would~~ could consider performing endoscopy and further assessments of his autism to explore the *possible* link with measles immunisation, *bowel inflammation and autism*

(amended to reflect the wording of the letter of Professor Walker-Smith's letter to Child 1's GP dated 21 June 1996, which you would have seen prior to undertaking the colonoscopy) Found proved.

iv. on or about 25 June 1996 Child 1's blood test results showed normal inflammatory indices,

Admitted and found proved

v. on 21 July 1996 Child 1 was admitted to hospital under Professor Walker-Smith's clinical care,

Admitted but found proved only to the word 'hospital' Found proved. The Panel was persuaded by the Royal Free hospital documentation.

vi. Child 1's admission clerking note recorded that he,

Admitted and found proved

a. had been referred for work-up of the possible relationship between autism/measles/IBD,

Admitted and found proved

b. had a history of watery diarrhoea, without blood or mucous, and undigested food,

Admitted and found proved

c. now had no bowel control, no blood, possibly occasional mucous; the stools were not offensive but occasionally pale,

Found proved. This statement reflects the entry on the admission clerking note of the Royal Free Hospital.

e. Between 21 July 1996 and his discharge on 26 July 1996, in addition to the attempted colonoscopy and colonoscopy referred to at 6.a. and 6.b. above, Child 1 also underwent an MRI scan of his brain, an EEG and a variety of blood and urine tests,

Admitted and found proved

f. On 23 October 1996 Child 1 was re-admitted as an inpatient under Professor Walker-Smith's clinical care and between 23 October 1996 and his discharge on 25 October 1996, Child 1 underwent a barium meal and follow-through and a lumbar puncture;

Admitted and found proved

'7. a. Child 1 underwent the programme of investigations for research purposes without there being Ethics Committee approval for such research,

Found proved. The Panel relied on the evidence of the admission clerking note dated 21 July 1996 and the readmission note dated 23 October 1996, together with the colonoscopy report

dated 22 July 1996 and Professor Walker-Smith's letter to Child 1's GP dated 21 June 1996, which you would have seen prior to undertaking the colonoscopy. It concluded that the programme of investigations was for research purposes for which there was no ethical approval.

b. The programme of investigations carried out on Child 1 was part of the ~~research study~~ *project* referred to at paragraphs 2.b. and 2.c. above,

(amended) Found proved. The Panel had regard to the investigations that were carried out on this child and has concluded that these were part of the project.

c. ~~The research study was carried out on~~ Child 1 *was investigated under the project* without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(amended) Found proved.

i. contrary to the conditions of approval for Project 172-96 Child 1 had been enrolled into the project ~~research study~~ before 18 December 1996,

(amended) Found proved. The child was investigated in July and October 1996.

ii. he did not qualify for the *project* ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,

(amended) Found proved. The child had been vaccinated with MMR.

iii. he did not qualify for the ~~research study~~ *project* as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above.

(amended) Found proved on the basis that Child 1 was admitted with an established diagnosis of autism.

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 1's clinical notes,

Found not proved. The Panel accepted you could not have seen the conditions for approval as set out in the letter to Professor Walker Smith from the Ethics Committee dated 7 January 1997, copied to you and others.

e. You attempted to carry out a colonoscopy on Child 1 when such an investigation was not clinically indicated,

Found proved. You wrote in your colonoscopy report dated 22 July 1996 that the child's history is "disintegrative disorder" and noted that the letter to the child's GP from Professor Walker-Smith concluded the child had features of toddler's diarrhoea. The Panel

concluded that these were not clinical indications to undergo a colonoscopy.

- f. You carried out a colonoscopy on Child 1 although,
- i. the first attempt at colonoscopy suggested that his loose stools were more consistent with overflow secondary to constipation than with diarrhoea,
Found not proved. The Panel could not be sure to the requisite standard.
 - ii. such investigation was not clinically indicated,
Found proved, for the reasons set out in 7e above.
- g. Your actions as set out at paragraphs 7.e. and 7.f. were contrary to your representations to the Ethics Committee that the procedures were clinically indicated,
Found proved. In view of the Panel's findings on 7e and 7fii and noting your admission in 2d, the Panel concluded that it was contrary to your representations.
- h. By reason of the matters referred to at paragraphs 7.c., ~~7.d.~~, 7.e., 7.fii. and 7.g. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,
(amended) Found proved. The Panel concluded that as a Responsible Consultant you had a duty to ensure adequate research governance. Whilst the Panel accepts you could not be held responsible for factors outwith your knowledge and expertise, nevertheless you had joint responsibility for overseeing the overall process governing the project.
- i. Your conduct as set out above was contrary to the clinical interests of Child 1;
Found proved.

Child 3

'8. Child 3 underwent a programme of investigations for research purposes in the circumstances set out below,
Found proved. The Panel is persuaded by the evidence, including a letter sent to Professor Walker Smith on 19 February 1996, by the Child's GP, which stated, "...grateful for you to have taken on (Child 3) for case study.." and Professor Walker-Smith's letter dated 4 April 1996, to the GP, wherein he gives background information regarding the project.

- a. On 19 February 1996 Child 3's General Practitioner referred Child 3 to Professor Walker-Smith indicating that Child 3 had behavioural problems of an autistic nature, severe constipation and

learning difficulties all associated by his parents with his MMR vaccination,

Admitted and found proved

b. Child 3 was admitted to hospital on or about 8 September 1996 under Professor Walker-Smith's clinical care,

Admitted but found proved only to the words 'September 1996'. Found proved in its entirety based on the Royal Free Hospital notes including the patient episode summary.

c. Between 8 September 1996 and his discharge on 13 September 1996, Child 3 underwent a colonoscopy, a barium meal and follow-through, an MRI scan of his brain, a lumbar puncture, an EEG and a variety of blood and urine tests;

Admitted and found proved

'9. a. Child 3 underwent the programme of investigations for research purposes without there being Ethics Committee approval for such research,

Found proved. The Panel is persuaded by the extensive documentary evidence, in particular the correspondence already noted under head of charge 8, above. There was no ethics approval for such research in September 1996.

b. The programme of investigations carried out on Child 3 was part of the project ~~research study~~ referred to at paragraphs 2.b. and 2.c. above,

(amended) Found proved. The Panel is satisfied that the programme of investigations followed closely the project protocol referred to in paragraphs 2.b and 2.c.

c. ~~The research study was carried out on~~ Child 3 *was investigated under the project* without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(amended) Found proved

i. contrary to the conditions of approval for Project 172-96 Child 3 had been enrolled into the project ~~research study~~ before 18 December 1996,

(amended) Found proved. Child 3 was admitted for investigation in September 1996.

ii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,

(amended) Found proved. Child 3 had been vaccinated with MMR.

iii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above,

(amended) Found proved. Child 3 had a diagnosis of autism spectrum disorder.

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 3's clinical notes,

Found not proved. The Panel accepts that at the time of Child 3's admission, you could not have known of the conditions of ethical approval which were set out in a letter dated 7 January 1997 and copied to you and others on 9 January 1997.

e. By reason of the matters referred to at paragraphs 9.c. and ~~9.d.~~ you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above;

(amended) Found proved. The Panel concluded that as a Responsible Consultant you had a duty to ensure adequate research governance. Whilst the Panel accepts you could not be held responsible for factors outwith your knowledge and expertise, nevertheless you had joint responsibility for overseeing the overall process governing the project.

Child 4

'10. a. On 30 September 1996 you carried out a colonoscopy on Child 4,

Admitted and found proved

b. The colonoscopy was one investigation in a programme of investigations carried out on Child 4 for research purposes,
Found proved. The Panel is persuaded by the evidence of your colonoscopy report dated 30 September 1996, wherein you stated, "...investigation performed because of disintegrative disorder variant of autism." The plan on admission included in the notes of this child refers to investigations which closely follow the project protocol and your ward round report dated 30 September 1996 also refers to the Schilling test. The Panel has concluded that these were carried out for research purposes.

c. As the Consultant carrying out the colonoscopy procedure you had a responsibility to ensure that it was clinically indicated by reference to Child 4's clinical history and presenting symptoms, as recorded in his medical records and set out below,

Found proved. The Panel is persuaded by your own evidence in cross examination on Day 118p1 that you had such a responsibility.

i. on 1 July 1996 Child 4's General Practitioner referred Child 4 for assessment regarding his possible autism and his bowel problems, which consisted of a history of intermittent diarrhoea and at least 2 episodes of gastrointestinal infection,

Admitted and found proved

ii. on 29 September 1996 Child 4 was admitted to hospital under Professor Walker-Smith's clinical care,

Admitted but found proved only to the word 'hospital'. Found proved in its entirety. The Panel relied on the patient episode summary in the Royal Free notes.

iii. Child 4's admission clerking note,
Admitted and found proved

a. stated that he had been "*admitted for study of disintegrative disorder/colitis/MMR*",

Admitted and found proved

b. indicated with respect to his diarrhoea, that he was presently well most of the time, that if he got exacerbation it seemed to be related to new foods, that his bowels opened once or twice a day, normal, no straining, abdominal pain resolved,

Admitted and found proved

d. Between 29 September 1996 and his discharge on 4 October 1996, in addition to the colonoscopy referred to at 10.a. above, Child 4 underwent an attempt at barium meal and follow-through, an MRI scan of his brain, an EEG, other clinical neurophysiological investigations, and a variety of blood and urine tests;

Admitted and found proved

'11. a. Child 4 underwent the programme of investigations for research purposes without there being Ethics Committee approval for such research,

Found proved. The Panel is persuaded by the admission clerking note and your colonoscopy report to conclude that the programme was for research purposes for which there was no ethical approval.

b. The programme of investigations carried out on Child 4 was part of the project ~~research study~~ referred to at paragraphs 2.b. and 2.c. above,

(amended) Found proved. The Panel is satisfied that the programme of investigations follows closely the project protocol set out in 2.b and 2.c.

c. ~~The research study was carried out on~~ Child 4 *was investigated under the project* without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(amended) Found proved.

i. contrary to the conditions of approval for Project 172-96 Child 4 had been enrolled into the project ~~research study~~ before 18 December 1996,

(amended) Found proved. The child was admitted in September 1996.

ii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above,

(amended) Found proved. This child did not have a diagnosis of disintegrative disorder.

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 4's clinical notes,

Found not proved. The Panel accepts that you could not have known of the terms of conditions of ethical approval at this time as they were set out subsequently in a letter dated 7 January 1997 and copied to you on 9 January.

e. You carried out a colonoscopy on Child 4 which was not clinically indicated,

Found proved. The Panel is persuaded by your colonoscopy report dated 30 September 1996 wherein you state "investigation performed because of disintegrative disorder variant of autism." The Panel is satisfied that this is not a legitimate clinical reason for performing a colonoscopy.

f. Your actions as set out at paragraph 11.e. were contrary to your representations to the Ethics Committee that the procedures were clinically indicated,

Found proved.

g. By reason of the matters referred to at paragraphs 11.c., ~~11.d.~~, 11.e. and 11.f. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,

(amended) Found proved.

h. Your conduct as set out above was contrary to the clinical interests of Child 4;

Found proved on the basis of the above findings.

Child 6

'12. Child 6 underwent a programme of investigations for research purposes in the circumstances set out below,

Found proved. The Panel was persuaded by the correspondence, in particular the letter dated 4 October 1996 from Professor Walker-Smith to the child's GP, wherein he states that Child 6 will have a colonoscopy

and that he is “entering our programme of investigation of children with autistic problems.”

a. On 9 August 1996 Child 6’s General Practitioner referred Child 6 stating that he had autism syndrome, and also bowel disorder, and that Child 6’s mother was interested in entering him into the trial,

Admitted and found proved

b. On 2 October 1996 Child 6 attended an outpatient consultation with Professor Walker-Smith following which Professor Walker-Smith wrote to the General Practitioner advising that Child 6 was to come in for a colonoscopy and to enter the programme of investigation of Children with autistic problems,

Admitted and found proved

c. Child 6 was admitted to hospital on or about 27 October 1996 under Professor Walker-Smith’s clinical care,

**Admitted but found proved only to the words ‘October 1996’.
Found proved on the basis of the patient episode summary contained within the Royal Free notes.**

d. Between his admission and his discharge on or about 1 November 1996 Child 6 underwent a colonoscopy, an MRI scan of his brain, a lumbar puncture, an EEG and other neurophysiological investigations;

Admitted and found proved

e. On or about 1 November 1996 Child 6 was seen by Dr Berelowitz who concluded that the most likely diagnosis was Asperger’s Syndrome.

Admitted and found proved

‘13. a. Child 6 underwent the programme of investigations for research purposes without there being Ethics Committee approval for such research,

Found proved. The Panel is persuaded by the letter dated 4 October 1996 from Professor Walker-Smith to the child’s GP wherein he states “I am arranging for him to come in...and entering our programme of investigations of children with autistic problems”. [GPR123]. There was no ethical approval for such a project at this time.

b. The programme of investigations carried out on Child 6 was part of the project ~~research study~~ referred to at paragraphs 2.b. and 2.c. above,

(amended) Found proved. The Panel is satisfied that the programme of investigations follows closely the project protocol referred to at paragraphs 2b and 2c.

c. ~~The research study was carried out on~~ Child 6 *was investigated under the project* without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(amended) Found proved. The Panel notes there was no relevant Ethics Committee approval at the time these investigations were carried out.

i. contrary to the conditions of approval for Project 172-96 Child 6 had been enrolled into the project ~~research study~~ before 18 December 1996,

(amended) Found proved. The Panel notes this child was admitted to the Royal Free on or about 27 October 1996.

ii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,

(amended) Found proved. This child had been vaccinated with MMR.

iii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out in paragraph 2(c) (ii) above,

(amended) Found proved. The child had a diagnosis of Aspergers' Syndrome.

d. By reason of the matters referred to at paragraph 13.c. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above;

Found proved. The Panel concluded that as a responsible consultant you had a duty to ensure adequate research governance. Whilst the Panel accepts you could not be held responsible for factors outwith your knowledge and expertise, nevertheless you had joint responsibility for overseeing the overall process governing the project.

Child 9

'14. Child 9 underwent a programme of investigations for research purposes in the circumstances set out below,

Found proved. The Panel concluded that Child 9 underwent these investigations for research purposes and was persuaded by the letter of Professor Walker Smith to Dr Spratt, paediatrician, dated 11 September 1996 enclosing "Dr Wakefield's detailed proposal". Dr Spratt's response of 25 September 1996, thanks him for his opinion and refers to the "proposed referral to Dr Wakefield's service."

a. Following correspondence between Professor Walker-Smith and Child 9's Consultant Paediatrician during September 1996, Child 9 was referred for investigation ~~under the research protocol~~,

(amended) Admitted and found proved

b. Prior to his referral Child 9's developmental delay had been provisionally attributed to a form of autism,
Admitted and found proved

c. Child 9 was admitted to hospital on 17 November 1996 under Professor Walker-Smith's clinical care,
Admitted but found proved only to the words 'November 1996'. Found proved. The Panel is persuaded by the patient episode summary as contained in the Royal Free notes.

d. Between 17 November 1996 and his discharge on 22 November 1996, Child 9 underwent a colonoscopy, a barium meal and follow-through, and blood and urine tests,
Admitted and found proved

e. On 9 December 1996 Child 9 was readmitted and underwent an MRI scan of his brain, an EEG and a lumbar puncture;
Admitted and found proved

'15. a. Child 9 underwent the programme of investigations for research purposes without there being Ethics Committee approval for such research,
Found proved. The Panel concluded that Child 9 underwent these investigations for research purposes and is persuaded by the letter of Professor Walker Smith to Dr Spratt, paediatrician, dated 11 September 1996 enclosing "Dr Wakefield's detailed proposal". Dr Spratt's response of 25 September 1996, thanks him for his opinion and refers to the "proposed referral to Dr Wakefield's service." Professor Walker-Smith again wrote to Dr Spratt on 8 November 1996 after the child's outpatient appointment, and stated, "We have now seen several children with autism and gastrointestinal symptoms...I...have arranged for him to have a colonoscopy...we will then endeavour to follow this with barium meal and follow through...and repeat lumbar puncture". The Panel is satisfied that the programme of investigations was for research purposes for which there was no Ethics Committee approval.

b. The programme of investigations carried out on Child 9 was part of the *project research study* referred to at paragraphs 2.b. and 2.c. above,

Found proved. The Panel concluded that the programme of investigations carried out on Child 9, and the reasons recorded for those investigations, follow closely the project protocol referred to at paragraphs 2.b and 2.c. The Panel has also taken into account the letter dated 9 September 1996 from a research colleague, John Linnell to Professor Walker-Smith, which states "...it was agreed that he should, if possible, be included in our first ten cases." In addition the Panel has noted that Child 9, having been discharged from the Royal Free in November 1996

with normal results on the investigations to date, was re-admitted on 9 December 1996 for completion of the programme of investigations.

c. ~~The research study was carried out on~~ Child 9 *was investigated under the project* without the approval of the Ethics Committee in that it was not research covered by any Ethics Committee application other than that for Project 172-96 and,

Found proved. The Panel concluded that there was no relevant Ethics Committee approval at this time.

i. contrary to the conditions of approval for Project 172-96 Child 9 had been enrolled into the project ~~research study~~ before 18 December 1996,

(amended) Found proved. The child was admitted on 17 November and 9 December 1996.

ii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,

(amended) Found proved. This child had been vaccinated with MMR.

iii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above,

(amended) found proved. The child had a form of autism.

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 9's clinical notes,

Found not proved. The Panel accepted that you could not have known the conditions at the time of this child's admission as they were set out in a letter from the Ethics Committee copied to you on 9 January 1997.

e. By reason of the matters referred to at paragraphs 15.c. and ~~15.d.~~ you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above;
Found proved for the reasons set out above.

Child 5

'16. a. On 2 December 1996 you carried out a colonoscopy on Child 5,
Admitted and found proved

b. The colonoscopy was one investigation in a programme of investigations carried out on Child 5 for research purposes,
Found proved. The Panel is persuaded by the evidence of the GP referral letter dated 1 October 1996 to Professor Walker Smith stating "This...autistic child's parents have been in contact with Dr Wakefield and have asked me to refer him to yourself

[Professor Walker-Smith] regarding your current study into association between autism and childhood bowel problems". The Panel has also seen your colonoscopy report dated 2 December 1996 quoting "colonoscopy for investigation of autism with diarrhoeal features."

c. As the Consultant carrying out the colonoscopy procedure you had a responsibility to ensure that it was clinically indicated by reference to Child 5's clinical history and presenting symptoms, as recorded in his medical records and set out below,

Found proved. The Panel is satisfied with your own evidence (Day 118p1) that you had such a responsibility.

i. on 1 October 1996 Child 5's General Practitioner referred Child 5 to Professor Walker-Smith in relation to the study into the association between autism and Childhood bowel problems,
Admitted and found proved

ii. the referral letter gave details of Child 5's developmental delay with classical features of autism but made no reference to any gastrointestinal symptoms,

Admitted and found proved

iii. on 8 November 1996 Child 5 attended an outpatient consultation with Professor Walker-Smith, who elicited a history of episodes of diarrhoea once a month and episodes of abdominal pain. No blood tests were undertaken to check Child 5's inflammatory markers,

Admitted (with the observation that the history as described is incomplete) and found proved.

iv. Child 5 was admitted to hospital on or about 1 December 1996 under Professor Walker-Smith's clinical care and his admission clerking note indicated that he had intermittent diarrhoea and abdominal pain but there was no blood or mucus in his stool, **Amended to read:** ' Child 5 was admitted to hospital on or about 1 December 1996 under Professor Walker-Smith's clinical care and his clinical note indicated that he had intermittent diarrhoea and abdominal pain but there was no blood or mucus in his stool',

Admitted as amended and found proved save for the words 'Professor Walker-Smith's clinical care'. Found proved. The Panel concluded that admission was arranged by Professor Walker-Smith after referral by the child's GP and was assessed in the outpatients clinic department by him. The Panel further noted the nursing care plan dated 1 December 1996 and the discharge notification dated 6 December 1996 within the Royal Free notes both name Professor Walker Smith as the consultant in charge of this child.

d. Between 1 December 1996 and his discharge on 6 December 1996, in addition to the colonoscopy referred to at

16.a. above, Child 5 underwent a barium meal and follow-through, an MRI scan of his brain, a lumbar puncture (although no results were obtained), an EEG and a variety of blood and urine tests,
Admitted and found proved with exception of the words 'lumbar puncture (although no results were obtained)'. Found not proved in respect of the words 'lumbar puncture (although no results were obtained)'. The Panel is not satisfied that a lumbar puncture was undertaken at this time.

e. On 3 December 1996 Child 5 was seen by Dr Berelowitz, Consultant Paediatric Psychiatrist, who concluded that the likely diagnosis was a developmental disorder, such as autism, but that chromosomal studies needed to be done,
Admitted and found proved

f. On 15 January 1997 Child 5 was readmitted and underwent a repeat barium meal and follow-through, because of a previous suspected stricture, and a repeat lumbar puncture;
Admitted and found proved with exception of the word 'repeat'. Found not proved in respect of the word "repeat" relating to the lumbar puncture.

- '17. a. Child 5 underwent the programme of investigations for research purposes without there being Ethics Committee approval for such research,
Found proved. The Panel is persuaded by the letter dated 1 October 1996 to Professor Walker-Smith, from the child's GP, stating "this ...child's parents have been in contact with Dr Wakefield and have asked me to refer him to yourself regarding your current study into association between autism and childhood bowel problems". Professor Walker Smith decided to admit this child for investigations after his assessment in the outpatients clinic. The Panel has further noted that this child had been referred to Dr Berelowitz by Dr Wakefield and the Panel notes the response letter dated 4 December 1996 from Dr Berelowitz which was copied to you, reporting on his assessment of the child. The Panel has therefore concluded that the programme of investigations that Child 5 underwent was for research purposes, for which there was no Ethics Committee approval.
- b. The programme of investigations carried out on Child 5 was part of the ~~research study~~ *project* referred to at paragraphs 2.b. and 2.c. above,
Found proved. The Panel finds that the programme of investigations carried out, together with the reasons recorded, follow closely the project protocol referred to at 2b and 2c.
- c. ~~The research study was carried out on~~ *Child 5 was investigated under the project* without the approval of the Ethics Committee in that it

was not research covered by any Ethics Committee application other than that for Project 172-96 and,

(amended) Found proved. The Panel is satisfied that there was no other relevant Ethics Committee approval at the time when these investigations were carried out.

i. contrary to the conditions of approval for Project 172-96 Child 5 had been enrolled into the project ~~research study~~ before 18 December 1996,

(amended) Found proved. Child 5 was first admitted to the Department at the Royal Free before 18 December 1996.

ii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,

(amended) Found proved. Child 5 had been vaccinated with MMR.

iii. he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above,

(amended) Found proved. The child was referred with “autism and disturbed behaviour”.

d. Contrary to the conditions of ethical approval for Project 172-96 you subsequently failed to ensure that a copy of the consent form and information sheet was included in Child 5’s clinical notes,

Found proved in relation to investigations undertaken after the second admission of this child on 15 January 1997. The letter from the Ethics Committee outlining the conditions was sent to Professor Walker-Smith on 7 January 1997 and copied to you on 9 January 1997.

e. You carried out a colonoscopy on Child 5 which was not clinically indicated,

Found proved. The Panel concluded that there were no significant GI signs and symptoms to justify colonoscopy at this time.

f. Your actions as set out at paragraph 17.e. were contrary to your representations to the Ethics Committee that the procedures were clinically indicated,

Found proved.

g. By reason of the matters referred to at paragraphs 17.c., 17.d., 17.e. and 17.f. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,

Found proved.

h. Your conduct as set out above was contrary to the clinical interests of Child 5;

Found proved in view of the above findings.

Child 12

- '18. a. On 6 January 1997 you carried out a colonoscopy on Child 12,
Admitted and found proved
- b. The colonoscopy was one investigation in a programme of investigations carried out on Child 12 for research purposes,
Found proved. The Panel is persuaded by the evidence of the plan on the admission clerking note within the Royal Free notes, your colonoscopy report dated 6 January 1997 where it states in the history that the child has disintegrative disorder, together with the letter from Professor Walker-Smith to Child 12's mother where he states "the children are ...admitted for a course of a week and various other aspects of the protocol are undertaken." The Panel also noted Professor Walker-Smith's letter dated 21 October 1996 to Dr Wakefield where he states that "I did not feel it right...to proceed with our intensive programme...until we have had ethical committee approval"
- c. As the Consultant carrying out the colonoscopy procedure you had a responsibility to ensure that it was clinically indicated by reference to Child 12's clinical history and presenting symptoms, as recorded in his medical records and set out below,
Found proved. The Panel is persuaded by your own evidence on Day 118p1 where you accepted that you had such a responsibility.
- i. on 23 September 1996 Child 12's General Practitioner referred Child 12 to Professor Walker-Smith stating that Child 12,
Admitted and found proved
- a. had had bowel problems for sometime but he did not present to her surgery until March 1996, when his mother attended to discuss his soiling habit, and at that time his abdomen was normal with an empty rectum,
Admitted and found proved
- b. might well have Asperger's Syndrome,
Admitted and found proved
- ii. Professor Walker-Smith saw Child 12 in his outpatient clinic on 18 October 1996 when he elicited a history of Child 12 soiling, not having diarrhoea and having variable abdominal pain,
Admitted and found proved
- iii. Child 12 underwent a blood test on 18 October 1996 which demonstrated that the indices of inflammation were normal save for a marginally raised C-reactive protein,

Admitted and found proved

iv. Professor Walker-Smith concluded and recorded that,

Admitted and found proved

a. Child 12 had minimal gastrointestinal symptoms,

Admitted and found proved

b. he felt it was not right to proceed with the intensive programme until Ethical Committee approval had been obtained and it was clear that the parents wished to proceed,

Admitted and found proved

v. on 25 November 1996 Professor Walker-Smith wrote to Child 12's mother stating that one of the blood tests was slightly abnormal and, as she was keen to proceed, he would admit Child 12 for a colonoscopy,

Admitted and found proved

vi. Child 12 was admitted to hospital on 5 January 1997 under Professor Walker-Smith's clinical care,

Admitted but found proved only to the words 'January 1997'. Found proved in its entirety. The Panel is satisfied on the basis of the patient episode summary contained within the Royal Free notes.

vii. Child 12's admission clerking note, dated 6 January 1997, indicated that,

Admitted and found proved

a. he was being admitted for investigation of autism and bowel problems,

Admitted and found proved

b. he had been clean by the age of three and he started soiling sometime later,

Admitted and found proved

c. he was currently soiling eight times a day,

Admitted and found proved

d. the stools were loose, pale and very smelly,

Admitted and found proved

e. he had abdominal pain about once a week,

Admitted and found proved

d. Between 6 January 1997 and his discharge on 10 January 1997, in addition to the colonoscopy referred to at 18.a. above, Child 12 underwent a barium meal and follow-through, an MRI scan of his brain, a lumbar puncture, an EEG and other neurophysiological tests, and a variety of blood and urine tests,

Admitted and found proved

e. On 10 January 1997 Child 12 was interviewed by Dr Berelowitz who concluded that Child 12 had language delay, possible Attention Deficit Disorder and possible features of Asperger's Syndrome;

Admitted and found proved

- '19. a. Child 12 underwent the programme of investigations as part of the project ~~research study~~ referred to at paragraphs 2.b. and 2.c. above,
(amended) Found proved. The Panel noted the evidence of the mother of this child (Day 28 p20) where she stated that the child was referred to Dr Wakefield via the GP for investigations which she understood to be research investigations. This evidence was not challenged on behalf of Professor Murch. The Panel was also persuaded by the letter dated 21 October 1996 to Dr Wakefield from Professor Walker-Smith advising, "I did not feel it right...to proceed with our intensive programme...until we have had ethical committee approval....". The letter from Mrs 12 to Professor Walker-Smith dated 20 October 1996 states, "We have also re-read Dr Wakefield's proposed clinical and scientific study notes" and "...My husband and I are happy for [Child 12] to be referred on to Dr Wakefield's study project."
- b. ~~The research study was carried out on~~ Child 12 was *investigated under the project* without the approval of the Ethics Committee in that he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at,
(amended)
- i. paragraph 2.c.i. above,
Found proved. The child had been vaccinated with MMR.
 - ii. paragraph 2.c.ii. above,
Found proved. This child was not diagnosed with disintegrative disorder.
- c. Contrary to the conditions of ethical approval for Project 172-96 you failed to ensure that a copy of the consent form and information sheet was included in Child 12's clinical notes,
Found not proved. The Panel concluded that at the time of the child's admission on 5 January 1997 you could not have been aware of the conditions as set out in a letter from the Ethics Committee dated 7 January 1997 and copied to you on 9 January 1997.
- d. You carried out a colonoscopy on Child 12 which was not clinically indicated,

Found proved. The Panel is satisfied that the slightly raised CRP, in conjunction with the overall clinical picture, did not warrant a colonoscopy.

e. Your actions as set out at paragraph 19.d. were contrary to your representations to the Ethics Committee that the procedures were clinically indicated,

Found proved. The Panel noted your admission to head of charge 2d.

f. By reason of the matters referred to at paragraphs 19.b., ~~19.c.~~, 19.d. and 19.e. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,
(amended) Found proved.

g. Your conduct as set out above was contrary to the clinical interests of Child 12;

Found proved on the basis of the above findings.

Child 8

'20. Child 8 underwent a programme of investigations for research purposes in the circumstances set out below,

Found proved. The Panel is persuaded by the referral letter from the GP to Dr Wakefield dated 3 October 1996, "...to accept...[Child 8] into your investigation programme. I gather this is a specific area of expertise relating to the possible effects of vaccine damage and her ongoing GI tract symptoms". It also noted the endoscopy clerking sheet dated 20 January 1997 which notes in the plan "Dr Wakefield protocol". Further the Panel notes the discharge summary dated 27 November 1997 which states "...for further investigation of possible association between developmental delay, gastrointestinal symptoms and vaccination."

a. On 3 October 1996 Child 8's General Practitioner referred Child 8 to the investigation programme into the possible effects of vaccine damage and her ongoing GI tract symptoms,
Admitted and found proved

b. Child 8 was admitted to hospital on 19 January 1997 under Professor Walker-Smith's clinical care,
Admitted and found proved

c. Between 19 January 1997 and her discharge on or about 25 January 1997 Child 8 underwent a colonoscopy, a barium meal and follow-through, an MRI scan of her brain, a variety of blood and urine tests and an interview with Dr Berelowitz,
Admitted and found proved

d. Dr Berelowitz concluded that Child 8 may have post vaccination encephalitis and that an autistic spectrum diagnosis was not merited;
Admitted and found proved

'21. a. Child 8 underwent the programme of investigations as part of the ~~research study~~ project referred to at paragraphs 2.b. and 2.c. above,
(amended) Found proved for the reasons set out above at head of charge 20 and your admission at 20c, naming the investigations which follow very closely the project referred to at paragraphs 2b and 2c.

b. ~~The research study was carried out on~~ Child 8 *was investigated under the project* without the approval of the Ethics Committee in that she did not qualify for the project ~~research study~~ as she failed to meet the inclusion criteria set out at

(amended)

i. paragraph 2.c.i. above,

Found proved. This child had a MMR vaccination.

ii. paragraph 2.c.ii. above,

Found proved. This child had not manifested disintegrative disorder.

c. Contrary to the conditions of ethical approval for Project 172-96 you failed to ensure that a copy of the consent form and information sheet was included in Child 8's clinical notes,

Found proved. The Panel is satisfied that the letter from the Ethics Committee dated 7 January 1997 was sent to Professor Walker-Smith and copied to you on 9 January 1997, setting out the conditions.

d. By reason of the matters referred to at paragraph 21.b. and 21.c. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above;
Found proved.

Child 7

'22. Child 7 underwent a programme of investigations for research purposes in the circumstances set out below,
Found proved. The Panel is persuaded by the referral letter dated 5 December 1996 from this child's GP to Professor Walker-Smith, which refers to his convulsions which "may make him eligible for your study". The Panel also noted the clinic letter to the GP, dated 17 January 1997 from Professor Walker Smith and copied to Dr Wakefield, which states, "There does seem to be a clear relationship between symptomatology and the MMR...he will be having other investigations as part of the protocol." The Panel notes the admission clerking note dated 26 January 1997 stating "admitted...for colonoscopy and investigations as

part of the disintegrative disorder/colitis study” and sets out the plan for investigations including “autism protocol.”

a. On or about 5 December 1996 Child 7’s General Practitioner referred Child 7 to Professor Walker-Smith stating that Child 7,
Admitted and found proved

i. probably did not have autism but he did have convulsions which the General Practitioner believed might make him eligible for the study,

Admitted (with the observation that this is an incomplete account of the circumstances) and found proved

ii. suffered from bowel problems similar to his brother [Child 6] who had recently been investigated,

Admitted and found proved

b. Child 7 was admitted to hospital on 26 January 1997 under Professor Walker-Smith’s clinical care,
Admitted but found proved only to the words ‘January 1997’.
Found proved in its entirety on the basis of the patient episode summary contained within the Royal Free notes.

c. Child 7’s admission clerking note recorded that he had been admitted for colonoscopy and investigations as part of the Disintegrative Disorder/Colitis study,
Admitted and found proved

d. Between 26 January 1997 and his discharge on 1 February 1997 Child 7 underwent a colonoscopy, a barium meal and follow-through, an MRI scan of the brain, a lumbar puncture, an EEG and other neurophysiological investigations, blood and urine tests;
Admitted and found proved

‘23. a. Child 7 underwent the programme of investigations as part of the project ~~research study~~ referred to at paragraphs 2.b. and 2.c. above,

(amended) Found proved for the reasons cited in 22, above.

b. ~~The research study was carried out on~~ Child 7 *was investigated under the project* without the approval of the Ethics Committee in that he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at,

(amended)

i. paragraph 2.c.i. above,

Found proved. The child had an MMR vaccination.

ii. paragraph 2.c.ii. above,

Found proved. The child did not have a diagnosis of disintegrative disorder.

- c. Contrary to the conditions of ethical approval for Project 172-96 you failed to ensure that a copy of the consent form and information sheet was included in Child 7's clinical notes,
Found proved. This child was admitted on 26 January 1997, after the letter dated 7 January 1997 from the Ethics Committee (setting out conditions for ethical approval) had been sent to Professor Walker Smith and copied to you on 9 January 1997.
- d. By reason of the matters referred to at paragraphs 23.b. and 23.c. you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above;
Found proved.

Child 10

- '24. a. On 17 February 1997 you carried out a colonoscopy on Child 10,
Admitted and found proved
- b. The colonoscopy was one investigation in a programme of investigations carried out on Child 10 for research purposes,
Found proved. The Panel is persuaded by the admission clerking note contained within the Royal Free Hospital records which states, "admitted for Ix (investigations) of disintegrative disorder/measles/IBD" together with the letter from the local paediatrician to Professor Walker Smith dated 6 February 1997, wherein he states "...look forward to the outcome of the research in due course" and the letter dated 20 February 1997 of Dr Berelowitz to Professor Walker-Smith, "...mother would not wish to participate in a research interview".
- c. As the Consultant carrying out the colonoscopy procedure you had a responsibility to ensure that it was clinically indicated by reference to Child 10's clinical history and presenting symptoms, as recorded in his medical records and set out below,
Found proved. The Panel is satisfied with your own evidence on Day 118p1 that you had such a responsibility.
- i. on 14 October 1996 Child 10's General Practitioner referred Child 10 to Professor Walker-Smith stating that,
Admitted and found proved
- a. Child 10 had a history of loss of acquired skills which appeared to follow a measles-type illness,
Admitted and found proved
- b. no actual diagnosis had been given for his condition but the most recent report referred to severe speech and language disorder with some autistic features,

Admitted and found proved

ii. the referral letter made no reference to gastrointestinal symptoms,

Admitted and found proved

iii. Professor Walker-Smith saw Child 10 in his outpatient clinic on 8 November 1996 when he elicited a history of intermittent episodes of watery diarrhoea and episodes of screaming when Child 10 clutched his abdomen, which he thought could have been related to abdominal pain. No blood tests were undertaken to check Child 10's inflammatory markers,

Admitted (with the observation that this is an incomplete account) and found proved

iv. Child 10 was admitted to hospital on 16 February 1997 under Professor Walker-Smith's clinical care,

Admitted and found proved only to the words 'February 1997'. Found proved in its entirety. The Panel is persuaded on the patient episode summary in the Royal Free Hospital documentation.

v. Child 10's admission clerking note recorded,

Admitted and found proved

a. that he had been admitted for investigation of disintegrative disorder/measles/IBD,

Admitted and found proved

b. a history of Child 10 pulling his knees up, clutching his abdomen and screaming but that his symptoms seemed to improve when dairy products were removed from his diet,

Admitted and found proved

c. that he had variable bowel habit with occasionally watery and occasionally dry stools; he occasionally had to strain at stool; there was no blood or mucous,

Admitted and found proved

d. Between 16 February 1997 and his discharge on 19 February 1997, in addition to the colonoscopy referred to at 24.a. above, Child 10 underwent a lumbar puncture and a variety of blood and urine tests,

Admitted and found proved

e. On 18 February 1997 Dr Berelowitz saw Child 10's father and concluded that Child 10 did not meet the criteria for either autism or disintegrative disorder and the most likely diagnosis was an encephalitic episode;

Admitted and found proved

- ‘25. a. Child 10 underwent the programme of investigations as part of the project ~~research study~~ referred to at paragraphs 2.b. and 2.c. above,
(amended) Found proved. In view of your admissions under 24(c)(v) and the Panel’s findings under 24b, the Panel is persuaded that the investigations were part of the project.
- b. ~~The research study was carried out on~~ Child 10 was *investigated under the project* without the approval of the Ethics Committee in that he did not qualify for the project ~~research study~~ as he failed to meet the inclusion criteria set out at,
(amended)
- i. paragraph 2.c.i. above,
Found proved. The child was vaccinated with MMR.
- ii. paragraph 2.c.ii. above,
Found proved. The child did not have a diagnosis of disintegrative disorder.
- c. Contrary to the conditions of ethical approval for Project 172-96 you failed to ensure that a copy of the consent form and information sheet was included in Child 10’s clinical notes,
Found proved. The Panel noted the child was investigated in February 1997, after the letter from the Ethics Committee setting out conditions for ethical approval was sent to Professor Walker Smith on 7 January 1997 and copied to you on 9 January.
- d. You carried out a colonoscopy on Child 10 which was not clinically indicated,
Found not proved. The Panel concluded that there was insufficient evidence to support this head of charge to the requisite standard.
- e. Your actions as set out at paragraph 25.d. were contrary to your representations to the Ethics Committee that the procedures were clinically indicated,
Found not proved.
- f. By reason of the matters referred to at paragraphs 25.b., 25.c., ~~25.d. and 25.e.~~ you failed to comply with your duties to the Ethics Committee as a named Responsible Consultant as set out at paragraph 3.g. above,
(amended) Found proved.
- g. Your conduct as set out above was contrary to the clinical interests of Child 10;
Found not proved. The Panel concluded that despite this child being subject to a programme of investigations, there is

insufficient evidence to make a finding that the investigations were contrary to the child's clinical interests.

The Lancet Paper

- '26. a. The investigations on the children whose individual circumstances are set out above were subsequently written up anonymised by numbers in a scientific paper entitled "*Ileal lymphoid-nodular hyperplasia, non-specific colitis and pervasive developmental disorder in children*" which was published in the Lancet journal vol.351 dated 28 February 1998 ("The Lancet paper"),
Admitted and found proved with exception of the word 'scientific'
Found proved in relation to the word "scientific". The Panel was satisfied that the contents of the paper including controls, data sets, statistical analysis and reporting of the study in an established format of a scientific paper, would be considered "scientific".
- b. The number of each Child herein corresponds with the number of that Child in the Lancet paper and Child 11 in the Lancet paper was a private patient from the USA,
Admitted and found proved
- c. You were one of the senior authors of the Lancet paper and as such you had a duty to ensure that the information in the paper was true and accurate;
Found not proved. The Panel could not be satisfied to the requisite criminal standard of proof as it heard evidence that the first and last named authors of the paper would be considered "senior" but there was debate relating to the status of the second-named author.
- '27. a. The Lancet paper stated that ~~the~~ investigations reported in it were approved by the Ethical Practices Committee of the Royal Free Hospital NHS Trust,
(amended) Found proved notwithstanding the admission, the Panel considered that it was in the interests of justice to amend the head of charge so that it accurately reflected the wording in the Lancet.
- b. In fact, you did not have ethical approval for the investigations in the circumstances set out in paragraphs 2. to 25. above,
Found proved. Paragraphs 2 to 25 have been found proved on the basis that this was Project 172-96 and therefore the Panel is sure that you did not have ethical approval for the investigations as set out in these paragraphs.

c. The statement you made in the Lancet paper with regard to ethical approval was therefore contrary to your duty as a senior author of the paper;'

Found not proved. The Panel could not be satisfied to the requisite criminal standard of proof that you were a senior author.

Having made the above findings of fact, the Panel went on to consider whether those facts found proved or admitted, were insufficient to amount to a finding of serious professional misconduct. The Panel concluded that these findings, which included Dr Murch failing in his duty as a responsible consultant and in some cases, not acting in the best clinical interests of the children, would not be insufficient to support a finding of serious professional misconduct. In the next session, commencing 7 April 2010, the Panel, under Rule 28, will hear evidence and submissions from prosecution counsel then Professor Murch's own counsel as to whether the facts as found proved do amount to serious professional misconduct, and if so, what sanction, if any, should be imposed on his registration.