

General Medical Council

Fitness to Practise Panel (PCC)

Session beginning: 16 July 2007

Regent's Place, 350 Euston Road, London NW1 3JN

New case of serious professional misconduct.

A. Dr Andrew Jeremy WAKEFIELD

B. Dr John Angus WALKER-SMITH

C. Professor Simon Harry MURCH

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

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,
 - 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,
 - c. An Honorary Consultant in Experimental Gastroenterology at the Royal Free Hospital;
- ‘2. Your Honorary Consultant appointment was subject to a stipulation that you would not have any involvement in the clinical management of 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,
 - 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”),
 - 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”),
 - 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,

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,

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

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
- ii. disintegrative disorder, and
- iii. gastrointestinal symptoms,

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

g. On 22 August 1996 the Legal Aid Board agreed to provide £55,000 to fund the items in the Costing Proposal as proposed by you and as set out at paragraph 3.d.,

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,

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;

‘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,
- 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,

- b. Your conduct as set out at paragraph 4.a.i. was,
 - i. dishonest,
 - ii. misleading,
- c. Your conduct as set out at paragraph 4.a.ii. was a misuse of public funds and was,
 - i. dishonest,
 - ii. in breach of your duty when managing finances, to ensure that the funds are used for the purpose for which they were intended,
 - iii. in breach of your duty to account for funds you did not need to the donor of those funds;

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"),

- a. Naming you, Professor Walker-Smith and Dr Murch as the responsible consultants,
- b. Seeking approval for a research study involving 25 children entitled "A new paediatric syndrome: enteritis and disintegrative disorder following measles/rubella vaccination",
- c. Describing a study which entailed a programme of investigations, including invasive gastrointestinal and neurological tests, to be carried out on children who had,
 - i. been vaccinated with the measles or measles/rubella vaccine, and
 - ii. disintegrative disorder, and
 - iii. symptoms and signs of intestinal disease or dysfunction namely pain, bloating, alternating constipation and diarrhoea, steatorrhoea and failure to thrive,
- d. Indicating that all the procedures you proposed to undertake were part of normal patient care and clinically indicated,
- e. Indicating that you would be responsible for arranging a number of those procedures including MRI, lumbar puncture and EEG,

- 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,
- 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.)*";
- '6 a. The application referred to at paragraph 5. above was allocated reference 172-96 ("Project 172-96"),
- b. The Chairman of the Ethics Committee, on behalf of the Committee, raised with you and Professor Walker-Smith concerns as to the intensive regime that children who took part in the study would have to undergo,
- 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,
- 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,
- i. only patients enrolled after 18 December 1996 would be considered to be in the trial,
- 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,
- iii. a copy of the consent form and the information sheet was to be lodged in the clinical notes of each patient,
- e. In a letter dated 9 January 1997, and copied to you, Professor Walker-Smith confirmed acceptance of these conditions,
- f. Between 16 September 1996 and 15 July 1998 you made no further applications to the Ethics Committee for approval in connection with Project 172-96 nor did you inform the Committee of any amendments to your initial application,

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,
- ii. only children who met the stated inclusion criteria for the research study were admitted to the study,
- iii. you were aware of and complied with the conditions attached by the Ethics Committee to any approval given,
- iv. the children whom you admitted under the protocol were treated in accordance with the terms of the approval given by the Ethics Committee,
- 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;

'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,

b. Your,

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

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,

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,
- ii. thereby deprived the Ethics Committee of information material to its consideration of the ethical implications of project 172-96;

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,
 - i. he knew that Child 2's parents had contacted Professor Walker-Smith and yourself,
 - ii. Child 2's condition fell within the diagnostic category of Autistic Spectrum Disorder,
 - 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,
 - 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,
 - d. On 24 June 1996 Professor Walker-Smith wrote to you stating that Child 2 was the most appropriate child to begin your programme,
 - e. Child 2 was admitted to the Royal Free Hospital on or about 1 September 1996 under Professor Walker-Smith's clinical care,
 - f. Child 2's admission clerking note recorded that he had been admitted for investigation of the possible association between gastrointestinal disease/autism/measles,
 - 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,
 - 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,
 - 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;

- '9. a. You caused Child 2 to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research,
- b. The programme of investigations carried out on Child 2 was part of the research study referred to at paragraphs 5.b. and 5.c. above,
- c. 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,
- i. contrary to the conditions of approval for Project 172-96 Child 2 had been enrolled into the research study before 18 December 1996,
- ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 5.c.i. above,
- 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,
- 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,
- 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,
- g. You ordered that the investigations set out at paragraph 8.h. above be carried out on Child 2,
- i. without having the requisite paediatric qualifications to do so,
- ii. in contravention of the limitations on your Honorary Consultant appointment as set out at paragraph 2. above,
- h. Your conduct as set out above was contrary to the clinical interests of Child 2;

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,

- b. Dr Barrow's referral letter made no reference to any gastrointestinal symptoms,
 - 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 no formal diagnosis of his condition had been reached,
 - d. On 21 July 1996 Child 1 was admitted to hospital under Professor Walker-Smith's clinical care,
 - e. Child 1's admission clerking note recorded that he had been referred for work-up of the possible relationship between autism/measles/IBD,
 - 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,
 - g. On 23 October 1996 Child 1 was re-admitted as an inpatient,
 - 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;
- '11.
- a. You caused Child 1 to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research,
 - b. The programme of investigations carried out on Child 1 was part of the research study referred to at paragraphs 5.b. and 5.c. above,
 - c. The research study was carried out on Child 1 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,
 - i. contrary to the conditions of approval for Project 172-96 Child 1 had been enrolled into the research study before 18 December 1996,
 - ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 5.c.i. above,
 - iii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 5.c.ii. above,

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,

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,

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

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,

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

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,

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

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

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

c. The research study was carried out on Child 3 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,

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

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

- iii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 5.c.ii. above,
- 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,
- e. You caused Child 3 to 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,
 - ii. which 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,
- 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,
- h. Your conduct as set out above was contrary to the clinical interests of Child 3;

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,
- 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*",
- 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,
- d. On 29 September 1996 Child 4 was admitted to hospital under Professor Walker-Smith's clinical care,
- e. Child 4's admission clerking note stated that he had been "*admitted for study of degenerative disorder/colitis/MMR*",

- 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,
 - 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*”,
 - 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;
- ‘15.
- a. You caused Child 4 to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research,
 - b. The programme of investigations carried out on Child 4 was part of the research study referred to at paragraphs 5.b. and 5.c. above,
 - c. The research study was carried out on Child 4 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,
 - i. contrary to the conditions of approval for Project 172-96 Child 4 had been enrolled into the research study before 18 December 1996,
 - ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 5.c.ii. above,
 - 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,
 - 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,
 - f. You ordered that the investigations set out at paragraph 14.g.i. above be carried out on Child 4,
 - i. without having the requisite paediatric qualifications to do so,

- ii. in contravention of the limitations on your Honorary Consultant appointment as set out at paragraph 2. above,
- 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,
- h. You exposed Child 4 to an unnecessary neurophysiology investigation in that there were no control values available thereby rendering the investigation un-interpretable,
- i. Your conduct as set out above was contrary to the clinical interests of Child 4;

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,
 - 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,
 - 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,
 - d. Child 6 was admitted to hospital on or about 27 October 1996 under Professor Walker-Smith's clinical care,
 - 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;
- '17.
 - a. You caused Child 6 to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research,
 - b. The programme of investigations carried out on Child 6 was part of the research study referred to at paragraphs 5.b. and 5.c. above,

- c. The research study was carried out on Child 6 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,
 - i. contrary to the conditions of approval for Project 172-96 Child 6 had been enrolled into the research study before 18 December 1996,
 - ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 5.c.i. above,
- 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,
- e. Your conduct as set out above was contrary to the clinical interests of Child 6;

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,
 - b. Thereafter, on 11 September 1996 Professor Walker-Smith wrote to Dr Spratt enclosing a copy of the research protocol and asking Dr Spratt whether he thought it was appropriate to investigate Child 9 in the protocol,
 - 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,
 - d. Dr Spratt's letter made no reference to Child 9 suffering from gastrointestinal symptoms,
 - 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 by Southampton University Hospital autism service but this provisional diagnosis was not accepted by his parents nor subsequently confirmed,
 - f. Child 9 was admitted to hospital on 17 November 1996 under Professor Walker-Smith's 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,
 - 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,
 - i. The results from the lumbar puncture were normal;
- '19.
- a. You caused Child 9 to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research,
 - b. The programme of investigations carried out on Child 9 was part of the research study referred to at paragraphs 5.b. and 5.c. above.
 - c. The research study was carried out on Child 9 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,
 - i. contrary to the conditions of approval for Project 172-96 Child 9 had been enrolled into the research study before 18 December 1996,
 - ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 5.c.i. above,
 - iii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 5.c.ii. above,
 - 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,
 - e. You caused Child 9 to 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,
 - ii. which was not clinically indicated,
 - 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,

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,

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

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,

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,

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,

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,

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

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,

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*",

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,

- 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;
- '21.
- a. You caused Child 5 to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research,
 - b. The programme of investigations carried out on Child 5 was part of the research study referred to at paragraphs 5.b. and 5.c. above,
 - c. The research study was carried out on Child 5 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,
 - i. contrary to the conditions of approval for Project 172-96 Child 5 had been enrolled into the research study before 18 December 1996,
 - ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 5.c.i. above,
 - iii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 5.c.ii. above,
 - 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,
 - 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,
 - f. You ordered that the investigation set out at paragraph 20.g. above be carried out on Child 5,
 - i. without having the requisite paediatric qualifications to do so,
 - ii. in contravention of the limitations on your Honorary Consultant appointment as set out at paragraph 2. above,
 - 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,
 - h. Your conduct as set out above was contrary to the clinical interests of Child 5;

Child 12

- '22. a. On 19 July 1996 you wrote to Child 12's mother,
- i. thanking her for her letter regarding her son,
 - ii. telling her to seek a referral to Professor Walker-Smith,
 - iii. asking that she provide you with the General Practitioner's phone number,
- 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*",
- c. On 23 September 1996 Dr Stuart wrote a letter addressed to Professor Walker-Smith but marked for your attention referring Child 12,
- 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,
- e. On 21 October 1996 Professor Walker-Smith wrote to you stating that,
- i. Child 12 really had features of autism but had rather minimal gastrointestinal symptoms,
 - ii. it was not right to proceed with the intensive study programme until you had ethical committee approval and it was clear that the parents wished you to proceed,
- 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,
- g. Child 12 was admitted to hospital on 5 January 1997 under Professor Walker-Smith's clinical care,
- h. Child 12's admission clerking note, dated 6 January 1997, indicated that he was being admitted for investigation of autism and bowel problems,
- 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,

- 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,
 - ii. the results of the lumbar puncture were normal,
- 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,
- 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;
- '23. a. You caused Child 12 to undergo a programme of investigations as part of the research study referred to at paragraphs 5.b. and 5.c. above,
- b. The 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,
 - i. paragraph 5.c.i. above,
 - ii. paragraph 5.c.ii. above,
- 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,
- d. You caused Child 12 to 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,
 - ii. which was not clinically indicated,
- 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,
- 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,

- g. You ordered that the investigations set out at paragraph 22.j.i. be carried out on Child 12,
 - i. without having the requisite paediatric qualifications to do so,
 - ii. in contravention of the limitations on your Honorary Consultant appointment as set out at paragraph 2. above,
- h. Your conduct as set out above was contrary to the clinical interests of Child 12;

Child 8

- '24. a. On 3 October 1996 Child 8's General Practitioner, Dr Jelley, wrote to you,
 - i. referring Child 8 to your investigation programme into the possible effects of vaccine damage and her ongoing GI tract symptoms,
 - 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,
 - 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,
 - c. Child 8 was admitted to hospital on 19 January 1997 under Professor Walker-Smith's clinical care,
 - 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,
 - e. Dr Berelowitz concluded that Child 8 may have post vaccination encephalitis and that an autistic spectrum diagnosis was not merited;
- '25. a. You caused Child 8 to undergo a programme of investigations as part of the research study referred to at paragraphs 5.b. and 5.c. above,
 - b. The research study was carried out on Child 8 without the approval of the Ethics Committee in that she did not qualify for the research study as she failed to meet the inclusion criteria set out at,
 - i. paragraph 5.c.i. above,

- ii. paragraph 5.c.ii. above,
- 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,
- 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,
- e. Your conduct as set out above was contrary to the clinical interests of Child 8;

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,
 - i. probably did not have autism but he did have convulsions which Dr Nalletamby believed might make him eligible for your study,
 - ii. suffered from bowel problems similar to his brother [Child 6] who had been recently investigated,
 - b. Child 7 was admitted to hospital on 26 January 1997 under Professor Walker-Smith's clinical care,
 - 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,
 - 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,
 - 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*";

- '27. a. You caused Child 7 to undergo a programme of investigations as part of the research study referred to at paragraphs 5.b. and 5.c. above,
- b. The research study was carried out on Child 7 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,
- i. paragraph 5.c.i. above,
 - ii. paragraph 5.c.ii. above,
- 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,
- 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,
- e. You ordered that the investigations set out at paragraph 26.e. above be carried out on Child 7,
- i. without having the requisite paediatric qualifications to do so,
 - ii. in contravention of the limitations on your Honorary Consultant appointment as set out at paragraph 2. above,
- 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,
- g. Your conduct as set out above was contrary to the clinical interests of Child 7;

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,
- i. Child 10 had a history of loss of acquired skills which appeared to follow a measles-type illness,
 - ii. he had previously been given the MMR and his measles antibody was significantly raised,
 - 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,

- b. Dr Hopkins' referral letter made no reference to gastrointestinal symptoms,
 - c. Child 10 was admitted to hospital on 16 February 1997 under Professor Walker-Smith's clinical care,
 - d. Child 10's admission clerking note recorded that he had been admitted for investigation of disintegrative disorder/measles/IBD,
 - 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,
 - f. The results from the lumbar puncture were normal,
 - 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;
- '29.
- a. You caused Child 10 to undergo a programme of investigations as part of the research study referred to at paragraphs 5.b. and 5.c.,
 - b. The research study was carried out on Child 10 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,
 - i. paragraph 5.c.i. above,
 - ii. paragraph 5.c.ii. above,
 - 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,
 - d. You caused Child 10 to 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,
 - ii. which was not clinically indicated,
 - 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,

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,

g. Your conduct as set out above was contrary to the clinical interests of Child 10;

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"),
- 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;
- '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,
- 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,
- ii. would attract intense public and media interest,
- 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,
- 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,
- 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;

- '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 the purpose of which was to investigate a postulated new syndrome comprising gastrointestinal symptoms and disintegrative disorder following vaccination,
- b. Your conduct as set out at paragraph 32.a. was,
- i. dishonest,
 - ii. irresponsible,
 - iii. resulted in a misleading description of the patient population in the Lancet paper;
- '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,
- 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,
 - ii. a routine process in which the investigators had played no active part;
- '34. a. Contrary to paragraph 33.b.i., the referrals of,
- i. Child 1 as set out at paragraphs 10.a. and 10.b.,
 - ii. Child 9 as set out at paragraphs 18.a. to 18.d.,
 - iii. Child 5 as set out at paragraphs 20.a. to 20.c.,
 - iv. Child 10 as set out at paragraphs 28.a. and 28.b.,
- did not constitute routine referrals to the gastroenterology department in relation to intestinal symptoms as the general practitioners 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,
- b. Contrary to paragraph 33.b.ii., the referrals of,
- i. Child 2 as set out at paragraphs 8.a. to 8.e.,

- ii. Child 9 as set out at paragraphs 18.a. to 18.c.,
- iii. Child 5 as set out at paragraphs 20.a. and 20.b.,
- iv. Child 12 as set out at paragraphs 22.a. to 22.c.,

included active involvement in the referral process by you,

c. The description of the referral process in the Lancet paper was therefore,

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

- '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,
- b. In the circumstances set out in paragraphs 32.a., 34.a. and 34.b. this statement was,
- i. dishonest,
 - ii. irresponsible,
 - iii. contrary to your duty to ensure that the information provided by you was accurate;
- '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",
- b. In the circumstances set out in paragraphs 32.a., 34.a. and 34.b. this statement was,
- i. dishonest,
 - ii. irresponsible,

- iii. contrary to your duty to ensure that the information provided by you was accurate;
- '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,
- b. In fact, you did not have ethical approval for the investigations in the circumstances set out in paragraphs 5. to 29. above,
- c. The statement you made in the Lancet paper with regard to ethical approval was therefore,
- i. dishonest,
 - ii. irresponsible,
 - iii. contrary to your duty to ensure that the information provided by you was accurate;

Non-Declaration of Disclosable Interests to The Lancet

- '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"),
- 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);
- '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,

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

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,
- b. On 2 February 1998 you 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*",
 - ii. naming Professor Walker-Smith as one of the Principal Clinical Investigators and you as Principal Scientific Investigator,
- c. The application referred to at paragraph 40.b. above was allocated reference 22-98 ("Project 22-98"),
- 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,
- 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"),
- 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,
 - 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,
 - ii. stating that Mr 10 was to be the Managing Director of the company,

- iii. stating that you were to be the Research Director,
 - iv. proposing that the equity in the company would be split between a number of parties including Mr 10 and yourself,
 - 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,
 - 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;
- '41.
- a. You inappropriately caused Child 10 to be administered Transfer Factor,
 - i. for experimental reasons,
 - ii. prior to obtaining information as to the safety of prescribing Transfer Factor to children,
 - iii. prior to obtaining ethical approval for a clinical trial of Transfer Factor,
 - iv. without,
 - a. recording the fact of or dose of the prescription in Child 10's medical records,
 - b. informing Child 10's General Practitioner that Child 10 had been prescribed it,
 - 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,
 - v. without having the requisite paediatric qualifications,
 - vi. in contravention of the limitations on your Honorary Consultant appointment as set out at paragraph 2. above,
 - b. Your actions as set out above were,
 - i. contrary to the clinical interests of Child 10,
 - ii. an abuse of your position of trust as a medical practitioner;

The Birthday Party

- '42. a. On a date unknown prior to 20 March 1999 at your son's birthday party you,
- i. took blood from a group of children to use for research purposes,
 - ii. paid those children who gave blood £5 each for doing so,
- b. On 20 March 1999 you gave a presentation to the MIND Institute, in California, USA in the course of which you,
- i. described the incident referred to in 42.a. above in humorous terms,
 - ii. expressed an intention to obtain research samples in similar circumstances in the future;
- '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,
 - ii. you took blood from children in an inappropriate social setting,
 - iii. you offered financial inducement to children in order to obtain blood samples,
 - iv. you showed a callous disregard for the distress and pain that you knew or ought to have known the children involved might suffer,
 - v. in the circumstances you abused your position of trust as a medical practitioner,
- b. Your conduct set out in paragraph 42.b. was such as to bring the medical profession into disrepute;'

"And that in relation to the facts alleged you have been guilty of serious professional misconduct."

B. Dr 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,
 - 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;

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”),

- a. Naming you, Mr Wakefield and Dr Murch as the responsible consultants,
 - b. Seeking approval for a research study involving 25 children entitled “A new paediatric syndrome: enteritis and disintegrative disorder following measles/rubella vaccination”,
 - c. Describing a study which entailed a programme of investigations, including invasive gastrointestinal and neurological tests, to be carried out on children who had,
 - i. been vaccinated with the measles or measles/rubella vaccine, and
 - ii. disintegrative disorder, and
 - iii. symptoms and signs of intestinal disease or dysfunction namely pain, bloating, alternating constipation and diarrhoea, steatorrhoea and failure to thrive,
 - d. Indicating that all the procedures you proposed to undertake were part of normal patient care and clinically indicated,
 - 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;
- ‘3. a. The application referred to at paragraph 2. above was allocated reference 172-96 (“Project 172-96”),

- b. The Chairman of the Ethics Committee, on behalf of the Committee, raised with you and Mr Wakefield concerns as to the intensive regime that children who took part in the study would have to undergo,
- 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,
- 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,
- i. only patients enrolled after 18 December 1996 would be considered to be in the trial,
 - 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,
 - iii. a copy of the consent form and the information sheet was to be lodged in the clinical notes of each patient,
- e. In a letter dated 9 January 1997 you confirmed your acceptance of these conditions,
- f. Between 16 September 1996 and 15 July 1998 you made no further applications to the Ethics Committee for approval in connection with Project 172-96 nor did you inform the Committee of any amendments to your initial application,
- 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,
 - ii. only children who met the stated inclusion criteria for the research study were admitted to the study,
 - iii. you complied with the conditions attached by the Ethics Committee to any approval given,
 - iv. the children whom you admitted under the protocol were treated in accordance with the terms of the approval given by the Ethics Committee;

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,
- b. Prior to his referral to you Child 2 had a history of gastrointestinal symptoms,
- 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,
- 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,
- e. On 16 May 1996 you wrote to Child 2's mother asking to see Child 2 again and stating that you and Mr Wakefield had a plan for investigations,
- f. On 21 June 1996 Child 2 attended an outpatient consultation with you at the Royal Free Hospital and you,
- i. noted that he was on an exclusion diet and developed diarrhoea when he had certain foods,
- ii. arranged for him to undergo blood tests which subsequently demonstrated that the indices of inflammation were normal,
- g. On 24 June 1996 you wrote to Mr Wakefield stating that Child 2 was the most appropriate child to begin your programme,
- h. On 28 June 1996 you wrote to Dr Cartmel stating that,
- i. Crohn's disease was unlikely but Mr Wakefield's view was that there might be some kind of other inflammation of relevance to Child 2's illness,
- ii. you and Mr Wakefield now had a programme for investigating children who had an association with autism and a possible reaction to immunisation,
- iii. you were arranging for Child 2 to be admitted for investigation,

- 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,
 - j. Child 2 was admitted to hospital on or about 1 September 1996 under your clinical 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,
 - ii. a history of intermittent diarrhoea and abdominal pain since 20 months,
 - iii. been started on an exclusion diet in April 1996, which seemed to have improved his abdominal pain,
 - 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,
 - m. Save that Child 2's haemoglobin was slightly low, the blood tests demonstrated that the inflammatory indices in the blood were normal,
 - 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;
- '5.
- a. You subjected Child 2 to a programme of investigations for research purposes without having Ethics Committee approval for such research,
 - b. The programme of investigations carried out on Child 2 was part of the research study referred to at paragraphs 2.b. and 2.c. above,
 - c. 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,
 - i. contrary to the conditions of approval for Project 172-96 Child 2 had been enrolled into the research study before 18 December 1996,

- ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,
- 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,
- e. You caused Child 2 to undergo a,
 - i. colonoscopy,
 - ii. barium meal and follow-through,which was 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,
- 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,
- 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,
- i. Your conduct as set out above was contrary to the clinical interests of Child 2;

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,
- b. Dr Barrow's referral letter made no reference to any gastrointestinal symptoms,
- 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 formal diagnosis for his condition,
- 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,

- 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,
 - ii. the diarrhoea that Child 1 had, had features of Toddlers diarrhoea,
 - iii. you would see Child 1 in three months' time,
 - iv. if Child 1's mother then felt it appropriate you would consider endoscopy and further assessments of his autism to explore the link with measles immunisation,
- f. On or about 25 June 1996 Child 1's blood test results showed normal inflammatory indices,
- g. On 21 July 1996 Child 1 was admitted to hospital under your clinical 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,
 - ii. had a history of watery diarrhoea, without blood or mucous, and undigested food,
 - iii. now had no bowel control, no blood, possibly occasional mucous; the stools were not offensive but occasionally pale,
- i. On 22 July 1996 an attempt was made at colonoscopy which failed due to gross faecal loading,
- 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,
- 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,
- l. The blood tests referred to at 6.k. demonstrated normal inflammatory indices,
- m. On 23 October 1996 Child 1 was re-admitted as an inpatient under your clinical 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,
 - o. Of the tests set out in 6.n. above,
 - i. the abdominal x-ray showed faecal loading throughout,
 - ii. barium meal and follow-through was normal;
- '7.
- a. You subjected Child 1 to a programme of investigations for research purposes without having Ethics Committee approval for such research,
 - b. The programme of investigations carried out on Child 1 was part of the research study referred to at paragraphs 2.b. and 2.c. above,
 - c. The research study was carried out on Child 1 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,
 - i. contrary to the conditions of approval for Project 172-96 Child 1 had been enrolled into the research study before 18 December 1996,
 - ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,
 - iii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above,
 - 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,
 - e. You caused Child 1 to undergo an attempt at colonoscopy when such an investigation was not clinically indicated,
 - f. You caused Child 1 to undergo a colonoscopy and a barium meal and follow-through although,
 - i. the first attempt at colonoscopy suggested that his loose stools were more consistent with overflow secondary to constipation than with diarrhoea,
 - ii. such investigations were not clinically indicated,

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

h. By reason of the matters referred to at paragraphs 7.c., 7.d., 7.e., 7.f. 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,

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

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

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,

b. On 3 April 1996 you,

i. saw Child 3 in your outpatients clinic,

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

iii. screened Child 3 with routine blood tests,

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

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

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 Mr Wakefield,

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,

- 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;
- ‘9. a. You subjected Child 3 to a programme of investigations for research purposes without having Ethics Committee approval for such research,
- b. The programme of investigations carried out on Child 3 was part of the research study referred to at paragraphs 2.b. and 2.c. above,
- c. The research study was carried out on Child 3 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,
- i. contrary to the conditions of approval for Project 172-96 Child 3 had been enrolled into the research study before 18 December 1996,
- ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,
- iii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above,
- 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,
- e. You caused Child 3 to undergo a,
- i. colonoscopy,
- ii. barium meal and follow-through,
- which was not clinically indicated,
- f. You caused Child 3 to 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,
- ii. which was not clinically indicated,
- g. Your actions as set out at paragraphs 9.e. and 9.f. were contrary to your representations to the Ethics Committee that the investigations were clinically indicated,

h. By reason of the matters referred to at paragraphs 9.c., 9.d., 9.e., 9.f. 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,

i. Your conduct as set out above was contrary to the clinical interests of Child 3;

Child 4

- '10. a. On 1 July 1996 Child 4's General Practitioner, Dr Tapsfield, wrote to Mr Wakefield referring Child 4 regarding his possible autism and his bowel problems,
- b. On 4 July 1996 Mr Wakefield passed on the referral of Child 4 whom he said "*sounds like a good candidate for our forthcoming study*",
- 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,
- ii. had a history of diarrhoea and 2 episodes of gastrointestinal infections with giardia in 1993 and shigella in 1994,
- d. On 28 August 1996 your registrar 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 Mr Wakefield,
- e. On 29 September 1996 Child 4 was admitted to hospital under your clinical care,
- f. Child 4's admission clerking note,
- i. stated that he had been "*admitted for study of disintegrative disorder/colitis/MMR*",
- 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,

- 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,
 - h. Of the tests set out in 10.g. above,
 - i. colonoscopy revealed mild granularity of the rectum, a normal colon but the ileum showed marked lymphoid nodular hyperplasia,
 - 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, normal architecture, no active inflammation, no granulomas,
 - iii. barium meal and follow-through could not be performed,
 - iv. blood tests including inflammatory indices were normal,
 - i. On 16 October 1996 your registrar Dr Casson sent a discharge summary setting out the histological findings as in 10.h.ii. above,
 - 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;
- ‘11.
- a. You subjected Child 4 to a programme of investigations for research purposes without having Ethics Committee approval for such research,
 - b. The programme of investigations carried out on Child 4 was part of the research study referred to at paragraphs 2.b.and 2.c. above,
 - c. The research study was carried out on Child 4 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,
 - i. contrary to the conditions of approval for Project 172-96 Child 4 had been enrolled into the research study before 18 December 1996,
 - ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above,

- 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,
- e. You caused Child 4 to undergo a colonoscopy which was not clinically indicated,
- 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,
- 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,
- 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,
- i. You failed to carry out markers of inflammation on Child 4 to assess the need for colonoscopy,
- 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,
- k. Your conduct as set out above was contrary to the clinical interests of Child 4;

Child 6

- '12. a. On 9 August 1996 Child 6's General Practitioner, Dr Nalletamby, wrote to Mr Wakefield stating that Child 6 had autism syndrome, and also bowel disorder, and that Child 6's mother was interested in entering him into Mr Wakefield's trial,
- b. On 11 September 1996 you wrote to Dr Nalletamby stating that you had been asked by Mr Wakefield to see Child 6 as you were the Paediatric Gastroenterologist associated with Mr Wakefield in your study on autism and bowel disorder,
- 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,
- d. Child 6 was admitted to hospital on or about 27 October 1996 under your clinical care,

- 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;
- '13.
- a. You subjected Child 6 to a programme of investigations for research purposes without having Ethics Committee approval for such research,
 - b. The programme of investigations carried out on Child 6 was part of the research study referred to at paragraphs 2.b. and 2.c. above,
 - c. The research study was carried out on Child 6 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,
 - i. contrary to the conditions of approval for Project 172-96 Child 6 had been enrolled into the research study before 18 December 1996,
 - ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,
 - 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,
 - e. Your conduct as set out above was contrary to the clinical interests of Child 6;

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 the research protocol and,
 - i. indicating that you had heard from Mr Wakefield about Child 9 whose parents were keen for him to be investigated,
 - ii. asking Dr Spratt whether he thought it was appropriate to investigate Child 9 in the protocol,
 - b. On 25 September 1996 Dr Spratt wrote to you indicating he would be pleased to take your advice about the proposed referral to Mr Wakefield's service,

- c. Dr Spratt's letter made no reference to Child 9 suffering from gastrointestinal symptoms,
- d. Prior to his referral to you,
 - i. Child 9's developmental delay had been provisionally attributed to a form of autism in 1995 by Southampton University Hospital autism service but this provisional diagnosis was not accepted by his parents nor subsequently confirmed,
 - ii. there are no notes relating to any significant gastrointestinal symptoms in Child 9's medical records,
- 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,
 - 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,
- f. Child 9 was admitted to hospital on 17 November 1996 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,
- 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,
- 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 and a marked increase in the size and number of lymphoid nodules,
 - ii. the histology report on the bowel mucosa indicated prominent lymphoid follicles but no histological abnormality,

- iii. the barium meal was reported as normal in the clinical records,
- iv. a full blood count including inflammatory indices was normal,
- v. the results from the lumbar puncture were normal,
- 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,
 - ii. the diagnosis for Child 9 was indeterminate colitis with lymphoid nodular hyperplasia,
 - iii. a therapeutic trial of mesalazine might be worthwhile,
 - iv. you wondered if he had any other similar cases in Jersey,
- k. Child 9 was treated with mesalazine initially and subsequently, on your advice, sulphasalazine was substituted;
- '15. a. You subjected Child 9 to a programme of investigations for research purposes without having Ethics Committee approval for such research,
- b. The programme of investigations carried out on Child 9 was part of the research study referred to at paragraphs 2.b. and 2.c. above,
- c. The research study was carried out on Child 9 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,
 - i. contrary to the conditions of approval for Project 172-96 Child 9 had been enrolled into the research study before 18 December 1996,
 - ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,
 - iii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above,
- 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,

- e. You caused Child 9 to undergo a,
 - i. colonoscopy,
 - ii. barium meal and follow-through,which was not clinically indicated,
- f. You caused Child 9 to 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,
 - ii. which was not clinically indicated,
- 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,
- 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,
- i. You failed to carry out markers of inflammation on Child 9 to assess the need for colonoscopy,
- 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,
- k. Your conduct as set out above was contrary to the clinical interests of Child 9;

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 Mr 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,
- 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,

- 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,
 - ii. there are no notes relating to any significant gastrointestinal symptoms in Child 5's medical records,
 - 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,
 - e. Child 5 was admitted to hospital on or about 1 December 1996 under your clinical care,
 - 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,
 - 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,
 - 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,
 - i. The blood tests set out at 16.g. above demonstrated that the inflammatory markers in the blood were normal,
 - 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;
- '17.
- a. You subjected Child 5 to a programme of investigations for research purposes without having Ethics Committee approval for such research,
 - b. The programme of investigations carried out on Child 5 was part of the research study referred to at paragraphs 2.b. and 2.c. above,
 - c. The research study was carried out on Child 5 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,

- i. contrary to the conditions of approval for Project 172-96 Child 5 had been enrolled into the research study before 18 December 1996,
 - ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,
 - iii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above,
- 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,
- e. You caused Child 5 to undergo a,
- i. colonoscopy,
 - ii. barium meal and follow-through,
- which was not clinically indicated,
- 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,
- 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,
- h. You failed to carry out markers of inflammation on Child 5 to assess the need for colonoscopy,
- i. Your conduct as set out above was contrary to the clinical interests of Child 5;

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

- 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,
- 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 raised C-reactive protein,
- d. You concluded that,
 - i. Child 12 had minimal gastrointestinal 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,
- 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,
- f. Child 12 was admitted to hospital on 5 January 1997 under your clinical 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,
 - ii. he had been clean by the age of three and he started soiling sometime later,
 - iii. he was currently soiling eight times a day,
 - iv. the stools were loose, pale and very smelly,
 - v. he had abdominal pain about once a week,
- 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,
 - 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,

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

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

iv. the results from the lumbar puncture were normal,

v. the inflammatory indices in the blood were normal,

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,

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,

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,

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,

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;

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

b. The 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,

i. paragraph 2.c.i. above,

ii. paragraph 2.c.ii. above,

- 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,
- d. You caused Child 12 to undergo a,
 - i. colonoscopy,
 - ii. barium meal and follow-through,which was not clinically indicated,
- e. You caused Child 12 to 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,
 - ii. which was not clinically indicated,
- 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,
- 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,
- 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,
- i. Although Child 12 was suffering from constipation you advised that treatment with laxatives be withheld,
- j. Your conduct as set out above was contrary to the clinical interests of Child 12;

Child 8

- '20. a. On 3 October 1996 Child 8's General Practitioner, Dr Jelley, wrote to Mr Wakefield,
 - i. referring Child 8 to his investigation programme into the possible effects of vaccine damage and her ongoing GI tract symptoms,

- 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,
- b. On 9 October 1996 Mr Wakefield wrote to you saying he had requested a letter of referral to you and confirming the referral,
- 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,
- d. Child 8 was admitted to hospital on 19 January 1997 under your clinical care,
- 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,
- 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,
- 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,
 - ii. the histology report concluded that there was minimal inflammatory change possibly the result of operative artefact,
 - iii. barium meal and follow-through appeared normal,
 - iv. all inflammatory indices were normal,
 - v. Dr Berelowitz informed you that he wondered if she had post vaccination encephalitis and he did not think autistic spectrum diagnosis was merited,
- 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,

- i. On 15 January 1998 Mr 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,
 - 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);
- '21.
- a. You subjected Child 8 to a programme of investigations as part of the research study referred to at paragraphs 2.b. and 2.c. above,
 - b. The research study was carried out on Child 8 without the approval of the Ethics Committee in that she did not qualify for the research study as she failed to meet the inclusion criteria set out at,
 - i. paragraph 2.c.i. above,
 - ii. paragraph 2.c.ii. above,
 - 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,
 - d. You caused Child 8 to undergo a,
 - i. colonoscopy,
 - ii. barium meal and follow-through,which was not clinically indicated,
 - 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,
 - 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,
 - 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,
 - h. You failed to carry out markers of inflammation on Child 8 to assess the need for colonoscopy,

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

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,
 - ii. suffered from bowel problems similar to his brother [Child 6] who you had recently investigated,
 - 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,
 - c. Thereafter you wrote to Dr Nalletamby advising that it would be appropriate for Child 7 to be investigated by colonoscopy,
 - d. Child 7 was admitted to hospital on 26 January 1997 under your clinical care,
 - 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,
 - ii. he had a history of severe constipation with blood and mucous alternating with diarrhoea without blood,
 - 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,

- g. Of the tests set out at 22.f. above,
 - 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,
 - ii. the histology report was normal,
 - 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,
 - iv. the inflammatory indices in the blood demonstrated minor abnormalities,
 - 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. You prescribed anti-inflammatory therapy, namely olsalazine;
- '23.
- a. You subjected Child 7 to a programme of investigations as part of the research study referred to at paragraphs 2.b. and 2.c. above,
 - b. The research study was carried out on Child 7 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,
 - i. paragraph 2.c.i. above,
 - ii. paragraph 2.c.ii. above,
 - 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,
 - 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,
 - 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,
 - f. You prescribed anti-inflammatory agents to Child 7 when there was no clinical indication to do so,
 - g. Your conduct as set out above was contrary to the clinical interests of Child 7;

Child 10

- '24. a. On 14 October 1996 Child 10's General Practitioner, Dr Hopkins, wrote to you referring Child 10 and stating that,
- i. he had a history of loss of acquired skills which appeared to follow a measles-type illness,
 - ii. he had previously been given the MMR and his measles antibody was significantly raised,
 - 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,
- b. Dr Hopkins' referral letter made no reference to gastrointestinal symptoms,
- c. Prior to his referral to you there are no notes suggesting any significant history of gastrointestinal symptoms in Child 10's medical records,
- 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,
- e. Child 10 was admitted to hospital on 16 February 1997 under your clinical care,
- f. Child 10's admission clerking note recorded,
- i. that he had been admitted for investigation of disintegrative disorder/measles/IBD,
 - 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,
 - 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,
- 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,

- h. Of the tests set out in 24.g. above,
 - i. the results from the lumbar puncture were normal,
 - ii. inflammatory indices in the blood were normal,
 - 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;
- '25.
- a. You subjected Child 10 to a programme of investigations designed to further the research study referred to at paragraphs 2.b. and 2.c. above,
 - b. The research study was carried out on Child 10 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,
 - i. paragraph 2.c.i. above,
 - ii. paragraph 2.c.ii. above,
 - 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,
 - d. You caused Child 10 to undergo a colonoscopy which was not clinically indicated,
 - e. You caused Child 10 to 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,
 - ii. which was not clinically indicated,
 - 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,
 - 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,
 - h. You failed to carry out markers of inflammation on Child 10 to assess the need for colonoscopy,

- i. Your conduct as set out above was contrary to the clinical interests of Child 10;

Transfer Factor

- '26.
 - a. In or about December 1997 you started Child 10 on a substance called Transfer Factor,
 - b. On 2 February 1998 Mr 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*",
 - ii. naming you as one of the Principal Clinical Investigators and Mr Wakefield as Principal Scientific Investigator,
 - c. The application referred to at paragraph 26.b. above was allocated reference 22-98 ("Project 22-98"),
 - d. Between July and November 1998 you and Mr Wakefield undertook research into the safety of Transfer Factor, which you submitted to the Ethics Committee,
 - 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;
- '27.
 - a. You inappropriately caused Child 10 to be administered Transfer Factor,
 - i. for experimental reasons,
 - ii. prior to obtaining information as to the safety of prescribing Transfer Factor to children,
 - iii. prior to obtaining ethical approval for a clinical trial of Transfer Factor,
 - iv. without,
 - a. recording the fact of or dose of the prescription in Child 10's medical records,
 - b. informing Child 10's General Practitioner that Child 10 had been prescribed it,

- 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,
- b. Your actions as set out above were,
 - i. irresponsible,
 - ii. contrary to the clinical interests of Child 10;

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"),
 - 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;
- '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,
 - 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,
 - ii. would attract intense public and media interest,
 - c. In the circumstances set out at paragraph 29.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,
 - 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;

- '30. a. You failed to state in the Lancet paper that the children whose referral and histories you described were part of a research study the purpose of which was to investigate a postulated new syndrome comprising gastrointestinal symptoms and disintegrative disorder following vaccination,
- b. Your conduct as set out at paragraph 30.a. was,
- i. dishonest,
 - ii. irresponsible,
 - iii. resulted in a misleading description of the patient population in the Lancet paper;
- '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,
- 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,
 - ii. a routine process in which the investigators had played no active part;
- '32. a. Contrary to paragraph 31.b.i., the referrals of,
- i. Child 1 as set out at paragraphs 6.a. and 6.b.,
 - ii. Child 9 as set out at paragraphs 14.a. to 14.c.,
 - iii. Child 5 as set out at paragraphs 16.a. to 16.b.,
 - iv. Child 10 as set out at paragraphs 24.a. and 24.b.,

did not constitute routine referrals to the gastroenterology department in relation to intestinal symptoms as the general practitioners 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,

- b. Contrary to paragraph 31.b.ii., the referrals of,
 - i. Child 2, as set out at paragraph 4.e.,
 - ii. Child 9, as set out at paragraph 14.a.,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,
 - ii. misleading,
 - iii. contrary to your duty to ensure that the information in the paper was accurate;
- '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,
 - i. that no children were invited to participate in the study which was the subject of the Lancet paper,
 - 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,
 - b. In the circumstances set out in paragraph 32.b., these statements were,
 - i. dishonest,
 - ii. irresponsible,
 - iii. contrary to your duty to ensure that the information provided by you was accurate;
- '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,
 - b. In fact, you did not have ethical approval for the investigations in the circumstances set out in paragraphs 2. to 25. above,

- c. The statement you made in the Lancet paper with regard to ethical approval was therefore,
 - i. dishonest,
 - ii. irresponsible,
 - iii. contrary to your duty to ensure that the information in the paper was accurate;

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 Mr Wakefield which was copied to you. Dr Mills stated that,
 - i. Mr 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,
 - ii. Child JS had had mild diarrhoea which had not really been a clinical problem,
 - iii. there had been no problems with Child JS' growth or weight gain,
- b. Prior to Mr Mills' letter Child JS had been diagnosed with atypical autism in February 1995,
- c. On 6 November 1996 Mr Wakefield wrote to you stating that he,
 - i. wanted Child JS to be included in your study if you considered him suitable,
 - ii. would be grateful if you would arrange to see Child JS as an outpatient to assess him for possible investigation in your trial,
- d. On 7 November 1996 you wrote to Dr Mills stating that,
 - i. through Mr 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,
 - ii. when gastrointestinal symptoms had been present you had so far found endoscopic abnormalities in all five children you had investigated,

- 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,
- 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 Child JS' family may disagree with his views,
- 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,
- g. On 16 April 1997, following a conversation you had had with Mr Wakefield, he wrote to you,
 - i. asking you to re-consider Child JS for admission and investigation,
 - ii. stating that Child JS' behaviour had deteriorated,
 - iii. stating that Child JS' mother was keen for Child JS to be investigated at your earliest convenience,
- 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,
- i. On 12 May 1997 Dr Mills wrote to you,
 - i. asking for details as to how your detailed gastroenterological investigations had helped children like Child JS who had a minimum of gastroenterological symptoms,
 - ii. stating that he had a responsibility to ensure that Child JS had appropriate investigations,
 - iii. indicating his concern about your contacts with Child JS' family,
- j. On 29 May 1997 you replied to Dr Mills stating that you were reacting to pressure from Child JS' parents,
- 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,

- I. On 30 July 1997, following you writing to Child JS' mother, Child JS attended an outpatient consultation with you and you noted that he,
 - i. had episodes of diarrhoea from about the age of two years, however his stools were much better now and only occasionally loose,
 - ii. normally passed two large stools per day and currently his episodes of diarrhoea were quite infrequent,
 - iii. sometimes had pain on defecation,
 - 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,
 - v. was very well nourished,
 - 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,
 - i. Child JS was within the autistic spectrum and he currently had some rather minor gastrointestinal symptoms,
 - ii. there was considerable parental concern about the role of MMR,
 - iii. Child JS would be suitable to have investigation by colonoscopy and other investigation under the protocol,
 - n. On 12 November 1997 Child JS was admitted as an inpatient under your clinical care,
 - o. A colonoscopy was carried out on Child JS under general anaesthetic on 14 November 1997,
 - p. Between 12 November 1997 and his discharge on 14 November 1997 Child JS also underwent blood tests which demonstrated normal inflammatory indices;
- '36. a. You subjected Child JS to a colonoscopy,
- i. in reaction to parental pressure,
 - ii. without any proper consideration to your duty to treat him in accordance with his best interests,

iii. for the purposes of yours and Mr Wakefield's research into a purported association between gastrointestinal symptoms, autistic symptoms and the MMR vaccine,

iv. without first carrying out markers of inflammation on Child JS to assess the need for colonoscopy,

v. which was not clinically indicated,

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

“And that in relation to the facts alleged you have been guilty of serious professional misconduct.”

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,
 - a. UK registered medical practitioner,
 - 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;

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”),
 - a. Naming you, Professor Walker-Smith and Mr Wakefield as the responsible consultants,
 - b. Seeking approval for a research study involving 25 children entitled “A new paediatric syndrome: enteritis and disintegrative disorder following measles/rubella vaccination”,
 - c. Describing a study which entailed a programme of investigations, including invasive gastrointestinal and neurological tests, to be carried out on children who had,
 - i. been vaccinated with the measles or measles/rubella vaccine, and
 - ii. disintegrative disorder, and
 - iii. symptoms and signs of intestinal disease or dysfunction namely pain, bloating, alternating constipation and diarrhoea, steatorrhoea and failure to thrive,
 - d. Indicating that all the procedures you proposed to undertake were part of normal patient care and clinically indicated,
 - 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;

- ‘3. a. The application referred to at paragraph 2. above was allocated reference 172-96 (“Project 172-96”),
- b. The Chairman of the Ethics Committee, on behalf of the Committee, raised with Professor Walker-Smith and Mr Wakefield concerns as to the intensive regime that children who took part in the study would have to undergo,
- 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,
- 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,
- i. only patients enrolled after 18 December 1996 would be considered to be in the trial,
 - 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,
 - iii. a copy of the consent form and the information sheet was to be lodged in the clinical notes of each patient,
- e. In a letter dated 9 January 1997 Professor Walker-Smith confirmed acceptance of these conditions,
- f. Between 16 September 1996 and 15 July 1998 you made no further applications to the Ethics Committee for approval in connection with Project 172-96 nor did you inform the Committee of any amendments to your initial application,
- 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,
 - ii. only children who met the stated inclusion criteria for the research study were admitted to the study,
 - iii. you were aware of and complied with the conditions attached by the Ethics Committee to any approval given,

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

Child 2

'4. a. On 2 September 1996 you carried out a colonoscopy on Child 2,

b. The colonoscopy was one investigation in a programme of investigations carried out on Child 2 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 2's clinical history and presenting symptoms, as recorded in his medical records and set out below,

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,

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,

b. on this occasion noted that Child 2 was on an exclusion diet and developed diarrhoea when he had certain foods,

c. arranged for Child 2 to undergo blood tests which subsequently demonstrated that the indices of inflammation were normal,

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

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,

b. a history of intermittent diarrhoea and abdominal pain,

c. been started on an exclusion diet which seemed to have improved his abdominal pain,

- 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;
- ‘5. a. Child 2 underwent the programme of investigations for research purposes without there being Ethics Committee approval for such research,
- b. The programme of investigations carried out on Child 2 was part of the research study referred to at paragraphs 2.b. and 2.c. above,
- c. 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,
- i. contrary to the conditions of approval for Project 172-96 Child 2 had been enrolled into the research study before 18 December 1996,
- ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,
- 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,
- e. You carried out a colonoscopy on Child 2 which was not clinically indicated,
- 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,
- 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,
- h. Your conduct as set out above was contrary to the clinical interests of Child 2;

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,
 - 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,
 - c. The attempted colonoscopy, and subsequent colonoscopy, was one investigation in a programme of investigations carried out on Child 1 for research purposes,
 - 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,
 - 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,
 - 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,
 - iii. on 21 June 1996 Professor Walker-Smith wrote to Dr Barrow indicating that,
 - a. he had arranged for routine blood tests to be done,
 - b. Child 1's diarrhoea had features of Toddlers diarrhoea,
 - c. he would see Child 1 in three months' time,
 - d. if Child 1's mother then felt it appropriate he would consider performing endoscopy and further assessments of his autism to explore the link with measles immunisation,
 - iv. on or about 25 June 1996 Child 1's blood test results showed normal inflammatory indices,
 - v. on 21 July 1996 Child 1 was admitted to hospital under Professor Walker-Smith's clinical care,

- vi. Child 1's admission clerking note recorded that he,
 - a. had been referred for work-up of the possible relationship between autism/measles/IBD,
 - b. had a history of watery diarrhoea, without blood or mucous, and undigested food,
 - c. now had no bowel control, no blood, possibly occasional mucous; the stools were not offensive but occasionally pale,
- 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,
- 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;
- '7. a. Child 1 underwent the programme of investigations for research purposes without there being Ethics Committee approval for such research,
- b. The programme of investigations carried out on Child 1 was part of the research study referred to at paragraphs 2.b. and 2.c. above,
- c. The research study was carried out on Child 1 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,
 - i. contrary to the conditions of approval for Project 172-96 Child 1 had been enrolled into the research study before 18 December 1996,
 - ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,
 - iii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above.
- 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,
- e. You attempted to carry out a colonoscopy on Child 1 when such an investigation was not clinically indicated,

- 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,
 - ii. such investigation was not clinically indicated,
- 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,
- h. By reason of the matters referred to at paragraphs 7.c., 7.d., 7.e., 7.f. 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,
- i. Your conduct as set out above was contrary to the clinical interests of Child 1;

Child 3

- '8. Child 3 underwent a programme of investigations for research purposes in the circumstances set out below,
 - 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,
 - b. Child 3 was admitted to hospital on or about 8 September 1996 under Professor Walker-Smith's clinical care,
 - 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;
- '9.
 - a. Child 3 underwent the programme of investigations for research purposes without there being Ethics Committee approval for such research,
 - b. The programme of investigations carried out on Child 3 was part of the research study referred to at paragraphs 2.b. and 2.c. above,

c. The research study was carried out on Child 3 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,

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

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

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

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,

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;

Child 4

'10. a. On 30 September 1996 you carried out a colonoscopy on Child 4,

b. The colonoscopy was one investigation in a programme of investigations carried out on Child 4 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,

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,

ii. on 29 September 1996 Child 4 was admitted to hospital under Professor Walker-Smith's clinical care,

iii. Child 4's admission clerking note,

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

- 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,
 - 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;
- '11.
 - a. Child 4 underwent the programme of investigations for research purposes without there being Ethics Committee approval for such research,
 - b. The programme of investigations carried out on Child 4 was part of the research study referred to at paragraphs 2.b. and 2.c. above,
 - c. The research study was carried out on Child 4 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,
 - i. contrary to the conditions of approval for Project 172-96 Child 4 had been enrolled into the research study before 18 December 1996,
 - ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above,
 - 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,
 - e. You carried out a colonoscopy on Child 4 which was not clinically indicated,
 - 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,
 - 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,
 - h. Your conduct as set out above was contrary to the clinical interests of Child 4;

Child 6

- '12. Child 6 underwent a programme of investigations for research purposes in the circumstances set out below,
- 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,
 - 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,
 - c. Child 6 was admitted to hospital on or about 27 October 1996 under Professor Walker-Smith's clinical care,
 - 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;
- '13. a. Child 6 underwent the programme of investigations for research purposes without there being Ethics Committee approval for such research,
- b. The programme of investigations carried out on Child 6 was part of the research study referred to at paragraphs 2.b. and 2.c. above,
 - c. The research study was carried out on Child 6 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,
 - i. contrary to the conditions of approval for Project 172-96 Child 6 had been enrolled into the research study before 18 December 1996,
 - ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,
 - 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;

Child 9

- '14. Child 9 underwent a programme of investigations for research purposes in the circumstances set out below,
- 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,
 - b. Prior to his referral Child 9's developmental delay had been provisionally attributed to a form of autism,
 - c. Child 9 was admitted to hospital on 17 November 1996 under Professor Walker-Smith's clinical care,
 - 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,
 - e. On 9 December 1996 Child 9 was readmitted and underwent an MRI scan of his brain, an EEG and a lumbar puncture;
- '15. a. Child 9 underwent the programme of investigations for research purposes without there being Ethics Committee approval for such research,
- b. The programme of investigations carried out on Child 9 was part of the research study referred to at paragraphs 2.b. and 2.c. above,
 - c. The research study was carried out on Child 9 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,
 - i. contrary to the conditions of approval for Project 172-96 Child 9 had been enrolled into the research study before 18 December 1996,
 - ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,
 - iii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above,
 - 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,

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;

Child 5

'16. a. On 2 December 1996 you carried out a colonoscopy on Child 5,

b. The colonoscopy was one investigation in a programme of investigations carried out on Child 5 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 5's clinical history and presenting symptoms, as recorded in his medical records and set out below,

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,

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,

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,

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,

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,

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,

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;

- '17. a. Child 5 underwent the programme of investigations for research purposes without there being Ethics Committee approval for such research,
- b. The programme of investigations carried out on Child 5 was part of the research study referred to at paragraphs 2.b. and 2.c. above,
- c. The research study was carried out on Child 5 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,
- i. contrary to the conditions of approval for Project 172-96 Child 5 had been enrolled into the research study before 18 December 1996,
- ii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.i. above,
- iii. he did not qualify for the research study as he failed to meet the inclusion criteria set out at paragraph 2.c.ii. above,
- 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,
- e. You carried out a colonoscopy on Child 5 which was not clinically indicated,
- 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,
- 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,
- h. Your conduct as set out above was contrary to the clinical interests of Child 5;

Child 12

- '18. a. On 6 January 1997 you carried out a colonoscopy on Child 12,
- b. The colonoscopy was one investigation in a programme of investigations carried out on Child 12 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 12's clinical history and presenting symptoms, as recorded in his medical records and set out below,

i. on 23 September 1996 Child 12's General Practitioner referred Child 12 to Professor Walker-Smith stating that Child 12,

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,

b. might well have Asperger's Syndrome,

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,

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,

iv. Professor Walker-Smith concluded and recorded that,

a. Child 12 had minimal gastrointestinal symptoms,

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,

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,

vi. Child 12 was admitted to hospital on 5 January 1997 under Professor Walker-Smith's clinical care,

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

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

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

- c. he was currently soiling eight times a day,
 - d. the stools were loose, pale and very smelly,
 - e. he had abdominal pain about once a week,
- 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,
- 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;
- '19. a. Child 12 underwent the programme of investigations as part of the research study referred to at paragraphs 2.b. and 2.c. above,
- b. The 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,
- i. paragraph 2.c.i. above,
 - ii. paragraph 2.c.ii. above,
- 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,
- d. You carried out a colonoscopy on Child 12 which was not clinically indicated,
- 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,
- 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,
- g. Your conduct as set out above was contrary to the clinical interests of Child 12;

Child 8

'20. Child 8 underwent a programme of investigations for research purposes in the circumstances set out below,

- 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,
- b. Child 8 was admitted to hospital on 19 January 1997 under Professor Walker-Smith's clinical care,
- 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,
- d. Dr Berelowitz concluded that Child 8 may have post vaccination encephalitis and that an autistic spectrum diagnosis was not merited;

'21. a. Child 8 underwent the programme of investigations as part of the research study referred to at paragraphs 2.b. and 2.c. above,

b. The research study was carried out on Child 8 without the approval of the Ethics Committee in that she did not qualify for the research study as she failed to meet the inclusion criteria set out at

- i. paragraph 2.c.i. above,
- ii. paragraph 2.c.ii. above,

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,

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;

Child 7

'22. Child 7 underwent a programme of investigations for research purposes in the circumstances set out below,

a. On or about 5 December 1996 Child 7's General Practitioner referred Child 7 to Professor Walker-Smith stating that Child 7,

- i. probably did not have autism but he did have convulsions which the General Practitioner believed might make him eligible for the study,

- ii. suffered from bowel problems similar to his brother [Child 6] who had recently been investigated,
 - b. Child 7 was admitted to hospital on 26 January 1997 under Professor Walker-Smith's clinical care,
 - 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,
 - 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;
- '23.
- a. Child 7 underwent the programme of investigations as part of the research study referred to at paragraphs 2.b. and 2.c. above,
 - b. The research study was carried out on Child 7 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,
 - i. paragraph 2.c.i. above,
 - ii. paragraph 2.c.ii. above,
 - 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,
 - 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;

Child 10

- '24.
- a. On 17 February 1997 you carried out a colonoscopy on Child 10,
 - b. The colonoscopy was one investigation in a programme of investigations carried out on Child 10 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 10's clinical history and presenting symptoms, as recorded in his medical records and set out below,

- i. on 14 October 1996 Child 10's General Practitioner referred Child 10 to Professor Walker-Smith stating that,
 - a. Child 10 had a history of loss of acquired skills which appeared to follow a measles-type illness,
 - 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,
- ii. the referral letter made no reference to gastrointestinal symptoms,
- 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,
- iv. Child 10 was admitted to hospital on 16 February 1997 under Professor Walker-Smith's clinical care,
- v. Child 10's admission clerking note recorded,
 - a. that he had been admitted for investigation of disintegrative disorder/measles/IBD,
 - 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,
 - 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,
- 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,
- 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;

- '25. a. Child 10 underwent the programme of investigations as part of the research study referred to at paragraphs 2.b. and 2.c. above,
- b. The research study was carried out on Child 10 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,
- i. paragraph 2.c.i. above,
- ii. paragraph 2.c.ii. above,
- 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,
- d. You carried out a colonoscopy on Child 10 which was not clinically indicated,
- 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,
- 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,
- g. Your conduct as set out above was contrary to the clinical interests of Child 10;

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"),
- 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,
- 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;
- '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,

b. In fact, you did not have ethical approval for the investigations in the circumstances set out in paragraphs 2. to 25. above,

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;'

“And that in relation to the facts alleged you have been guilty of serious professional misconduct.”

**The Panel will be chaired by Dr Surendra Kumar
MB BS FRCGP**