Case No: CO/7039/2010

Neutral Citation Number: [2012] EWHC 503 (Admin)
IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION
ADMINISTRATIVE COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 07/03/2012

Before :

MR JUSTICE MITTING

- -

Between :

PROFESSOR JOHN WALKER-SMITH	**Appellant**
- and -	
GENERAL MEDICAL COUNCIL	**Respondent**

- -

(Transcript of the Handed Down Judgment of
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Official Shorthand Writers to the Court)

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MR STEPHEN MILLER QC AND MS ANDREA LINDSAY-STRUGO
(instructed by **EASTWOODS SOLICITORS**) for the **Appellant**
MISS JOANNA GLYNN QC AND MR CHRISTOPHER MELLOR
(instructed by **FIELD FISHER WATERHOUSE LLP**) for the **Respondent**

Hearing dates: 13th. 14th, 15th, 16th & 17th February 2012

- -

Judgment
As Approved by the Court

MR JUSTICE MITTING :

Procedural history

1. On 15th October 2004 charges of serious professional misconduct brought by the General Medical Council (GMC) against Dr. Andrew Jeremy Wakefield, Professor John Angus Walker-Smith and Professor Simon Harry Murch were referred by the Preliminary Proceedings Committee to a Fitness to Practise Panel (the panel). The hearing took place under the old rules – the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules Order of Council 1988. They required the charges to be established to the criminal standard and for them to be determined in a two stage process: to decide which facts, in addition to those admitted, were proved and whether such facts would be insufficient to support a finding of serious professional misconduct; if not, to decide whether each practitioner was guilty of serious professional misconduct and, if so, what, if any, sanction should be imposed upon him. The hearing began on 16th July 2007. After 149 days of submissions and evidence, the panel began to consider its decision at the end of the first stage. It deliberated in camera for approximately 45 days. On 28th January 2010, it handed down written findings as to the facts which were admitted and which it found proved and its conclusion that they were not insufficient to give rise to a finding of serious professional misconduct. After three further days of submissions and evidence, concluding on 14th April 2010, the panel reserved its decision on the second issues. In a written decision handed down on 24th May 2010, it concluded that Dr. Wakefield and Professor Walker-Smith were guilty of serious professional misconduct, but that Professor Murch was not. It ordered that the names of Dr. Wakefield and Professor Walker-Smith be erased from the register of medical practitioners. Both initially appealed, but Dr. Wakefield has subsequently abandoned his appeal. Professor Walker-Smith challenges the findings made against him at both stages of the procedure and the outcome – that he had been guilty of serious professional misconduct and that his name should be erased from the register. This appeal was originally set down for two weeks. In the event, thanks to the detailed written materials supplied to me before the hearing and, above all to the helpful and thoughtful submissions of Mr. Miller QC, for Professor Walker-Smith and Miss Glynn QC (who did not appear below) for the GMC, the hearing has taken only five days.

Undisputed facts

2. From 1992 until May 1997 Dr. Wakefield was Senior Lecturer in medicine and histopathology and Director of Research of the Inflammatory Bowel Disease Study Group at the Royal Free Hospital School of Medicine. Although trained as a surgeon, he was not a clinician and was not allowed to practise as such. In May 1997 he was promoted to reader in Experimental Gastroenterology at the same hospital. Professor Pounder was head of his department. By the early 1990s, he had discerned a potentially significant correlation between inflammatory diseases of the bowel, in particular Crohn's disease, and measles virus, including that introduced by measles vaccine. On 4th October 1994, he wrote to Dr. Salisbury, Principal Medical Officer at the Department of Health, to express his fear that the programme of re-vaccination of children might cause "a potential catastrophe" in the form of an epidemic of Crohn's disease. On 29th April 1995, the Lancet published a paper by Dr. Wakefield and three other authors, of whom one was Professor Pounder, which suggested that measles

virus, whether contracted naturally or as the intended result of measles vaccine, "has a part in the aetiology of inflammatory bowel disease", in particular Crohn's disease and ulcerative colitis. On 5th May 1995, the Joint Committee on Vaccination and Immunisation convened by the Department of Health, dismissed the research as unsound. Dr. Wakefield's research coincided with the growth of increased public concern about a possible link between the triple vaccine for measles, mumps and rubella (MMR) and the occurrence of developmental disorders in young children, often diagnosed as autism. Some parents had begun to investigate the possibility of litigation against the manufacturers of the MMR vaccine.

3. From 1973 until September 1995, Professor Walker-Smith practised as a Consultant Paediatric Gastroenterologist in the academic departments of child health at St. Bartholomew's Hospital and Queen Elizabeth's Hospital for children. From April 1985 until September 1995, he was Professor of Paediatric Gastroenterology at St. Bartholomew's. In September 1995 he and his team, including his senior lecturer Dr. Murch transferred to the Royal Free Hospital. Before he did so, he sought and received permission from the Ethics Committee of the Royal Free Hospital to continue his and his team's practice of taking two extra mucosal biopsies for research purposes in addition to the four to six biopsies taken for diagnostic purposes during colonoscopy.

4. On 16th September 1996 an application, signed by Professor Pounder on 6th August 1996 as head of the Academic Department of Medicine was made for approval of a research project, entitled "A new paediatric syndrome: enteritis and disintegrative disorder following measles/rubella vaccination". Professor Walker-Smith, Dr. Murch and Dr. Wakefield were named as responsible consultants. Dr. Harvey, a Consultant Neurologist and Dr. Berelowitz, a Consultant Child Psychiatrist, signed as heads of collaborating departments. The application was given the reference number 172-96 by the Ethics Committee and was referred to as "Project 172-96" at the hearing before the panel and in its decision. The hypothesis which it was designed to test was "that in genetically susceptible children, measles vaccination is associated with persistent enteric (and possibly CNS [Central Nervous System]) infection, enteritis and mal-absorption of vitamin B_{12}." Children, referred either by their general practitioner or by the Vitamin B_{12} Unit at Chelsea and Westminster Hospital "who manifest disintegrative disorder and symptoms and signs of intestinal disease" would be admitted to the Malcolm Ward of the Royal Free Hospital for one week under Professor Walker-Smith's care, during which, with fully informed parental consent, they would undergo a number of investigations, including ileocolonoscopy and upper gastrointestinal endoscopy and 10 biopsies, barium meal and follow-through, MRI, EEG, lumbar puncture and a Schilling test. The procedures involved sedation or general anaesthesia. A more detailed description of the two conditions being investigated was given in the text. Disintegrative disorder – Heller's disease – occurred when normally developing children show marked behavioural changes and developmental regression after age 2 often in association with bowel or bladder problems. Enteritis was manifested by pain, bloating, constipation and diarrhoea, steatorrhoea and failure to thrive. Both behavioural and intestinal disturbances occurred in parallel. Two working hypotheses were set out for the possible link between measles/rubella vaccine in a previously healthy child and the subsequent development of enteritis, Cbl deficiency and disintegrative disorder. Project 172-96 was drafted by Dr. Wakefield. The timing of its genesis was uncertain, but the text of

a proposed clinical and scientific study, bearing the same heading (but with a question mark at the end) was submitted by Dawbarns, a firm of solicitors who proposed to conduct litigation on behalf of children thought to have been damaged by MMR vaccine to the Legal Aid Area Office dealing with funding for the claims, on 6th June 1996. The GMC suggested that the first proposals for the study may have pre-dated a draft summary of the information to be given to parents which was included in the documents supplied to the Ethics Committee which bore the date 12th October 1995.

5. In the light of Dr. Wakefield's developing views and of subsequent events, there are two curious features of Project 172-96; the hypothesis to be tested was the link between enteritis and disintegrative disorder – not autism – and measles/rubella vaccination – not MMR vaccination. As Professor Rutter explained to the panel, disintegrative disorder is a recognised, but rare condition, which psychiatrists distinguish from autism; and Dr. Wakefield's concern then and subsequently was primarily focussed on MMR vaccine, not on single or double vaccines. A costing proposal, which Dr. Wakefield admitted that he had provided to Dawbarns which was also supplied by them to the Legal Aid Area Office on 6th June 1996, stated that the objective of the protocol described in it was to seek evidence of the causative connection between either MMR or measles/rubella vaccines and Crohn's disease and inflammatory bowel disease and symptoms akin to autism. The cost per child of investigating the "new syndrome" of enteritis/disintegrative disorder covered four nights stay in hospital, plus colonoscopy, MRI and subsequent analysis. The GMC did not suggest that Professor Walker-Smith knew of the existence of this document or proposal until 2004, at the earliest.

6. Project 172-96 was approved for registration by Dr. Pegg, Chairman of the Ethics Committee, on 13th September 1996. On 15th October 1996, Dr. Pegg wrote to Professor Walker-Smith telling him that Project 172-96 would be discussed at the next meeting of the Ethics Committee. He set out his reservations and invited comments. He categorised some of the investigations as "high risk", in the categorisation adopted by the British Paediatric Association in guidance published in August 1992, which advised that it would be unethical to submit child subjects to more than minimal risk when the procedure offers no or a slight or very uncertain benefit to them. Accordingly, he sought confirmation "that the child would undergo this regimen even if it was not in a trial". He also raised a query about the consent form which parents would be required to sign before the investigations required by the study were performed on their child. This elicited a reply from Professor Walker-Smith dated 11th November 1996, the relevant part of which states:

> "…Clearly this is an intensive regime with procedures that could be regarded as "high" risk although they are particularly used for the investigation of children with chronic inflammatory bowel disease. These children suffer from a disease with a "hopeless prognosis" in relation to their cerebral disintegrative disorder. They have often not had the level of investigation which we would regard as adequate for a child presenting with such a devastating condition. In relation to their gastrointestinal symptoms which will be present in all the children we investigate, these have often been under-investigated. We have so far investigated five such children on

> a clinical need basis, all in fact have proved to have evidence of chronic bowel inflammation. One child has already had a significant response to enteral feeding. Certainly there is a measurable benefit to the child:
>
> i) establishing a diagnosis and excluding metabolic and other causes.
>
> ii) commencing on a therapeutic regime.
>
> This whole study is parent/patient driven as every case referred has been initiated by the GP by the parents of the child.
>
> I can confirm that children would have these investigations even if there were no trial. I must make clear that we would not be investigating children without gastrointestinal symptoms."

On 13th November 1996, the Ethics Committee discussed Project 172-96. The minutes record that it was not approved: "improvements required on patient information sheet and clarification as to whether this is a study or normal patient investigation". Confusingly, the secretary to the Ethics Committee wrote to Dr. Wakefield on 14th November 1996 to tell him that Project 172-96 was approved at the meeting. That did not happen until the next meeting, held on 18th December 1996, at which it was approved, "subject to modification of patient consent form and removal of Schilling test". On 7th January 1997 Dr. Pegg wrote to Professor Walker-Smith notifying him of that approval, subject to three conditions: only patients enrolled after the date of the December meeting would be considered to be in the trial; the Schilling test was to be removed from the protocol; and the consent form was to be modified so that possible complications of lumbar puncture were explained. He also required the patient consent form and information sheet to be lodged with the clinical notes. Professor Walker-Smith acknowledged Dr. Pegg's letter on 9th January 1997. On the same date, he sent his clinical team and Dr. Wakefield a copy of the Ethics Committee's recommendations "for our study" and said "we need to implement this now". On 3rd February 1997, Dr. Wakefield wrote to Dr. Pegg telling him that "the pilot study" had demonstrated that MRI and EEG studies were all normal so that there was no need to continue them unless specifically indicated. He requested an amendment to authorise overnight fasting and an analysis of a urine sample to investigate intestinal permeability. On the same date, Dr. Wakefield wrote to Professor Walker-Smith to explain why he thought it right to become involved in what he described as "the legal aspect of these cases" – i.e. the litigation then being proposed by Dawbarns, pursuant to which the Legal Aid Board had provided £25,000 in December 1996 towards the costs of the "MMR investigation". Professor Walker-Smith responded on 20th February 1997:

> "My position as with measles, MMR and Crohn's disease is that the link with MMR is so far unproven. It is clear that the legal involvement by nearly all the parents will have an effect on the study as they have a vested interest. I myself simply will not appear in court on this issue.
>
> I would have been less concerned by legal involvement if our work were complete and we had a firm view. Never before in

> my career have I been confronted by litigant parents of research work in progress. I think this makes our work difficult, especially publication and presentation.
>
> I am very excited by this work and it is very worthwhile. Simon Murch and I met today and have drawn up a draft for patient selection for your comment please."

That document set out primary and secondary criteria for "patient selection for study of enterocolitis and regressive autism". It is dated February 1997.

7. Between 21st July 1996 and 16th February 1997 eleven children were admitted to the Malcolm Ward at the Royal Free Hospital for investigation under Professor Walker-Smith and his team. The case histories of those eleven children plus a twelfth child were subsequently summarised in a paper published in the Lancet under the heading "Early report ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children" on February 28th 1998. I will deal with the issues which arise out of the publication of that paper under the heading "The Lancet Paper" below. At a press conference, which Professor Walker-Smith did not attend, convened to accompany publication, Dr. Wakefield stated publicly the view which he had previously expressed privately to Professor Walker-Smith that he could no longer support the giving of MMR vaccine. The joint view of Professor Walker-Smith and Dr. Murch, stated in a letter to Dr. Wakefield on 21st January 1998, was that it was inappropriate to emphasize the role of MMR vaccine in publicity about the paper and that they supported government policy concerning MMR until more firm evidence was available for them to see for themselves. They published a press release to coincide with publication stating their support for "present public health policy concerning MMR". Dr. Wakefield's statement and subsequent publicity had a predictable adverse effect upon the take up of MMR vaccine of great concern to those responsible for public health. There is now no respectable body of opinion which supports his hypothesis, that MMR vaccine and autism/enterocolitis are causally linked.

8. Despite the justified reservations of Professor Walker-Smith and Dr. Murch about Dr. Wakefield's hypothesis, they were both convinced that the investigations into the twelve "Lancet children" had been of diagnostic value for all of them and therapeutic value for most of them. On 14th October 1997, Professor Walker-Smith wrote to Dr. Salisbury, following a meeting at the Department of Health:

> "On the issue of autism, I am completely astounded by the clinical features of these children with autism and bowel inflammation. Very often the gastrointestinal symptoms have been ignored by a succession of the doctors and the findings on ileo-colonoscopy appear to be quite distinctive. This seems to me a whole new syndrome which is in urgent need of clarification".

That was the conclusion of the published paper.

A fundamental issue: the distinction between medical practice and research

9. At the heart of the GMC's case against Professor Walker-Smith were two simple propositions: the investigations undertaken under his authority on eleven of the twelve Lancet children were done as part of a research project – Project 172-96 – which required, but did not have, Ethics Committee approval; and they were clinically inappropriate. Professor Walker-Smith's case was that the investigations were clinically appropriate attempts at diagnosis of bowel and behavioural disorders in children with broadly similar symptoms and, where possible, treatment of the bowel disorders or alleviation of their symptoms. The GMC's case was that he was conducting research which required Ethics Committee approval. His case was that he was conducting medical practice which did not. Accordingly, an unavoidable and fundamental question which the panel had to answer was: what is the distinction between medical practice and research?

10. Both parties made careful and extensive submissions about the issue to the panel. The GMC's case was that "the question of whether a set of procedures undertaken on a group of patients is or is not research must…be an objective one". Professor Walker-Smith's case was that it was his intention which was determinative.

11. The basic distinction between medical practice and research can be simply stated: the aim of medical practice is to benefit the individual patient; the aim of research is to improve the stock of knowledge for the benefit of patients generally. Both sides accepted the basic definition given in the January 1990 guidance of the Royal College of Physicians in the report entitled "Research involving patients":

> "What constitutes research in patients?
>
> 2.2 When an activity is undertaken solely with the intention of benefitting an individual patient, and where there is a reasonable chance of success, the activity may be considered to be part of "medical practice". The progressive modification of methods of investigation and treatment in the light of experience is a normal feature of medical practice and is not to be considered as research.
>
> 2.3 In contrast, where an activity involving a patient is undertaken with the prime purpose of testing a hypothesis and permitting conclusions to be drawn in the hope of contributing to general knowledge, this is "research". The fact that some benefit expected or unexpected, may result from the activity does not alter its status as research".

12. What was, and was not, "medical practice" and "research" was a matter of judgment for the panel. The distinction between the two is not straightforward as the Royal College itself acknowledged in paragraph 2.4 of its report:

> "The distinction between "medical practice" and "research" is often less clear than is suggested above because both are practised simultaneously".

Its own guidance hovers between an objective and a subjective test. The concluding sentence of paragraph 2.4 states,

> "Any activity which affects the patient in any way which is additional to ordinary medical practice is to be regarded as research".

Yet in paragraph 3.1 of a report published at the same time, "Guidelines on the practice of Ethics Committees in medical research involving human subjects", the Royal College restated the importance of intention:

> "The definition of research continues to present difficulties, particularly with regard to the distinction between medical practice and medical research. The distinction derives from the *intent*. In *medical practice* the sole intention is to benefit the *individual* patient consulting the clinician, not to gain knowledge of general benefit, though such knowledge may incidentally emerge from the clinical experience gained. In *medical research* the primary intention is to advance knowledge so that *patients in general* may benefit; the individual patient may or may not benefit directly".

Again, in the opening sentence of paragraph 3.2 of the same report,

> "Thus, when a clinician departs in a significant way from standard or accepted practice entirely for the benefit of a particular individual patient, and with consent, the innovation need not constitute research, though it may be described as an experiment in the sense that it is novel and un-validated".

13. If, as both parties urged upon the panel, its starting point was the guidance given by the Royal College, it could not reasonably have concluded that the intention of the practitioner was irrelevant to the determination of the question, medical practice or research?; or even that it was of little weight. The guidance, read as a whole, treats the intention of the person conducting the activity as an essential factor in the determination of the difference. For this purpose, there is no practical difference between "intention" and "purpose" in paragraphs 2.2 and 2.3 of the first paper, as paragraph 3.1 of the second makes plain. The purely objective test proposed by the GMC is not a reasonable interpretation of the Royal College's guidance. If the panel had founded its determination on the GMC's interpretation of the guidance, it would have been wrong to do so.

14. It is unclear from its written determination what, if anything, the panel did decide about this important basic issue. It made no finding at all upon it. Its only comment on research ethics was to state that it accepted the uncontroversial guidance given by the British Paediatric Association in guidelines published in August 1992 (the reference in the determination to "RCP, 1990" is mistaken) that in relation to children "if research is of no therapeutic benefit then it can be of no more than minimal risk".

15. The issue is of critical importance to the case for and against Professor Walker-Smith, not least because of the advice given to the panel by the legal assessor Nigel Seed QC:

> "Whether or not the individual doctor's intention at the time is relevant is a significant issue in dispute between the parties and you have their respective submissions on that and the relevant guidelines. If you are sure that the GMC is right when it submits that the intention of the individual doctor is not relevant you do not have to go on to consider the individual intentions. If, however, you think that the doctor's submissions are right or might be right – that the intention at the time is a relevant consideration – then you must consider the intention of each doctor separately".

Thus, if the panel accepted that the GMC's interpretation of the guidance was correct, it would have decided that if what was being undertaken by Professor Walker-Smith was, objectively viewed, research, he would have been undertaking research even if his sole intention was to benefit his patients. Given the absence of any finding about Professor Walker-Smith's state of mind (as to which see more below), that is a conclusion which the panel may well have reached. If it did, it would not have been a sustainable finding.

16. Given that conclusion, it is neither necessary nor desirable that I should express a dogmatic view about the meaning of the guidance. I understand the GMC's concern that a purely subjective test would significantly water down the obvious requirement for medical research to be approved and monitored by Ethics Committees: if the intention of the practitioner is the sole or even principal determinant, that undesirable result may occur. The control mechanism is to be found in the second requirement in paragraph 2.2 for medical practice – there must be a reasonable chance of success. That test is objective, even if qualified by the *Bolam v. Friern Hospital Management Committee* [1957] 1WLR 582 principle, but it cannot resolve all difficulties. When the person undertaking the activity has two purposes or when different people participating in the same series of activities have different purposes, it may be very difficult to say into which category the activities fall. This difficulty is particularly likely to arise in activities undertaken by an academic clinician and/or in a teaching hospital with a research department. These difficulties arose in this case: Dr. Wakefield's purpose was undoubtedly research; Professor Walker-Smith's may have lain anywhere on the spectrum. It was for the panel to determine where it did; but first, it had to determine what his intention in fact was.

Professor Walker-Smith's intention

17. The panel made no express finding on this issue and cannot have appreciated the need to do so. It was not helped by the premise upon which the GMC's case was founded. There was a good deal of evidence, to which I refer in greater detail below, that Professor Walker-Smith and his team were undertaking what any reasonable body of medical practitioners would categorize as research – but also that he intended and genuinely believed that what he was doing was solely or primarily for the clinical benefit of the children. When such an issue arises, a panel will almost always have to determine the honesty or otherwise of the practitioner. The issue arose starkly in this case. In his letter to Dr. Pegg of 11th November 1996, cited in paragraph 6 above Professor Walker-Smith expressly stated that he and his team had so far investigated five children with gastrointestinal symptoms who also suffered from a disease categorized as cerebral disintegrative disorder "on a clinical need basis" with a

measurable benefit for them: establishing a diagnosis and excluding metabolic disorder and commencing a therapeutic regime. He could not have honestly written that statement if his primary purpose was to test a hypothesis for the benefit of others. He was aware of the need to obtain Ethics Committee approval for research – hence, the application for Project 172-96 and his earlier application for permission to take two extra biopsies for research purposes. The statement was either a lie told to Dr. Pegg and to the Ethics Committee or a genuine statement of belief which must have reflected his original intention in authorising the investigative procedures (which I will deal with in detail in the case of each of the eleven Lancet children). Further, the letter contained an unmistakeable implied statement: that investigations under Project 172-96 had not yet begun.

18. I am told by Miss Glynn that the GMC, after careful consideration, decided not to accuse Professor Walker-Smith of lying to Dr. Pegg and the Ethics Committee. Accordingly, their case was that he was in fact undertaking research, which required Ethics Committee approval, without realising that he was doing so. This is an untenable proposition, as the analysis of the letter of 11th November 1996 above demonstrates. In consequence, not only was the panel invited by the GMC not to determine Professor Walker-Smith's intention, it was also invited not to determine his truthfulness in his dealings with the Ethics Committee.

19. The following is a non-exhaustive list of the principal facts from which the panel might have inferred that Professor Walker-Smith did intend to test a hypothesis and so misled the Ethics Committee or did not do so.

Facts supporting the proposition

a) It was Dr. Wakefield who first perceived a link between behavioural and gastrointestinal disorders and between both and measles/measles vaccines. As a researcher, he was, throughout, principally interested in testing his hypotheses. Dr. Wakefield played an unusual role for a researcher in the referral of many of the Lancet children to the clinical team for investigation.

b) Between April and September 1996 (a period spanning the admission of the first three children, beginning with child 1 on 21st July 1996) Professor Walker-Smith wrote to Dr. Wakefield, to the parents of children 2 and 6 and to other medical practitioners referring to a "plan" or "programme" for investigation, to a "proposed" or "forthcoming" study and to "our study of autism and bowel disorder". He also suggested sending a copy of Project 172-96 to the mother of child 2 and did send a copy of it to the local Consultant Paediatrician for child 9.

c) There was no complete written clinical protocol separate from Project 172-96.

d) The investigations carried out on the Lancet children substantially replicated those set out in Project 172-96 and did so irrespective of the detailed clinical history and presentation of each child.

e) The Lancet paper contained a statement that investigations had been approved by the Ethics Committee. No other investigations apart from Project 172-96

and the general permission to take two additional biopsies given to Professor Walker-Smith had been so approved.

(I will deal with the cases of the individual children, the expert evidence relating to them and with the Lancet paper in detail below.)

Facts negating the proposition

i) None of the five clinicians involved in the investigation of the Lancet children who gave evidence to the panel considered that they were following Project 172-96.

ii) None of the children fitted the hypothesis to be tested under Project 172-96, in that none of them had both received a single or double vaccine and had developed disintegrative disorder. The great majority had received MMR vaccine and been diagnosed with autism.

iii) No parent was required to sign either the consent form in the proposals submitted to the Ethics Committee or in the revised form approved by it. With one exception (child 2 – see paragraph 34 below) the only consent forms signed were for diagnostic colonoscopy and the additional research biopsies approved in September 1995.

iv) In every case investigations were followed by a discharge letter prepared by Dr. Casson which set out a diagnosis of the child's condition and by a recommendation for treatment. In some cases, the treatment produced an apparent marked improvement in gastrointestinal symptoms and behaviour.

v) Dr. Pegg was not the only responsible person to whom Professor Walker-Smith stated that the investigations were clinically indicated; he told Mr. Else, Chief Executive of the Royal Free NHS Trust that they were, as Mr. Else confirmed to Dr. Wakefield on 4th September 1996; he gave a lecture at the Wellcome Trust on 20th December 1996 in which he spoke of the investigations and gastrointestinal diagnoses of the first seven Lancet children; on 6th February 1997, he wrote to Dr. O'Connor, a Consultant in Public Health Medicine responsible for funding the referrals of children 6 and 7 to him, enclosing a five page explanation of the rationale, aims and potential therapeutic implications of the investigations, in which he and Dr. Wakefield set out the clinical justification for them. Although the latter document was described by the GMC as "defensive" it was never suggested to Professor Walker-Smith that he deliberately misled his interlocutors about his intention.

vi) Professor Walker-Smith had no rational motive to begin research before it was authorised, carry it out in breach of the requirements of the Ethics Committee after it was authorised or deliberately to mislead the Ethics Committee and others about his intention. Unlike Dr. Wakefield, he was agnostic or cautious about the claimed link between MMR and autism and gastrointestinal disorders. On 29th and 31st July 1997 he wrote privately to Dr. Wakefield to express his and Dr. Murch's concern that their professional reputation would be damaged by association with work prematurely leaked to the media.

vii) As Miss Glynn accepts, a clinical protocol can, in principle, prescribe multiple identical investigations into patients with complex and intractable problems in an attempt to diagnose their condition.

(Again, I deal with the cases of individual children and the Lancet paper below).

20. These, and no doubt other factors, required to be considered by the panel. If the panel did consider them, some explanation of its decision upon them should have been given in its determination. All that it said on the first issues was:

> "The panel has heard that ethical approval had been sought and granted for other trials and it has been specifically suggested that Project 172-96 was never undertaken and that in fact, the Lancet twelve children's investigations were clinically indicated and the research parts of those clinically justified investigations were covered by Project 162-95 [the general permission given to Professor Walker-Smith in September 1995]. In the light of all the available evidence the panel rejected this proposition."

In its decision on the second issues, it reiterated that conclusion, without explaining its reasons for doing so further. It hinted at lack of probity on the part of Professor Walker-Smith, without expressly finding that he had acted without probity and/or explaining its reasons for doing so:

> "The conditions for approval for Project 172-96 and the inclusion criteria for it were not complied with and thus the expectation of the Ethics Committee and their reliance on the probity of Professor Walker-Smith as a responsible consultant were not met".

Its conclusion that Professor Walker-Smith was guilty of serious professional misconduct in relation to the Lancet children was in part founded upon its conclusion that the investigations into them were carried out pursuant to Project 172-96. The only explanation given for that conclusion is that it was reached "in the light of all the available evidence". On any view, that was an inadequate explanation of the finding. As it may also have been reached upon the basis of two fundamental errors – that Professor Walker-Smith's intention was irrelevant and that it was not necessary to determine whether he had lied to the Ethics Committee, it is a determination which cannot stand unless it is justified by the detailed findings made in relation to the eleven relevant Lancet children.

The Lancet children

21. Separate groups of charges were laid in respect of each of the eleven Lancet children. Each set out a number of undisputed facts about the admission of the child and the investigations performed. There were minor differences about facts of marginal importance and failures in record keeping which could not give rise to findings of misconduct, let alone serious professional misconduct. The significant charges were as follows:

i) In relation to all eleven children, that Professor Walker-Smith subjected them to a programme of investigation for research purposes without Ethics Committee approval (either because the investigations were carried out before approval was given or because the childrens' condition did not meet the selection criteria or because they were carried out in breach of the conditions of approval).

ii) In relation to all but two of the children (6 and 7) he caused them to undergo colonoscopy although it was not clinically indicated.

iii) In relation to seven of the children (all but 4, 6, 7 and 10) he caused them to undergo barium meal and follow through although not clinically indicated.

iv) In relation to three of the children (3, 9 and 10) he caused them to undergo a lumbar puncture which was not clinically indicated.

v) In relation to all eleven children, his conduct was contrary to their clinical interests.

Allegations (ii) and (iii) stood or fell together: if colonoscopy was not clinically indicated, barium meal and follow through – a procedure designed to investigate part of the bowel which colonoscopy and endoscopy could not reach – would also not have been clinically indicated. It was not suggested that if colonoscopy was clinically indicated, barium meal and follow through would not be.

22. Although the panel found that child 4 was investigated under Project 172-96 without Ethics Committee approval, it found that Professor Walker-Smith was not responsible for subjecting him to the investigations (because he did not see this child until after he had been admitted) but did find that he had failed to comply with his duties to the Ethics Committee as a named responsible consultant on the basis that he had joint overall responsibility for the project. This finding did not lead to a finding of serious professional misconduct in respect of child 4 and is not the subject of a specific ground of appeal. This finding stands or falls with the overall finding that the investigations of the Lancet children were undertaken under Project 172-96 and adds nothing to it.

23. Expert evidence was given on both sides about the ten remaining children: Professor Sir Michael Rutter and Professor Ian Booth for the GMC; and Dr. Neil Thomas and Dr. Victor Miller for Professor Walker-Smith. Various criticisms were made of the experts on both sides: that as a Child and Adolescent Psychiatrist, Professor Rutter was less well qualified to comment on neurological issues than Dr. Thomas, a Consultant Paediatric Neurologist; that Professor Booth was opinionated and had become an advocate for everything for which the GMC contended, rather than an independent expert commenting objectively on the facts; and that Dr. Miller was inadequately qualified as an academic clinician and, by reason of long professional association with Professor Walker-Smith, lacked objectivity. No criticism was made of Dr. Thomas. It is a striking feature of the panel's decision that it expressed no view about the expertise and objectivity of the experts; and even more striking that, when their views were in conflict, it expressed no conclusion about which of them it preferred. This is a serious weakness in its reasoning, frankly acknowledged by Miss

Glynn. I would go further. In the case of each child, the experts were asked to consider whether the investigations undertaken were clinically indicated and, if not, contrary to the clinical interests of the child. It was common ground that the *Bolam* test applied to both issues. When, as was in fact the case, Dr. Miller and Dr. Thomas expressed the view, respectively, that colonoscopy (and if appropriate barium meal and follow through) or lumbar puncture were clinically indicated and were not contrary to the clinical interests of the child, a finding that their view was not one held by a responsible body of medical opinion would have been an essential pre-requisite to the dismissal of their evidence in respect of that child. The panel made no such finding. Miss Glynn, recognising the difficulty it creates for the GMC, has attempted to analyse the case of each child, to show that, despite the lack of an express finding, the panel must have preferred the opinion of Professor Rutter and Professor Booth to that of Dr. Thomas and Dr. Miller; and in her skeleton argument she has sought to demonstrate why that must be so. Even if that exercise is permissible on appeal, which I doubt, it does not go far enough. It would be necessary for her to demonstrate that the panel must have rejected the opinion of Dr. Miller and, in part, of Dr. Thomas, as being outside the ambit of responsible medical opinion. She has not attempted that task, sensibly recognising that the material which would permit it to be discharged cannot be found in that submitted to the panel.

24. I now turn to the cases of the ten relevant Lancet children. I deal with them in the same order as that set out in the charges.

Child 2

25. Child 2 was born on 29th July 1988. MMR vaccine was given on 8th November 1989. Global developmental delay was first diagnosed in February 1991. Diarrhoea was first noted in the general practice records in January 1992. "Autistic-like regression" was first suggested in a joint report of April 1992 by Dr. Cass a Senior Paediatric Registrar and Miss Price a Speech Therapist at the Woolfson Centre. In September 1992 Dr. Warner a Professor of Child Health at Southampton General Hospital suggested a diagnosis of Asperger's Syndrome. Various non-invasive investigations were undertaken at the same hospital. An assessment was made at its children's centre in February 1993 and a provisional diagnosis of autism made. In August 1993, he was referred to Dr. Cavanagh, a Consultant Paediatric Neurologist, at Chelsea and Westminster Hospital to assess his behavioural and bowel symptoms. Dr. Cavanagh considered that his history pointed strongly to an underlying dietary sensitivity. In January 1994, Dr. Tuck, a Consultant Paediatrician at Peterborough District Hospital thought that his clinical picture fitted well with Asperger's Syndrome. By March 1995, Dr. Cavanagh had detected some improvement; his parents felt that he was calmer and no longer had diarrhoea. However, by then, child 2's parents and his general practitioner Dr. Cartmel were at a loss to understand the underlying cause of his condition or how it might be permanently treated or alleviated. On 20th March 1995, his general practitioner sought the assistance of Dr. Wozencroft, a Consultant in Child and Family Psychiatry at Peterborough District Hospital.

26. On 29th June 1995 Dr. Wozencroft wrote to Professor Walker-Smith asking him to see child 2. He expressed the view that he and child 2's parents felt that there was a strong physical component to his difficulties, which were all deteriorating. Professor Walker-Smith saw him at St. Bartholomew's on 1st August 1995. In the clinical history sheet written by him, he accurately summarised child 2's history. On 4th

August 1995, he wrote to Dr. Wozencroft and to Dr. Cavanagh. In his letter to the latter he said that child 2 had been referred to him via Dr. Wakefield because of his mother's perception that his illness began with MMR and because of a possible link between measles and Crohn's disease. He said that there was nothing to suggest a diagnosis of Crohn's disease and that his gastrointestinal condition sounded more like multiple food allergy/irritable bowel syndrome than inflammatory bowel disease or coeliac disease. He said that he had done routine blood markers and planned to review him again, at the Royal Free Hospital, in two months time. He told Dr. Wozencroft that there was no evidence of Crohn's disease. After seeing child 2 again at the Royal Free Hospital or reviewing his file (it is not clear which) he wrote to Dr. Cartmel, Dr. Wozencroft and Dr. Cavanagh on 13th September 1995 and stated that he thought inflammatory bowel disease was extremely unlikely. As a result of observations made by Dr. Bhatt at the Vitamin B_{12} Unit at Chelsea and Westminster Hospital, he thought that the best way forward was a Schilling test.

27. Meanwhile, child 2 was seen by Dr. Beattie, a Consultant Paediatrician at Peterborough District Hospital, who referred him to Dr. Hunter, a Consultant Physician at Addenbrooke's. His main research interest was the role of food intolerance in the pathogenesis of gastrointestinal disease. He prescribed a diet which child 2's mother thought had led to considerable improvement – an observation confirmed to Dr. Beattie by her on 12th June 1996.

28. On 16th May 1996, Professor Walker-Smith wrote to child 2's mother in the following terms:

> "I think it would be very helpful if I saw (child 2) again. I have had discussions about (child 2) with Dr. Wakefield. We have a plan for investigation but I think if it were convenient for you, it would be helpful for me to see (child 2) first in the outpatients and discuss and plan what we have in mind…"

A slightly postponed outpatient appointment was fixed for 21st June 1996, at which child 2 was examined by Professor Walker-Smith.

29. On the basis of this letter, the GMC suggested that it was Professor Walker-Smith who invited child 2 to be assessed at his outpatient clinic. Given the terms of the letter, the suggestion was unsurprising. However, the panel found that it was ill-founded – not in the part of its determination which dealt with the admission of child 2, but in that part which dealt with the Lancet paper. The panel accepted Professor Walker-Smith's evidence that he had written to child 2's mother on 16th May 1996 in response to her telephone call saying that her child's symptoms had worsened. In the history sheet dated 21st June 1996, Professor Walker-Smith noted that after he had last seen child 2, he had had diarrhoea, weight loss and been very ill. He recorded the exclusion diet prescribed by Dr. Hunter and that his behaviour was now stable and that he was much calmer then when last seen. He noted: "Arrange admission with Dr. Wakefield".

30. On 28th June 1996, he wrote to Dr. Cartmel, Dr. Hunter and Dr. Wakefield. He said that he thought that Crohn's disease was unlikely, but that Dr. Wakefield had the view that there "may be some kind of other inflammation which may be a relevant factor in (child 2's) illness and we now have a programme for investigating children who have

an association with autism and a possible reaction to immunisation". He told Dr. Hunter that he had been asked "via" Dr. Wakefield to consider doing a colonoscopy and general assessment to consider whether bowel inflammation of some kind might be playing a role in his illness. He said to Dr. Wakefield that "I think he is now the most appropriate child to begin our programme" and that child 2's mother might like a copy of "the protocol that we are using". Dr. Hunter replied on 3rd July 1996, explaining the treatment which he had prescribed for child 2 and stating that he would have been reluctant to do a colonoscopy.

31. Meanwhile, child 2 was also referred, perhaps by Dr. Hunter, to Dr. Cass at University College and Middlesex School of Medicine. She noted that there was a lack of an established neuropathological basis for child 2's condition, but that the key changes observed by his mother included an episode, albeit less severe than earlier major regressions, of illness and withdrawal, lasting about six weeks, in January 1996. In her opinion it was important to investigate child 2 for "the full range of neurodegenerative conditions" for which purpose she had arranged a joint consultation with Dr. Surtees at Great Ormond Street Hospital on 22nd August 1996. The notes of that examination include Dr. Surtees's note that he should undergo an MRI scan and EEG and, by necessary inference, lumbar puncture (hence, the note on the left hand margin of the second page of the clinical notes in Dr. Surtees's handwriting, "metabolic – CSF lactate"). He confirmed his recommendations apart from lumbar puncture to Dr. Cass, by then a senior lecturer in paediatric neurology, in a letter of 23rd August 1996. The recommendations which he made mirrored the neurological investigations which were actually carried out on child 2 and the other children. On 2nd September 1996, the day after child 2 was admitted to the Royal Free Hospital for investigations, he sent a copy of that letter by fax to Dr. Thomson the third Consultant Paediatric Gastroenterologist in Professor Walker-Smith's team and, according to Dr. Murch, discussed child 2 with him. In his handwriting on the fax cover sheet is the following:

> "<u>CSF</u>
>
> Protein electrophoresis
>
> Measles Ab
>
> Cytokines
>
> Lactate, pyruvate, glucose".

The irresistible inference is that Dr. Thomson discussed the reasons for obtaining cerebrospinal fluid by a lumbar puncture with Dr. Surtees and agreed with him that one of the purposes would be to exclude metabolic disorder – hence, "lactate, pyruvate, glucose". Dr. Thomson and Dr. Casson also made handwritten notes on a typed protocol for investigations of possible degenerative disorders of the CNS, which Dr. Thomson had brought with him from the Birmingham Children's Hospital where he practised before his move to the Royal Free Hospital.

32. Child 2 was admitted to the Royal Free Hospital for investigations on 1st September 1996. Professor Walker-Smith was in Scotland for the whole of that week and played no part in the investigations. The endoscopy clerking sheet, completed by a junior

doctor, records that the reason for the proposed colonoscopy biopsy and Schilling test was "chronic diarrhoea". The clinical notes, in Dr. Casson's handwriting, which are misdated 20/09/96, but were in fact made on 2nd September 1996 begin,

> "Referred for Ix [investigation] of ? assoc between GI [gastrointestinal] disease/autism/measles"

A lengthy and detailed clinical history is then set out. Towards the end, Dr. Casson noted that child 2 had "started going down hill again" and had been to the B_{12} Unit at Chelsea and Westminster. He described his current condition as follows:

> "Presently → has "episodes" about every 18 months. Last in April. Last up to 3/52.
>
> ? Association jaundice and pale stools.
>
> Poor sleep, increased diarrhoea, screaming."

He then noted that he had been prescribed an exclusion diet and bacteria by Dr. Hunter at Addenbrooke's which seemed to have eased abdominal pain.

33. Colonoscopy was performed on the 2nd September 1996 by Dr. Murch. His report of the same date noted that colonoscopy was "performed in the further investigation of disintegrative disorder" and was abnormal in the following respects: minor abnormalities of the vascular pattern in the rectum; one definite aphthoid ulcer near the hepatic flexure; multiple prominent colonic lymphoid follicles, each with an erythematous rim and a central pale swollen core in the caecum; and lymphoid nodular hyperplasia in the terminal ileum. The histology report of 5th September 1996 confirmed a mild patchy generalised increase in inflammatory cells with lymphoid aggregates and follicles, in keeping with low grade quiescent inflammatory bowel disease.

34. On 3rd September 1996 Dr. Casson noted that a Schilling test was to be performed on Thursday "as per protocol". Dr. Casson said in evidence that he presumed it was a reference to the timetable of planned investigations which was ultimately submitted to the Ethics Committee. Dr. Murch said that he thought that it referred to a protocol for performing a Schilling test. Dr. Murch's suggestion, which was not put to Dr. Casson (a forensic omission which cannot be laid at the door of Professor Walker-Smith) appears to be supported by an otherwise unexplained consent form, signed by child 2's mother, giving her consent to his participation in a "cohort study to evaluate the role of polymeric nutrition in children with Crohn's disease" which, according the form, had been approved by the local research ethics committee. This form immediately precedes the results of the Schilling test. It may relate to it. Dr. Casson's "presumption" may well have been wrong.

35. Dr. Berelowitz saw child 2 with his mother on 5th September 1996. She told him that she was confident that changes in his diet affected his behaviour and he had diarrhoea from 20 months, "largely unabated". Dr. Berelowitz summarised his opinion in a letter to Dr. Murch dated 30th September 1996, in which he also stated his provisional diagnosis: that child 2's history and presentation were very typical of autism or a

related disorder. He concluded by saying that he awaited "the next patient with considerable interest".

36. On 16th September 1996, Dr. Casson wrote his discharge report to Dr. Cartmel. He began by saying that child 2 had been admitted "for further investigation of several problems" and then set out the detailed and comprehensive clinical history which he had already recorded in the clinical notes. He described the investigations performed and the available results, which revealed "a significant finding of patchy inflammation within the colon". He noted the treatment plan proposed: an enteral feeding regime using CT3211. He said that child 2 would be reviewed in clinic in two weeks time and would have to undergo a repeat colonoscopy after having been on the diet for eight weeks.

37. On 2nd October 1996, child 2 was seen at outpatient's clinic by Professor Walker-Smith and Dr. Fell, a Research Fellow in Paediatric Gastroenterology at the Royal Free Hospital. On 4th October 1996, Dr. Fell wrote to Dr. Beattie stating the child 2 was responding very well to the course of enteral nutrition.

38. On 10th November 1996, child 2 was re-admitted for a follow up colonoscopy. Dr. Fell's colonoscopy report noted normal findings apart from a slightly abnormal vascular pattern in the sigmoid colon, with follicles visible. The histologist's report stated that the specimens received were within normal histological limits.

39. Dr. Berelowitz again saw child 2, on 12th November 1996. He could see no change in his behaviour, although his mother reported a dramatic improvement.

40. Professor Walker-Smith saw child 2 at his clinic on 27th November 1996. On 2nd December 1996 he wrote to the school doctor at child 2's special school, noting that his behaviour had altered quite significantly with a series of food re-introductions. He seemed altogether better when on CT3211 as the sole form of enterel feeding. On 13th December 1996, he wrote again, stating that child 2 had been treated with enteral feeding "as if he were Crohn's disease" with good effect: repeat endoscopy had revealed disappearance of inflammation. Dr. Wozencroft noted the same improvement in a letter to Dr. Cartmel of 17th December 1996: he looked "enormously better" – an improvement ascribed to his liquid diet.

41. Child 2 continued to be seen intermittently by Professor Walker-Smith at the Royal Free Hospital until his retirement in October 2000 and by Dr. Murch, before and after it. Their purpose then was clearly therapeutic.

42. The evidence that child 2 was admitted in September 1996 for the purpose of undergoing a systematic set of gastrointestinal and neurological investigations is compelling and undisputed. There is no challenge to the panel's finding that Dr. Wakefield's purpose was research: to investigate and, if possible, demonstrate the link between MMR vaccine, regressive autism and gastrointestinal disorders. The critical question in the case of Professor Walker-Smith was whether that was his primary purpose as well. His evidence was that his purpose was to attempt to find out what was wrong with child 2 – something which no previous investigation had achieved. He thought that he had been over cautious in 1995 in not suggesting a colonoscopy. He accepted that the idea that there might have been a kind of bowel inflammation in a child who had had MMR vaccine and developed autism had come from Dr.

Wakefield, but did not suggest colonoscopy to test whether or not Dr. Wakefield's idea was correct, but, in the child's interests to sort out what was wrong with him. He did so in circumstances in which child 2's mother had stated on a number of occasions, and to different people, that his bowel disorder and abdominal pain had in recent months deteriorated.

43. Professor Walker-Smith and Dr. Murch gave detailed evidence about the results of the investigation which, in their view, confirmed the presence of bowel inflammation, suggestive of Crohn's disease. Their evidence was unequivocally supported by Dr. Miller who said that he was "absolutely certain that this child had active disease that required clinical management". He also gave unequivocal support to Professor Walker-Smith's decision to admit him for the investigations, because of child 2's long history of undiagnosed troublesome clinical symptoms. He could not have put it more strongly:

> "It is, I think, a responsibility of such a doctor to investigate that child as fully and comprehensively as he can, to try and determine what is wrong with him".

44. Professor Booth gave evidence that this was a research admission. He based his conclusion on the letters written by Professor Walker-Smith to child 2's mother on 16th May 1996 and to Dr. Wakefield on 24th June 1996, cited above; on the fact that Professor Walker-Smith appeared to be devising a plan for investigations with Dr. Wakefield; and on the fact that the investigations accorded with those set out in Project 172-96. Professor Booth also gave evidence that the gastrointestinal investigations were not clinically indicated. He agreed with Professor Walker-Smith's assessment in 1995 that there was nothing to indicate chronic inflammatory bowel disease and said that nothing had occurred before admission in September 1996 to cause him to revise that view. On the contrary, the apparent success of the dietary regime prescribed by Dr. Hunter had led to an improvement in his condition.

45. The panel's findings on the critical disputed issues in relation to child 2 were as follows:

> "5a. You subjected child 2 to a programme of investigations for research purposes without having Ethics Committee approval for such research,
>
> Found proved
>
> The panel were satisfied that you admitted the child under your care after discussion with Dr. Wakefield, and reassessing the child on 21st June 1996. You also sent the child's mother a copy of the protocol for investigations and arranged the investigations. You wrote to child 2's GP on 28th June 1996 stating "I think Crohn's disease is unlikely. Dr. Wakefield has the view that there may be some kind of other inflammation which may be a relevant factor in child 2's illness and we now have a programme for investigating children who have autism and a possible reaction to immunisation." The panel has concluded, on the basis of the medical records, that the

programme of investigations that child 2 underwent was for research purposes for which there was no ethical approval.

b. The programme of investigations carried out on child 2 was part of the project referred to at paragraphs 2b and 2c above (i.e. Project 172-96)

Found proved

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

…

e. You caused child 2 to undergo a,

i. colonoscopy

Found proved

ii. barium meal and follow through,

Found proved

Which was not clinically indicated,

Found proved

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

…

i. your conduct as set out above was contrary to the clinical interests of child 2,

Found proved in the light of the panel's findings above."

46. No charge was laid against Professor Walker-Smith that he had caused child 2 to undergo a lumbar puncture and/or Schilling test which were not clinically indicated. This was unsurprising, given that both had independently been suggested by Dr. Surtees at Great Ormond Street Hospital on 23rd August 1996 and confirmed by him to Dr. Thomson on 2nd September 1996. Both were investigations identified in Project 172-96.

47. The panel's reasons are laconic. That would not matter if they were, in themselves, sufficient, or if sufficient unexpressed reasons underlying the stated reasons could be discerned. Neither is the case. The first three sentences of paragraph 5a stated two uncontroversial facts: that child 2 was admitted after discussion with Dr. Wakefield and re-assessment at the outpatients clinic on 21st June 1996; and that Professor Walker-Smith wrote to Dr. Cartmel in the terms cited on 28th June 1996. The second sentence is wrong – Professor Walker-Smith did not send a copy of Project 172-96 to child 2's mother – but the error is inconsequential, because he suggested that should be done to Dr. Wakefield. The panel's finding is, in terms, based on the medical records: "the panel has concluded, on the basis of the medical records, that the programme of investigations that child 2 underwent was for research purposes…". On the premise that the panel founded its conclusion on the totality of the medical records, this "reason" is not sufficient to support the conclusion. As is apparent from the extracts summarised above, the medical records are equivocal. They do not point clearly either to the undertaking of a research project or to clinical diagnostic investigation. Both sides were able to make cogent submissions on the basis of the contents of the medical records to support their respective propositions. Further, a brief explanation was required of which parts of the oral evidence given by the participants the panel accepted or rejected – and why. If the panel had concluded that that was unnecessary, because the test was purely objective, it would have fallen into the error identified in paragraph 15 above.

48. The finding of the panel in paragraph 5b begins with an uncontroversial sentence: that the programme of investigations followed those set out in Project 172-96 closely. The second sentence was also uncontroversial: that Professor Walker-Smith's letter to Dr. Wakefield contained the words cited. Neither, however, dealt with or expressly rejected the evidence of Professor Walker-Smith and Dr. Murch that an unwritten clinical protocol was developed for clinical purposes. This evidence was central to their case. It deserved a clear answer, which it did not receive. If the panel was relying on the evidence of Professor Booth, it should have said so. If it had done, it would have had also to explain why it rejected the evidence of Dr. Miller and considered that his view lay outside the spectrum of reasonable medical opinion. It would also have had to have dealt with the awkward facts (from the point of view of the GMC's case) that the neurological investigations, as well as following the project protocol, also followed the recommendations of Dr. Surtees, which were undoubtedly made for clinical diagnostic purposes and Dr. Thomson's Birmingham protocol. The single instance specifically identified by the panel – that at least four paired biopsies were taken at colonoscopy – does not bear the weight apparently placed upon it. The histology report records that six pots were received in the laboratory, containing ten pieces of beige tissue. No reliance was placed by the GMC on this fact in their closing submissions or, as far as I know, in the evidence of Professor Booth or in cross-examination of the clinicians. Professor Walker-Smith told the Ethics Committee in his letter of 24th August 1995 that 4 – 6 biopsies were routinely taken for diagnostic purposes. He sought, and was given, permission for an extra two for research purposes. If the panel's arithmetic is correct, the number of biopsies taken was consistent both with that general permission and with Project 172-96, which sought permission for ten biopsies.

49. An adverse finding against Professor Walker-Smith in respect of child 2 would have been open to the panel even if it had not found proved, to the criminal standard, that

he had subjected child 2 to a programme of research. Its finding under paragraph 5e was of critical importance. The finding that Professor Walker-Smith had caused child 2 to undergo a colonoscopy and barium meal and follow through which was not clinically indicated was founded on a single sentence of reasoning: the panel accepted his evidence that child 2's condition was improving. That finding was an inadequate and distorted summary of Professor Walker-Smith's evidence; and it was factually unsound. There was evidence of improvement in child 2's condition, as Dr. Beattie and Dr. Hunter reported. Professor Walker-Smith noted in his clinical notes of 21st June 1996 that on examination he was "much calmer than seen last time", but also, that since then he had had diarrhoea, weight loss and had been very ill; but, his evidence was that even if Dr. Hunter was providing symptomatic relief, he was not advancing the diagnosis. Further, Professor Walker-Smith's limited admission – justified by the facts – had to be set in its proper context. That included the fact that the medical notes contained references to recent significant episodes of illness, diarrhoea and weight loss in January and April 1996 and its acceptance that Professor Walker-Smith had written to child 2's mother on 16th May 1996 "in response to her telephone call saying that her child's symptoms had worsened". In those circumstances, the panel was wrong to place decisive reliance on Professor Walker-Smith's limited admission. Further, it did not begin to address the serious debate between Professor Booth and Dr. Miller about this issue. Unless it was able, rationally, to dismiss Dr. Miller's firm view as outwith the spectrum of reasonable medical opinion, it could not sustainably have reached the conclusion that colonoscopy and barium meal and follow through were not clinically indicated.

50. The panel's conclusion that Professor Walker-Smith's conduct was contrary to the clinical interests of child 2 depends upon the conclusions analysed above. Because they are inadequate or wrong, this conclusion falls with them.

51. I have dwelt at length upon the case of child 2, because it was the case upon which both sides placed greatest reliance. I will be able to deal more shortly with the cases of the other Lancet children; but my analysis of their cases is informed by the conclusions which I have reached about the case of child 2.

Child 1

52. Child 1 was born on 14th January 1993. MMR vaccination was given on 19th January 1994. A diagnosis of autism was recorded in his general practice records on 1st November 1995. On 12th March 1996 Dr. Hauck, a Consultant Psychiatrist at Leicester Frith Hospital, wrote to the Senior Medical Officer at the airforce base at which child 1's parents were stationed, noting that he suffered from loose stools on most days and was a choosy and slow eater. On 17th May 1996, his general practitioner Dr. Barrow referred child 1 to Professor Walker-Smith, noting that he had reached normal milestones until about 15 months old, had then regressed and was now diagnosed as autistic. He was seen by Professor Walker-Smith on 20th June 1996 at an outpatients clinic. He noted that he was referred through the autistic society and,

> "Has problems with eating – picky eater. Has undigested food in stools, has no control. Has had blood occasionally in stools."

He arranged for routine blood tests to be performed. On 21st June 1996, he wrote to Dr. Barrow stating that it was difficult to associate a clear historical link with MMR vaccine and,

> "As part of Dr. Wakefield's and mine interest in the relationship between immunisation and chronic inflammatory bowel disease, I have arranged for a routine blood test to be done for screening for C-reactive protein etc. The diarrhoea which (child 1) currently has does have the features of toddler's diarrhoea. His mother is concerned by the diarrhoea…
>
> My plan would be to see him again in 3 month's time and then if (child 1's mother) feels that it is appropriate we could consider performing endoscopy and a further assessment neurologically and psychologically of his autism to explore the possible link between measles immunisation, bowel inflammation and autism."

On the same day, he wrote to Dr. Wakefield telling him that he had seen child 1. The blood test results revealed that haemoglobin was below normal range, at 10.8 – which Professor Walker-Smith said in evidence was a mild but significant degree of anaemia and in accord with the history of passing rectal blood. He accordingly reconsidered his diagnosis of toddler's diarrhoea and arranged for child 1 to be admitted for investigations.

53. On admission on 21st July 1996, Dr. Casson's clerking notes recorded that diarrhoea had started at 1 ½ years, five times a day, watery with presence of undigested food. It was now seven times a day. He had no bowel control. There was no blood but occasional mucous. Similar symptoms were noted in a second clerking note by the Paediatric Senior House Officer. An attempt at colonoscopy was made on 22nd July 1996, but abandoned due to gross faecal loading. An endoscopy was performed by Dr. Thomson and a repeat colonoscopy by Dr. Murch on 25th July 1996. Endoscopy revealed no obvious lesions. Colonoscopy revealed some evidence of "scoppe" (sic) trauma in the descending colon. The histology reports on the colon and upper gastrointestinal tract recorded patchy chronic inflammatory infiltrate in the caecum and mild gastric changes in the upper intestinal tract. Dr. Casson's discharge summary of 9th August 1996 set out the same clinical history and histological findings. Child 1 was due to attend an outpatient clinic on 28th August 1996, but was unable to do so. In consequence, Professor Walker-Smith spoke to his mother by telephone and suggested a therapeutic trial of anti-inflammatory syrup.

54. Child 1 was readmitted for further investigations on 23rd October 1996. The clerking note recorded that he had runny stools six times a day with fresh blood in the stools. An abdominal x-ray and a barium meal and follow through were performed, with difficulty. The conclusion was that he had a normal small bowel. A lumbar puncture was performed.

55. On 17th January 1997 Professor Walker-Smith saw child 1 at his outpatients clinic and recommended that he should continue taking paraffin and anti-inflammatory syrup. On 22nd January 1997, he wrote to Dr. Luckens, child 1's general practitioner, explaining his reason for that prescription: "we have found other children who have

had this kind of colitis have responded well to this therapeutic approach". On 18th June 1997, Professor Walker-Smith noted at his outpatient clinic that his behaviour had improved. Further improvement was noted six months and twelve months later.

56. Dr. Miller unequivocally supported Professor Walker-Smith and Dr. Murch in their view that the first and repeat colonoscopies were justified clinical investigations. Given the history described, he said that colonoscopy was "absolutely necessary". Professor Booth disagreed and said that he agreed with Professor Walker-Smith's original diagnosis of toddler's diarrhoea.

57. The panel's determinative findings were as follows:

> "7a. You subjected child 1 to a programme of investigations for research purposes without having Ethics Committee approval for such research,
>
> Found proved
>
> The panel was satisfied that you saw this patient, that you expedited his admission and that there was no Ethics Committee approval for these investigations in July or October 1996. Child 1 underwent a colonoscopy, MRI scan of his brain, an EEG and a variety of blood and urine tests. These were some of the investigations listed in the programme of the project. He was again admitted in October 1996 for further investigations regarding the "aetiology of the autism" again for no obvious clinical gastro-intestinal reasons. During this admission child 1 underwent a barium meal and follow through and a lumbar puncture which were also investigations listed in the project. The panel concluded that child 1 underwent these for research purposes for which there was no Ethics Committee approval.
>
> b. The programme of investigations carried out on child 1 was part of the project referred to at paragraphs 2b and 2c above,
>
> Found proved
>
> The panel had regard to the letter dated 21st June 1996 from you to child 1's GP which states "As part of Dr. Wakefield's and mine interest in the relationship between immunisation and chronic inflammatory bowel disease, I have arranged for routine blood tests to be done for screening for C-reactive protein etc." The panel also took into account the discharge summary dated 9 August 1996 that states "Child 1 was admitted for further investigations into his autism and specifically to look into a possible association between his neurological condition and any gastro-intestinal disorders." On the basis of the investigations carried out, the panel has concluded these were part of the project.

…

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

Found proved

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

f. You caused child 1 to undergo a colonoscopy and a barium meal and follow through although

…

ii. such investigations were not clinically indicated,

Found proved, for the reasons set out above.

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

Found proved

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

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

Found proved in the light of the panel's findings above".

58. Apart from the observation that there were "no obvious gastro-intestinal reasons" for the second admission of child 1 in October 1996 and the conclusion that he underwent the investigations for research purposes, paragraph 7a does no more than set out uncontroversial facts. The finding that there were "no obvious clinical gastro-intestinal reasons" for the investigations appears to be founded on the panel's conclusion at 7e and I will analyse it under that head.

59. Again, save for the conclusion that the investigations were part of the project, its findings at 7b do no more than set out undisputed facts. Again, the critical finding relies on the finding at 7e. There is, however a notable omission. Child 1 was the first child to be admitted. It was not until Professor Walker-Smith obtained the abnormal blood test result that he doubted his provisional diagnosis and arranged for further investigations to be carried out – facts which were inconsistent with the commencement of an already determined research protocol.

60. The panel's determinative finding at 7e was inadequate. The questions which the panel had to address but did not, were: did Professor Walker-Smith change his mind in the light of the blood test result? If so, was his decision to admit child 1 for a series of investigations including colonoscopy justifiable? To answer those questions, it had to address his own evidence and that of Dr. Murch and Dr. Miller's opinion that colonoscopy was "absolutely necessary" and that it would have been a dereliction of duty for the clinicians not to have repeated it when it failed. The absence of necessary findings cannot be rescued retrospectively by the proposition that the panel must have preferred Professor Booth's opinion. As in the case of child 2, it would have had to have rejected Dr. Miller's opinion as outwith the spectrum of reasonable medical opinion.

61. The panel's conclusion that Professor Walker-Smith's conduct was contrary to the clinical interests of child 1 depends upon its previous findings and stands or falls with them. There is no appeal against the finding at paragraph 7i which was a conclusion open to the panel; but it was a minor criticism of Professor Walker-Smith's conduct. Even if it could amount to professional misconduct, which I doubt, it could not amount to serious professional misconduct.

Child 3

62. Child 3 was born on 1st January 1990. MMR vaccine was given on 1st March 1991. The first note of concern about his development in his general practice notes is dated 17th June 1992. He was admitted to Alder Hey Children's Hospital on 5th April 1993 for investigation into possible autism, a diagnosis confirmed on 10th June 1993. On 30th October 1995, Dr. Balachandran, a Consultant Community Paediatrician referred child 3 to June Rogers, a specialist nurse (who was to visit the family) noting that according to child 3's parents, he was still in nappies and had no control over his bladder and bowel.

63. On 19th February 1996 child 3's general practitioner Dr. Shantha referred him to Professor Walker-Smith. The referral letter was in curious terms:

> "Thank you for asking to see this young boy who developed behavioural problems of autistic nature, severe constipation and learning difficulties after MMR vaccination….His severe constipation is requiring frequent enemas and oral medication. The parents are very convinced that the difficulties in his behaviour etc. started only after vaccination. I am extremely grateful for you to have taken on (child 3) for case study."

The GMC did not suggest that Professor Walker-Smith had asked to see child 3. Dr. Wakefield said in evidence that it was very likely that he had had contact with the parents before the referral was made. Professor Walker-Smith replied on 22nd February 1996, saying that he had arranged for an outpatient appointment to be sent. On 27th February 1996, in a letter to Dr. Shantha, Dr. Balachandran noted a history of constipation and blood in stools, for which the parents had used lactulose and micro enemas on the advice of the specialist nurse.

64. Professor Walker-Smith saw child 3 at an outpatient's clinic on 3rd April 1996. As usual, a careful clinical history was taken. It noted the coincidence of MMR

vaccination and the beginning of abnormal behaviour; and that he had developed constipation, with bleeding, from the age of six months. He was noted to be anaemic and not toilet trained.

65. On 4th April 1996 Professor Walker-Smith wrote to Dr. Wakefield, Dr. Rosenbloom a Consultant Paediatric Neurologist at Alder Hey Hospital and Dr. Shantha. He told Dr. Wakefield that he had told child 3's mother that they would like to consider colonoscopy, but had not yet booked one "until we have got the full details of the investigative protocol worked out". He told Dr. Rosenbloom that child 3 was referred to him by his GP "because of the work of my colleague Dr. Andy Wakefield at this hospital concerning the role of MMR in the genesis of Crohn's disease and more recently possibly in relationship to the association with autistic behaviour". He added, probably inaccurately, that they had seen "several children who have had both features of Crohn's disease and autistic behaviour related to MMR vaccination". He sought Dr. Rosenbloom's views about child 3. He repeated the same statement to Dr. Shantha, but added:

> "Whether this is causally related I simply don't know at present. (Child 3's mother) is keen that we pursue this avenue. In the first instance I have screened (child 3) with routine blood tests etc. and we will consider in due course whether it is appropriate to go ahead and perform a colonoscopy. A colonoscopy offers the opportunity to demonstrate if there is any ongoing infection in the gastro-intestinal tract which could in some way be causally related to his present problems".

On 23rd April 1996, Dr. Rosenbloom provided child 3's notes to Professor Walker-Smith and asked for references available for the link between MMR vaccine, autistic behaviour and Crohn's disease. Professor Walker-Smith replied on 16th May 1996, saying that he had passed on his letter to Dr. Wakefield "who is the inspiration of our work linking MMR, autistic behaviour and Crohn's disease and I am asking him to write to you to fill you in on our proposed study."

66. On 17th July 1996 child 3 was seen by Professor Walker-Smith at his outpatients clinic. It was noted that he had had constipation since seen last, but had now improved. Admission for colonoscopy was arranged for 8th September 1996. On 18th July 1996 Professor Walker-Smith told Dr. Rosenbloom that child 3 was being admitted for colonoscopy even though the initial blood screens for bowel inflammation were negative, "However Dr. Wakefield is of the opinion that subtle changes in relation to inflammation may be present in such children". On the same day, he confirmed the lack of evidence of bowel inflammation on routine blood tests to Dr. Wakefield. The copy of his letter in the Royal Free Hospital notes has an annotation by Dr. Casson dated 23rd August 1996: "For COLONOSCOPY ONLY as d/w (discussed with) JAWS (Professor Walker-Smith) + Dr Murch".

67. The clerking notes made on admission contain the usual clinical history. Gastrointestinal symptoms are described as follows:

> "No abdominal pain – no joint pain. No rash. Suffers from constipation from the age of six months. Rectal bleeding with hard stools – not mucosy…

No gastro symptoms"

The endoscopy clerking sheet gives the reason for the procedure as,

> "? CROHN'S DISEASE. (Severe constipation intermittent PR bleeding from 8/12 – 4 ½ years)."

Dr Thomson's colonoscopy report notes an increase in the number of lymphoid follicles in the terminal ileum. There is no explanation in the transcribed clinical notes supplied to me for the decision, which must have been made after 23rd August 1996, to undertake procedures other than colonoscopy. There was, apparently, a handwritten note by Dr. Thomson on his colonoscopy report of 9th September 1996, "Plan: other Ix [investigations] as per protocol". A barium meal and follow through was planned for 11th September 1996, but cancelled. An MRI scan, and EEG and lumbar puncture were performed on 12th September 1996. The EEG was requested by Dr. Harvey for "disintegrative disorder + possible enteritis". A barium meal and follow through was performed on 13th September 1996, which revealed no evidence of (?) [possibly inflammation]. Dr. Dhillon's histology report of 13th September 1996 noted mild inflammatory and reactive changes in the small bowel samples of uncertain significance. The discharge notification of the same date diagnosed Crohn's Disease with autistic behaviour and prescribed lactulose and sytron for the bowel condition. Dr. Casson's discharge notes dated 4th October 1996 set out the procedures undertaken and their outcome and concluded that he did not appear to have significant bowel disease.

68. In December 1996, shortly before his lecture at the Wellcome Trust on 20th December 1996, Professor Walker-Smith reviewed child 3's histology reports with Dr. Dhillon, at the same time as the other six children who had by then been investigated. As a result, they arrived at final diagnosis: lymphoid nodular hyperplasia and indeterminate colitis. On 31st December 1996, Professor Walker-Smith wrote to Dr. Shantha to inform her of the final diagnosis. The discharge notes were appropriately amended. He suggested that an anti-inflammatory drug might be of some therapeutic value. Child 3's behaviour and gastrointestinal symptoms remained problematic, as the medical notes, which cease in 2003, demonstrate.

69. Professor Walker-Smith's evidence was that child 3's condition could not just be explained by constipation – a symptom of an underlying disease rather than a disease. Rectal bleeding and anaemia, of sufficient severity to require his general practitioner to give iron, was untypical of constipation. A colonoscopy would offer the opportunity to demonstrate whether or not there was ongoing "infection" (i.e. inflammation) in the gastrointestinal tract. Dr. Miller supported his approach: constipation requiring regular enemas, rectal bleeding and anaemia meant that this was not a simple case of constipation. He said that he saw nothing wrong in Professor Walker-Smith's decision to undertake colonoscopy, even after the inflammatory markers came back normal.

70. Professor Booth disagreed and would only have undertaken colonoscopy if, after the bowel had first been fully emptied, the patient was still bleeding, in his opinion, reviewing the medical notes, child 3 was investigated for the purposes of research.

71. Professor Rutter expressed the opinion that the lumbar puncture carried out on child 3 was not clinically indicated. Dr. Thomas said that it was. In his opinion, there were strong similarities between child 3 and child 2 (in whose case it was accepted that a lumbar puncture was clinically indicated as explained above).

72. The critical findings of the panel in relation to child 3 were as follows:

> "9a. You subjected child 3 to a programme of investigations for research purposes without having Ethics Committee approval for such research,
>
> Found proved
>
> In reaching its decision that you subjected this child to the programme of investigations, the panel is persuaded by child 3's Royal Free Hospital records, in particular the letter dated 4 April 1996 from you to Dr. Wakefield in which you state that you have not yet booked child 3 for a colonoscopy as you were waiting for the "full details of the investigative protocol" to be worked out. It also noted your letter dated 18 July 1996 to Dr. Wakefield which states, "We are arranging for (child 3's) admission for colonoscopy on Sunday 8 September, followed by you intensive investigations". The panel concluded on this basis that the programme of investigations that child 3 underwent was for research purposes and that there was no Ethics Committee approval for such research.
>
> b. The programme of investigations carried out on child 3 was part of the project referred to at paragraphs 2b and 2c above,
>
> Found proved
>
> The panel is satisfied that the programme of investigations carried out on child 3, and the reasons recorded in the clinical notes for those investigations, followed closely the project protocol referred to at paragraph 2b and 2c. In addition, the panel took into account the letter dated 16 May 1996 from you to the Paediatric Neurologist which states, "I am actually passing on (your) letter to my colleague, Dr. Andy Wakefield, who is the inspiration of our work linking MMR, autistic behaviour and Crohn's disease and I am asking him to write to you to fill you in on our proposed study…"
>
> …
>
> e. You caused child 3 to undergo a,
>
> i. colonoscopy,
>
> Found proved.

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

ii. Barium meal and follow through,

Found proved

The letter dated 18 July 1996 from you to Dr. Wakefield where you state child 3 will undergo colonoscopy "followed by your intensive investigations", together with the clinical notes of this child persuaded the panel that he had undergone barium meal and follow through and because he was under your clinical care, you had caused it.

Which was not clinically indicated,

Found proved

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

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

Found proved.

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

…

iii. Which was not clinically indicated,

Found proved

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

…

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

Found proved.

The panel had regard to its findings above".

73. As Miss Glynn concedes, the reasons for the panel's findings that colonoscopy, barium meal and follow through and lumbar puncture were not clinically indicated are wrong. Dr. Miller did not agree that a colonoscopy and therefore barium meal and follow through were not clinically indicated. His evidence was more nuanced. He said that he might or would not have done a colonoscopy at that stage, but that Professor Walker-Smith was, given the knowledge which he had acquired about autism and bowel disease, entitled "to use what clinical modality he thinks appropriate to reach a diagnosis" or, put more colloquially, to follow a hunch. In this instance, Dr. Miller identified the very difficult question at the heart of the case against Professor Walker-Smith: determining what was, and was not, permissible as medical practice in a specialist field, by an acknowledged expert academic clinician, in a case in which the aetiology of the disorders he was investigating was uncertain. The error in the case of Dr. Thomas's evidence was stark. The panel had to apply the *Bolam* test on this issue. Because no criticism was made of Dr. Thomas's expertise or evidence, the finding that a lumbar puncture was not clinically indicated was not open to the panel and was wrong.

74. In paragraphs 9a and b the panel follows the by now established pattern of referring to the hospital records compendiously and to the terms of specific letters written by Professor Walker-Smith. The panel was entitled to conclude that the terms were consistent with and suggestive of research. Such a conclusion was supported by the firm evidence of Professor Booth. The explanation of Professor Walker-Smith and Dr. Murch – that they and fellow clinicians were developing an unwritten clinical protocol – may not have sat easily with the terms of the letters; but as in the case of child 2, it deserved a clear answer which it did not receive. It required a finding about their honesty as witnesses and, in the case of Professor Walker-Smith about his truthfulness in his dealings with the Ethics Committee. Further, as in all of the cases, findings about Professor Walker-Smith's purpose in undertaking the investigations were bound to be influenced – perhaps determinatively – by the panel's findings on clinical indications for the major investigations. The fact that its findings on those issues are insupportable undermines its findings under paragraphs 9a and b.

75. The finding at 9i stands or falls with the remaining findings.

Child 6

76. Because the panel made no finding of serious professional misconduct in relation to child 6 except, that he was admitted for the purpose of unapproved research, his case can be taken shortly.

77. Child 6 was born on 29th April 1992. On 25th March 1993, there is a note in his general practice records: "Getting over ? measles". MMR vaccine was given on 15th June 1993. Behavioural and gastrointestinal problems, including diarrhoea and abdominal pain are consistently noted from May 1994 onwards. A probable diagnosis of Asperger's Syndrome was made by Dr. Bennett, a Consultant Community Paediatrician, on 7th December 1995. On 25th March 1996, his general practitioner discussed the association between measles, and autism and inflammatory bowel disease with Dr. Wakefield. On 9th August 1996, his general practitioner Dr. Nalletamby asked Dr. Wakefield to see his mother, who was "interested in entering him into your trial". Dr. Wakefield forwarded that letter to Professor Walker-Smith, who wrote to Dr. Nallatamby on 11th September 1996: "I have been asked by Dr.

Wakefield to see (child 6) as I am the Paediatric Gastroenterologist associated with Dr. Wakefield in our study on autism and bowel disorder." An outpatient appointment was fixed for 2nd October 1996, during which Professor Walker-Smith took his usual detailed clinical history, which included abdominal pain and diarrhoea with blood in stools intermittently from 18 months. Blood tests were performed with normal inflammatory markers. On 4th October 1996, Professor Walker-Smith wrote to Dr. Wakefield and to Dr. Nalletamby. To the former, he said that child 6 "fits well into the spectrum of children we need to investigate" and to the latter that he fitted "into the spectrum of a child diagnosed as autistic who also has bowel symptoms". He arranged for him to be admitted on 27th October 1996. During the following week, colonoscopy (but not a barium meal and follow through), and neurological investigations, including a lumbar puncture, were performed. The diagnosis which resulted from the investigations was indeterminate colitis, for which he was prescribed an anti-inflammatory drug. It is not necessary to set out the clinical findings or the validity of that diagnosis, because it was not alleged that colonoscopy and the lumbar puncture were not clinically indicated. Professor Walker-Smith continued to assist in the management of child 6's gastrointestinal condition from 1997 until 2000.

78. Against that background, the GMC's only purpose in bringing a charge in respect of child 6 must have been to establish that all eleven Lancet children were admitted for the purpose of research.

79. The panel's findings were:

> "13a. You subjected child 6 to a programme of investigations for research purposes without having Ethics Committee approval for such research,
>
> Found proved.
>
> In reaching its decision that you subjected child 6 to a programme of investigations, the panel is satisfied by the evidence of the medical records, in particular the letter from you to the child's GP dated 4 October 1996 wherein you state, "I am arranging for him to come in to have a colonoscopy and entering our programme of investigation of children with autistic problems." The panel has concluded that the programme of investigations that this child underwent was for research purposes for which there was no ethical approval.
>
> …
>
> e. Your conduct as set out above was contrary to the clinical interests of child 6,
>
> Found not proved.
>
> The panel found that despite this child being subject to a programme of investigations rather than specific ones tailored

> to his needs, there was insufficient evidence to make a finding that the investigations were contrary to his clinical interests."

80. Child 6's case illustrates why it was necessary for the panel to make findings upon the evidence of Professor Walker-Smith and Dr. Murch that they were undertaking investigations pursuant to a clinical, not research, protocol. As the panel expressly found in paragraph 13ciii of its determination, this child did not fit the research hypothesis – not only for the usual reason, that he had not had the single or double vaccine, but because his diagnosis was Asperger's Syndrome. Further, one of the investigations set out in Project 172-96 – barium meal and follow through – was not performed. It was not alleged that the invasive and other procedures were not clinically indicated; and he received therapeutic care from Professor Walker-Smith and his colleagues in the three years that followed the investigations. This case did not fit the pattern for which the GMC contended and was consistent with the cases of Professor Walker-Smith and Dr. Murch. The panel's reliance on the single sentence in Professor Walker-Smith's letter of 4th October 1996 and on unspecified aspects of the medical records is superficial and inadequate to address a difficult question. The wording of its finding at paragraph 13e is puzzling, but because the allegation was not found proved it is unnecessary for me to say more about it.

Child 9

81. Child 9 was born on 11th June 1990. MMR vaccine was given on 31st October 1991. Severe communication difficulties led to suggestions of autism in mid 1993 and to his referral to Dr. Rolles, a Consultant Paediatrician at Southampton General Hospital. In November 1993, he concluded that child 9 had a number of autistic characteristics. He was referred to Southampton General Hospital for assessment on 13th April 1994, when it was noted that he was not toilet trained and had autistic characteristics. On 10th January 1995, he was admitted to Chelsea and Westminster Hospital under the care of Dr. Cavanagh. On 13th February 1995, he recommended vitamin B_{12} metabolism studies. On 13th March 1995, Dr. Bhatt, the director of the Vitamin B_{12} Unit at Chelsea and Westminster Hospital, proposed absorption studies including a modified Schilling test. On 18th May 1995, a lumbar puncture was performed. The discharge letter of 24th October 1995 diagnosed deficiency in vitamin B_{12} absorption and autism. The discharge letter recommended that he be referred to Professor Walker-Smith. It seems that it was not immediately acted upon.

82. On 9th September 1996, John Linnell, a researcher at the Royal Free Hospital, wrote to Professor Walker-Smith:

> "You may remember that at the project meeting last Tuesday, this child was briefly discussed and it was agreed he should if possible be included in our first ten cases. I have since spoken to the mother and it appears that she received a discharge letter from the Chelsea and Westminster last October, recommending that child 9 be referred to you! Since I gather you know 'Clifford Spratt (child 9's Consultant Paediatrician in Jersey), I wonder if you would be able to telephone him and activate the referral?"

On 11th September 1996 Professor Walker-Smith wrote to Dr. Spratt:

> "We recently have become aware of a syndrome of enteritis and disintegrative disorder or autism. We have in fact investigated two children so far and during treatment they both had evidence of bowel inflammation. Whether this relates to Crohn's disease or whether it is related to measles immunisation or measles itself is quite unclear. However, I have heard from Dr. Wakefield that there is a child called child 9 who is resident in Jersey whose parents would be quite keen for us to investigate the child in our protocol. I am just wondering whether you think this is at all appropriate. If you felt it appropriate I would be happy to see the child.
>
> Just in case you would be interested I am enclosing a copy of Dr. Wakefield's detailed proposal."

The proposal was Project 172-96. On 25th September 1996 Dr. Spratt wrote two letters to Professor Walker-Smith: the first, a formal request for his opinion, addressed to the Royal Free Hospital; and the second, much longer letter, to Professor Walker-Smith's home address. He said that child 9 had been a vexed case for him since September 1992, that he distrusted Dr. Bhatt's diagnosis and proposed treatment and was not aware of "any convincing bowel symptoms in his history".

83. Child 9 was seen by Professor Walker-Smith at his outpatients clinic on 8th November 1996. As usual, he recorded a detailed clinical history, which included noting that since the age of two, he passed one loose stool per day, was not toilet trained, and had screaming attacks related to food. On the same day, he wrote to Dr. Spratt, setting out those findings and stating,

> "We have now seen several children with autism and gastrointestinal symptoms, all of whom on gastrointestinal investigation have proved to have some kind of bowel inflammation. It is quite difficult to relate this directly to autism. Dr. Wakefield as you know, believes that immunisation may play some part, although I remain neutral on this issue for the moment. However the parents are keen that we should endeavour to investigate child 9, and I have therefore arranged for him to come in to have a colonoscopy and barium meal and follow through and a repeat lumbar puncture".

84. Child 9 was admitted on 17th November 1996. The admission clerking note includes reference to one loose stool per day since the age of 2-3 years with abdominal pain and screaming episodes which lasted for 10 – 30 minutes. Dr. Thomson's colonoscopy report of 18th November 1996 begins "Disintegrative disorder" and noted a small area in the ileum at the hepatic flexure which was slightly erythematous and a marked increase in the size and number of prominent lymphoid nodules. A barium meal and follow through revealed a normal terminal ileum. The histology report revealed no active inflammation or abnormality. It was not possible to perform an MRI scan or lumbar puncture, because of likely distress in child 9. Dr. Murch postponed them until 10th December 1996.

85. Child 9 was one of the children whose histology reports were reviewed by Dr. Dhillon and Professor Walker-Smith in December 1996. Their diagnosis was indeterminate colitis. On 31st December 1996, Professor Walker-Smith wrote to Dr. Spratt setting out his conclusions: endoscopy had revealed a marked increase in the size and number of prominent lymph nodes in the terminal ileum. Histology revealed an increase in chronic inflammatory cells throughout the colon. His diagnosis was indeterminate colitis with lymphoid nodular hyperplasia. He suggested that a therapeutic trial of an anti-inflammatory drug might be worthwhile. Dr. Malik's discharge summary of 14th January 1997 conformed to Professor Walker-Smith's letter. Thereafter, correspondence continued between Professor Walker-Smith and Dr. Spratt about modifications to the drug regime recommended (and about a finding of abnormally high lead values in his blood) until May 1998.

86. Professor Walker-Smith said in evidence that he had admitted child 9 for colonoscopy for the reasons which he explained to Dr. Spratt and Dr. Cavanagh in his letter of 8th November 1996, written immediately after his outpatients clinic on the same day: he and his team had recently seen a number of children with autism and bowel problems, which had, on examination, proved to be some kind of bowel inflammation. That letter was written three days before his reply to Dr. Pegg, in which he said the same thing. His decision was supported by Dr. Miller: although he would not have undertaken a colonoscopy at that stage, he accepted that the additional knowledge gained by Professor Walker-Smith and his team justified his decision to do. Professor Booth disagreed. In his opinion, a colonoscopy was not clinically indicated. Both he and Dr. Rutter thought that the picture demonstrated by the documents and the pattern of referral indicated research rather ordinary clinical practice.

87. In the case of child 9, Professor Walker-Smith decided that he should have a lumbar puncture at his outpatient clinic. He did so because he suspected that he might have an organic basis for his neurological problems and that the analysis of the cerebrospinal fluid obtained at the lumbar puncture performed at the Chelsea and Westminster Hospital, to determine B_{12} absorption, did not deal with that. Dr. Rutter said that a lumbar puncture was not clinically indicated. Dr. Thomas said that it was, to exclude a metabolic disorder.

88. The determinative findings of the panel in relation to child 9 were as follows:

> "15a. You subjected child 9 to a programme of investigations for research purposes without having Ethics Committee approval for such research
>
> Found proved
>
> In reaching this decision that you subjected the child to the programme of investigations, the panel is persuaded by the evidence, in particular your letter dated 11 September 1996 to the local Consultant Paediatrician, Dr. Spratt, in which you enclosed, "Dr. Wakefield's detailed proposal" and state that child 9's parents are keen "for us to investigate the child in our protocol" and that if Dr. Spratt felt it appropriate, you would be happy to see child 9. Having seen the child in outpatients, you wrote to Dr. Spratt on 8 November 1996, stating, "we have now

seen several children with autism and gastrointestinal symptoms…I…have arranged for him to have a colonoscopy…we will then endeavour to follow this with barium meal and follow through…and repeat lumbar puncture." The panel is satisfied that the programme of investigations that child 9 underwent was for research purposes, for which there was no Ethics Committee approval.

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

Found proved

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

…

e. You caused child 9 to undergo a,

i. colonoscopy,

Found proved

ii. barium meal and follow through,

Found proved

Which was not clinically indicated

Found proved. The panel is persuaded by the evidence in the clinical notes and also accepted the evidence of both experts called by the GMC and defence, who agreed they would not have undertaken these procedures and therefore they were not clinically indicated at this stage.

f. You caused child 9 to undergo a lumbar puncture,

Found proved on the basis of your letter dated 8 November 1996 to the local Consultant Paediatrician, informing him that your plan included a repeat lumbar puncture.

…

ii. Which was not clinically indicated,

Found proved.

The panel is satisfied that there had been no evidence of recent further neurological deterioration to warrant a repeat lumbar puncture.

…

k. Your conduct as set out above was contrary to the clinical interests of child 9,

Found proved on the basis of above findings."

89. The reasoning of the panel in sub-paragraphs 15e and f is in part flawed and in part wrong. The panel correctly stated that Dr. Miller would not have undertaken colonoscopy and barium meal and follow through himself, but failed to deal with his opinion that, in the light of the knowledge that he had gained, Professor Walker-Smith was justified in doing so. The panel could only have rejected that evidence if satisfied that Dr. Miller's opinion was outwith the spectrum of reasonable medical opinion. It did not do so. The only alternative basis upon which it could have upheld this charge was that Professor Walker-Smith had not told the truth about his reasons for admitting child 9 for a colonoscopy. Given the contemporaneous evidence of his state of mind provided by his letters of 8th November 1996, that would have been an unlikely finding. In any event, it was not made.

90. The finding at 15f that lumbar puncture was not clinically indicated appears to have been based upon a submission made in closing by Counsel for the GMC. The submission was based on a statement made early in Dr. Thomas's evidence that a general label of autism would not necessarily preclude further investigation if there were additional changes that had precipitated the referral or the presentation of the child. Because there were none, apart from bowel symptoms and/or a perception that they were connected with neurological disorders, a further lumbar puncture was not justified. It is not clear what the evidential basis for this submission was, because Dr. Thomas's opinion, expressed in evidence was firmly that a repeat lumbar puncture was justified. Miss Glynn submits that the panel must have rejected his evidence. It did not do so expressly and, in the absence of any challenge to Dr. Thomas's expertise, it is difficult to see how such a finding could have been justified, given that the panel had to apply the *Bolam* test to this issue. On the evidence, this finding was wrong.

91. Apart from the terms of the three letters cited in paragraphs 15a and b of its determination, the only reasons given for the panel's findings are that it "is persuaded by the evidence" that the programme of investigations was for research purposes. This was not an adequate explanation of its reasons for reaching that conclusion. As in the cases of the other children, it was necessary for the panel to address the case advanced by Professor Walker-Smith about the letters and about his reasons for admitting child 9 for investigation. It did not do so. Its conclusion is also undermined

by the inadequacies and errors in its reasoning in sub-paragraphs 15e and f. Further, unless the panel rejected the evidence of Professor Walker-Smith and Dr. Murch and its contemporaneous expression in the documents as untrue, by the time that child 9 was admitted, both believed that they had identified an inflammatory bowel condition in the five children already investigated. The time at which Professor Walker-Smith's state of mind was to be judged was when he made the decision to admit, on 8th November 1996. Given that experience, his case that child 9 was admitted for clinical reasons, not research, was stronger than it may have been in relation to the children admitted earlier. None of this finds any echo in the panel's decision.

92. The finding at 17k stands or falls with the earlier findings and adds nothing to them. There was an additional finding, at 15j that Professor Walker-Smith failed to record the difference between the histological description provided to Dr. Spratt on 31st December 1996 and the clinical histology report. Professor Walker-Smith accepted that this omission was highly unsatisfactory. There is no appeal against the finding, but if, which I doubt, the omission amounted to professional misconduct, it could not have amounted to serious professional misconduct.

Child 5

93. Child 5 was born on 10th December 1988. On 24th November 1989 he had febrile convulsions, diagnosed as such at West Berkshire Hospital on 26th November 1989. MMR vaccine was given on 10th April 1990. In March 1991, delayed language and social development was noted, together with unregulated toilet habits. On 16th January 1992, Dr. Williams, a Divisional Clinical Psychologist in West Berkshire noted that his parents thought that febrile epileptic seizures continued to the present day and that he was not yet properly toilet trained. On 23rd February 1995, his general practitioner Dr. Shillam referred him to Dr. Richer, a Consultant Paediatric Psychologist at John Radcliffe Hospital with a diagnosis of autism. Dr. Richer confirmed that diagnosis and saw him on a number of subsequent occasions in 1995 and 1996. The prescription of nystatin produced some improvement in his behaviour.

94. On 30th September 1996, the general practice duty doctor noted a telephone call from Dr. Wakefield, in which he gave a very lengthy case for (child 5) to be referred to Professor Walker-Smith, "as they have findings suggesting that there is an association between inflammatory bowel disease/enteritis causing a failure to absorb B_{12} which is needed to myelinate until age ten → neurological problems/autism. (Measles vaccine may be implicated but that is being researched and uncertain of implications.)". Dr. Shillam obliged. In his referral letter of 1st October 1996, he said that child 5 had the classical features of autism and stated his parents concerns about the possible link between MMR vaccine, childhood enteritis and possible brain damage.

95. On 8th November 1996 at the same outpatients clinic as that in which he had seen child 9, Professor Walker-Smith took his usual careful note of the clinical history. It included the fact that since the age of two, he had been holding his abdomen and may have been in pain nearly every day and had bouts of diarrhoea once a month. In his letter to Dr. Shillam dated 12th November 1996 he said that child 9 had demonstrated how difficult his behaviour can be and (by implication, so) he did not proceed with blood tests. He noted the episodes of abdominal pain and diarrhoea. He said that "several of these children with autism have had gastrointestinal symptoms and on

investigation have proved to have gastrointestinal pathology". He arranged for his admission for a colonoscopy on 1st December 1996.

96. The admission clerking notes record the same symptoms. The endoscopy clerking sheet gives as the reason for the procedure "c/o Autism and behavioural problems. Recurrent abdominal pains and diarrhoea. To rule out gastrointestinal pathology." Dr. Murch's endoscopy report noted mild proctitis, with a granular mucosa and loss of vascular pattern in the colon and patchy loss of vascular pattern in the caeceum. There were prominent follicles in the ileum, but not sufficient to be called lymphoid hyperplasia. Dr. Davis's histology report of 4th December 1996 noted a minimal increase in chronic inflammatory cells within the superficial lamina propria in the large bowel which did not amount to the diagnosis of inflammatory bowel disease. A later handwritten annotation after the report had been seen by Professor Walker-Smith stated, "seem to be more significant inflammation than indicated in this report". Dr. Berelowitz, who saw child 5 on 3rd December 1996, thought that the likely diagnosis was a developmental disorder such as autism. Barium meal and follow through was performed on 6th December 1996 and was thought to reveal a 5 cm tight structure just proximal to the insertion of the terminal ileum and a granular mucosal appearance in its terminal portions. The appearances were noted to be highly suggestive of Crohn's disease. The discharge notification of 6th December 1996 gave a diagnosis of autism, noted the x-ray evidence of Crohn's and histological evidence of colitis and recommended the prescription of an anti-inflammatory liquid. Dr. Casson's discharge letter of 27th December 1996 set out those findings in detail.

97. On 15th January 1997, child 5 was admitted for barium meal and follow through under sedation and a lumbar puncture. The radiology report of the same date noted that the anatomy of the ileocaecal junction was unusual, but detected no stricture in the terminal ileum or evidence of Crohn's disease. A lumbar puncture was performed on 16th January 1997.

98. On 5th March 1997 Professor Walker-Smith saw child 5 at his outpatients clinic. He concluded that the anti-inflammatory drug prescribed had produced a big improvement and that abdominal pain had gone. He changed the medication for the reason explained in his letter to Dr. Shillam of 7th March 1997: child 5's mother was adopting an unorthodox means of administering the drug. The letter concludes with a significant paragraph:

> "In relation to the research that is being done concerning this group of children I suggest that you or (child 5's mother) should be directly in touch with Dr. Andy Wakefield who is directing the research aspect of this study. If you have any further queries please do not hesitate to contact me."

99. Professor Walker-Smith remained involved in the analysis and treatment of child 5's condition until 2000. One of the procedures which he recommended, in 1998 and 1999 was an upper endoscopy and repeat lower colonoscopy, to investigate continuing abdominal pain and other symptoms. Eventually, a laparotomy had to be performed, which revealed the presence of multiple foreign bodies throughout his abdomen.

100. Professor Walker-Smith gave evidence that his reason for admitting child 5 for a colonoscopy was that set out in his letter to Dr. Shillam of 12th November 1996: his and his team's experience of the five children already admitted with similar symptoms suggested that his abdominal pain and episodes of diarrhoea were caused by an inflammatory condition in his bowel. Dr. Murch gave concurring evidence. Dr. Miller said that admission for that purpose was clinically indicated. In the case of this child only, Professor Booth made a qualified concession that it was not unreasonable for the admission to have occurred.

101. No charge was laid in respect of the lumbar puncture performed on 15th January 1997.

102. The determinative findings of the panel were as follows:

> "17a. You subjected child 5 to a programme of investigations for research purposes without having Ethics Committee approval for such research,
>
> Found proved. In reaching its decision that you subjected child 5 to a programme of investigations, the panel is persuaded by the letter dated 1st October 1996 to you, from his GP, stating "This…child's parents have been in contact with Dr. Wakefield and have asked me to refer him to yourself regarding your current study into association between autism and childhood bowel problems" and your decision to admit, copied to Dr. Wakefield as detailed in your response dated 12 November 1996, "…I saw him in the clinic…I am arranging for him to come in for a colonoscopy." The panel has concluded that the programme of investigations that child 5 underwent was for research purposes, for which there was no Ethics Committee approval.
>
> …
>
> e. You caused child 5 to undergo a,
>
> i. colonoscopy,
>
> Found proved
>
> ii. barium meal and follow through,
>
> Found proved
>
> Which was not clinically indicated,
>
> Found proved. The panel concluded that there were not significant GI signs and symptoms to justify colonoscopy and BMFT at that time
>
> …

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

Found proved on the basis of the above findings."

103. The panel's reasoning in paragraph 17a and b is inadequate for similar reasons to those set out above in paragraph 91 above relation to child 9. The panel's finding that colonoscopy and barium meal and follow through were not clinically indicated is inadequate because it did not address the truthfulness of Professor Walker-Smith in his evidence and in contemporaneous documents and because it did not address the evidence of Dr. Miller. To reach the decision it did, the panel had to find that his view was outwith the spectrum of reasonable medical opinion and did not do so.

104. I have less confidence in accepting Mr. Miller's further point – that Professor Booth's qualified admission meant that there was no expert evidence that the procedures were not clinically indicated. I have not seen a full transcript of his evidence. The GMC did assert that his view was that preliminary non-invasive investigations should have been carried out first. Even though it is not clear what those might have been – the only investigation which was not carried out, which was performed in all the other cases was a venepuncture, which was not possible in this case because of child 5's behaviour at the clinic. Further, the panel was invited to find that Professor Walker-Smith had failed to carry out markers of inflammation (in blood obtained by venepuncture) on child 5 to assess the need for colonoscopy and had found it not proved, because, "the inflammatory markers were not essential". This finding is inconsistent with its finding in sub-paragraph 17e, unless, in its view, colonoscopy would only have been indicated by what were described as "barn door" symptoms. I cannot tie up this loose end.

105. I can find no reference in the written submissions to the panel (and there is none in its determination) to the conclusion of the letter from Professor Walker-Smith to Dr. Shillam of 7th March 1997 cited above. It is the first express reference in the medical records, in point of time, which I have found by Professor Walker-Smith to "research". It is significant because, unless it, like the explanation given to Dr. O'Connor of 6th February 1997 is, as the GMC suggested, "defensive", it is cogent evidence that Professor Walker-Smith had the distinction between the clinical investigations which he said he and his team were conducting and the research undertaken by Dr. Wakefield (for which permission had, by then, been granted) clearly in mind.

106. The findings of the panel under sub-paragraph 17i stand or fall with the earlier findings and add nothing to them.

Child 12

107. Child 12 was born on 18th December 1990. MMR vaccine was given on 6th March 1992. His mother began to be concerned about difficult behaviour and soiling which began when he was between 18 months and two years old. In March 1996, she told Helen Hopkins, a Family Centre worker in Brighton, that child 12 had had regular bouts of sickness and diarrhoea with a high temperature. In April 1996, his general practitioner was unable to detect any abdominal abnormality on examination. On 21st June 1996 he was seen by Dr. Ing, a Consultant Child and Adolescent Psychiatrist at

the Royal Alexandra Hospital. Dr. Ing's provisional diagnosis was that he had Asperger's Syndrome.

108. Child 12's mother then wrote to Dr. Wakefield, in a letter which has not been preserved. He replied to her on 19th July 1996, stating that "we have recently taken a profound interest in this subject, particularly in view of the link between bowel problems and Asperger's Syndrome". He invited her to seek a referral from her general practitioner to Professor Walker-Smith. On 30th July 1996, a call from Dr. Wakefield was noted in the general practice records: "Needs colonoscopy B_{12} absorption tests HO [history of] measles vacc[ination] reaction". On 23rd September 1996, child 12's general practitioner Dr. Stuart wrote to Dr. Wakefield, explaining, briefly, his earlier clinical history. The letter was stamped as received at the Royal Free Hospital on 28th September 1996. The day before, Professor Walker-Smith told Dr. Stuart that he had arranged for an outpatient appointment to be sent.

109. Professor Walker-Smith saw child 12 at his outpatients clinic on 18th October 1996. The clinical note which he took contained details not retrieved from the general practice file or from other hospital records. At age 4 he had been monitored for attention deficit disorder. At age 5 ½, a school doctor had referred him to an Educational Psychologist, suspecting that he was within the autistic spectrum. He was seen by Professor Cox at Guys and provisionally diagnosed with Asperger's Syndrome. He appeared to be toilet trained aged 3 years. Professor Walker-Smith noted his current bowel condition:

> "Soils – not had diarrhoea
>
> Has variable abdominal pain – occurs every week. Stops him eating".

He arranged for blood tests to be performed.

110. On 20th October 1996, child 12's mother wrote separately to Professor Walker-Smith and Dr. Wakefield. She must have been provided with Dr. Wakefield's "Proposed clinical and scientific study notes", because she referred to re-reading them in the opening paragraph of her letter to Professor Walker-Smith. She continued,

> "We do feel that (child 12) does have a problem in that most children his age do not soil themselves a number of times a day. As well as being pale in colour and foul smelling (as are his motions in general), this soiling is always very loose which makes plain why he is not always aware that he has done anything. Although I would not say it was diarrhoea exactly.
>
> Obviously I do not wish to put my son through any procedures unnecessarily but there must be reason why he has these problems. Also as I mentioned to you at our meeting, Matthew is not growing our putting on weight like my other two children.
>
> I keenly await the results of the blood tests and if you feel they warrant further investigations my husband and I are happy for

> him to be referred onto Dr. Wakefield's study project. As you pointed out it might not help Matthew, but if not hopefully it will be of benefit to others. There is also the chance that Matthew has a problem that can be detected and helped."

The mother of child 12 was the only parent to be called by the GMC. She said that she did not remember the conversation described in her letter. Professor Walker-Smith gave evidence that he remembered it in somewhat different terms. He explained to her what colonoscopy involved and its possible outcomes, including that nothing would be found. He told her that autistic children had not been studied to any degree and that their bowel problems had been rather dismissed as features accompanying a psychiatric illness – and that a normal result would be of interest as well as an abnormal result. In her letter to Dr. Wakefield, child 12's mother repeated her description of his soiling, but also spoke about her appointment with Professor Walker-Smith, who "took some blood from Matthew for analysis but did not feel sure that Matthew would need referring to yourself for further investigations. His main reasons were the absence of blood in the faeces and the lack of diarrhoea". She said that she did not think that she had stressed his symptoms sufficiently to Professor Walker-Smith.

111. On 21st October 1996, before the results of the blood tests were known, Professor Walker-Smith wrote two significant letters, to Dr. Stuart and to Dr. Wakefield. He told Dr. Stuart that child 12 seemed to fit the spectrum of autism, but did not have "very significant gastrointestinal symptoms" or evidence of faecal loading. He was gaining weight and growing satisfactorily.

> "Some of the previous children I have had referred to me with autism have had clear cut gastrointestinal symptoms with quite severe abdominal pain and intermittent bleeding and we have gone ahead with our programme of colonoscopy and intensive investigation. However in (child 12's) case there is relatively minor gastrointestinal symptoms, I felt it right to perform a full blood count ESR, CRP".

To Dr. Wakefield, he wrote,

> "It is interesting to see this child who really has the features of autism but rather minimal gastrointestinal symptoms. I did not feel it right in fact to proceed with our intensive programme at the moment until we have had ethical committee approval and it is clear that the parents wish us to proceed".

112. The blood test results were normal, apart from C-reactive protein (CRP) which, at 6, was above the reference range of 0-5. On 25th November 1996, Professor Walker-Smith acknowledged child 12's mother's letter of 20th October:

> "I have now got back the blood tests. One was slightly abnormal. As I see that you are keen for us to proceed with investigation I think it would be appropriate for us to arrange for (child 12) to come in for a colonoscopy….The children are

usually admitted for the course of a week and various other aspects of the protocol are undertaken".

A handwritten note on the letter states:

"'Go ahead and arrange colonoscopy for New Year".

Child 12's mother responded on 28th November 1996 confirming her agreement to the investigations going ahead and asking for an explanation of the blood test abnormality. Professor Walker-Smith responded on 27th December 1996, explaining that one of the markers of information was "just slightly above the normal range, it just means that we should go ahead".

113. Child 12 was admitted on 5th January 1997. The admission clerking note states that he was "admitted for investigation of autism and bowel problems" and identified autism, soiling and abdominal pain. He was noted to have been clean and dry by the age of three, but then started soiling sometime later and now soiled up to eight times a day, without realising that he has done so. The endoscopy clerking sheet noted "autistic features – soiling/pale stools/occasional abdominal pain ?joint pain (knee)". Dr. Murch's endoscopy report noted minor changes in the rectum and caecum – slight changes in vascularity and prominent lymphoid follicles. At his ward round on 6th January 1997, Professor Walker-Smith noted the colonoscopy results and directed that child 12 should not have the planned MRI scan or lumbar puncture, but was to have the barium meal and follow through. The histology report dated 8th January 1997, on four or five biopsies, noted lymphoid follicles with germinal centres in the large bowel, but no other symptoms.

114. Despite Professor Walker-Smith's direction that no MRI scan or lumbar puncture should be performed, both were performed on 9th January 1997. The clinical notes contain no explanation for this change and none of the clinicians who gave evidence were able to remember or explain the reason. No abnormalities were revealed. Dr. Berelowitz saw child 12 on 10th January 1997. He noted that child 12 was "not quite Asperger's but does have autistic spectrum disorder".

115. Dr. Casson's discharge summary dated 22nd January 1997 noted the minor changes in the rectum and caecum found on colonoscopy and said that the barium meal and follow through demonstrated lympho nodular hyperplasia of the terminal ileum (a finding not otherwise recorded in the retrieved notes). He also noted that child 12's behaviour appeared to improve following the clearing out of his bowel and, in view of that it was conceivable that many of his problems were associated with constipation, for which liquid paraffin was prescribed.

116. On 25th April 1997, prompted by a request from child 12's mother to Dr. Wakefield, Professor Walker-Smith recommended the prescription of an anti-inflammatory drug for child 12, because "these drugs appear not only to help gastro-intestinal symptoms but also rather surprisingly helped behavioural symptoms". Child 12 was seen by Dr. Casson and Dr. Malik at Professor Walker-Smith's clinic on two further occasions in 1997, when his drug regime was modified.

117. Professor Walker-Smith said in evidence that on the basis of what he knew from the clinical records and discovered at the outpatients clinic on 18th October 1996,

colonoscopy was not clinically indicated. He wanted to await the results of the blood tests before making a decision. Both Professor Booth and Dr. Miller agreed with his decision. He said that it was the abnormal CRP result which changed his mind. He explained that the reference to that result as "slightly abnormal" in his letter to child 12's mother was gentle language used to avoid alarming her. Dr. Murch considered that the result meant that they had "reached a tipping point", in favour of investigation. Dr. Miller agreed: an abnormal marker was precisely that and a clinician was entitled to act upon it, in particular, one who had already gained considerable experience from previous cases. At the hearing before the panel, Mr. Miller drew attention to evidence in the literature stressing the importance of diagnosing inflammatory bowel disease as early as possible. Professor Booth's opinion was that the fact that one of several inflammatory markers was raised "to the smallest possible degree" did not justify colonoscopy, without further prior investigation. Professor Rutter said that the documents and circumstances suggested research not clinical investigation.

118. As I explain below, child 12's case contained particular features which required careful analysis and consideration by the panel. If its expressed reasons are an accurate summary of the panel's analysis, it did not fulfil that requirement. Its determinative reasons were as follows:

> "19a. You subjected child 12 to a programme of investigations as part of the project referred to at paragraphs 2b and 2c above,
>
> Found proved. In reaching its decision that you subjected this child to a programme of investigations, the panel is satisfied with the evidence contained within the letter from (child 12's mother) to you of 20 October 1996, where she makes it plain that she had seen the "Proposed clinical and scientific study" and that she is "happy for (child 12) to be referred onto Dr. Wakefield's study project", and your response to her dated 25 November 1996, in which you state that as she is keen to proceed with investigation, you will arrange it, and the children are usually admitted for the course of a week and various other aspects of the protocol are undertaken. The panel also noted your letter dated 21 October 1996 to Dr. Wakefield in which you state "I did not feel it right in fact to proceed with our intensive programme at the moment until we have had Ethical Committee approval and it is clear that the parents wish us to proceed"
>
> …
>
> d. You caused child 12 to undergo a
>
> i. colonoscopy,
>
> Found proved
>
> ii. barium meal and follow through,

Found proved

Which was not clinically indicated,

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

…

j. Your conduct as set out above was contrary to the clinical interests of child 12,

Found proved on the basis of the above findings."

119. What the panel had to determine under paragraph 19a was whether Professor Walker-Smith admitted child 12 for a colonoscopy and other investigations for the purpose of research. The fact that child 12's mother had been sent a copy of Project 172-96 by Dawbarns, may have cast light on the motivations of Dr. Wakefield and of child 12's mother; but it was of limited significance in casting light upon Professor Walker-Smith's purpose. To discern that, it is necessary to look at what he did. His actions permit only one rational conclusion. In the light of the minimal gastrointestinal symptoms then present, he told Dr. Wakefield that he did not feel it right to proceed with "our intensive programme" until Ethics Committee approval and parental consent had been given. He was recognising that to proceed with colonoscopy without further signs of abnormality revealed by the blood tests would amount to research, which would require Ethics Committee approval. The panel treated this letter as decisive evidence that Professor Walker-Smith did decide to undertake unauthorised research in the case of child 12. That would have been a perverse conclusion unless the panel was satisfied that the abnormal CRP did not cause Professor Walker-Smith to change his mind. They did not so decide or, if they did, did not say so. This episode also has a wider consequence. It provides unequivocal evidence that Professor Walker-Smith had the distinction between clinical practice and research clearly in mind as children were being admitted for the investigations. He wrote the letter five days after receiving Dr. Pegg's letter of 15th October 1996 asking him to confirm "that the child would undergo this regime even if it was not in a trial". Because the GMC did not challenge the truthfulness of Professor Walker-Smith's reply three weeks after the letter to Dr. Wakefield, it did not suggest that Professor Walker-Smith's initial caution in relation to child 12 was prompted by Dr. Pegg's request for confirmation. In the absence of such a suggestion, this episode is cogent evidence that Professor Walker-Smith did tell the truth to Dr. Pegg – a fact which casts clear light on his intention in undertaking the investigations of all of the Lancet children.

120. Against that background, the critical issues in the case of child 12 were: did Professor Walker-Smith change his mind as a result of the abnormal CRP result? And, if so, was his decision to proceed to colonoscopy clinically indicated? In her written closing submissions Counsel for the GMC did not submit that Professor Walker-Smith's evidence about the reason for his change of mind was false – merely that it was unjustified. The sole critical issue was, therefore, whether it was. On this issue, the panel failed, as in the other cases to express any decision upon the expert

evidence. If it had done, it would have had to have concluded that the opinions of Professor Walker-Smith, Dr. Murch and Dr. Miller were outwith the spectrum of reasonable medical opinion before concluding that colonoscopy and barium meal and follow through were not clinically indicated. It did not do so.

121. At paragraph 19e, the panel found that it was not proved that Professor Walker-Smith had caused child 12 to undergo a lumbar puncture. Given the notes about the ward round of 6th January 1997, this conclusion was unsurprising. It also had a wider consequence in the case of child 12. Cancellation of investigations prescribed as part of a programme of research is inconsistent with rigorous fulfilment of that programme. It suggests clinical practice.

122. There was a further, minor, indication that child 12 was not being investigated under Project 172-96: only four or five biopsies were submitted to the histology department, not the ten prescribed by Project 172-96.

123. The finding at paragraph 19j stands or falls with the other findings and adds nothing to them.

124. For the reasons given above, on the case presented by the GMC, the panel's conclusion that Professor Walker-Smith was guilty of serious professional misconduct in the handling of child 12's case was not merely flawed, but wrong.

Child 8

125. Child 8 (the only girl of the Lancet children) was born on 6th July 1993. Early general practice notes record that she had a congenital heart disease, which was corrected surgically, and was developmentally delayed. MMR vaccine was given on 27th January 1995. She had a grand mal convulsion in February 1995 two weeks later. She was never the same again. She had frequent diarrhoea, but ate well and gained weight. On 13th February 1995 she was admitted to North Tyneside General Hospital, to investigate her febrile convulsion "in association with gastro-enteritis". No neurological abnormalities other than developmental delay were found. She was readmitted to the same hospital on 1st November 1995 because she was screaming constantly and had diarrhoea. The ward round note stated: "? Toddler diarrhoea". On 1st December 1995 Mrs Clydesdale, a Consultant Clinical Psychologist, raised the possibility of an autistic type of disorder, which she discounted. She was still screaming and experiencing diarrhoea in early 1996. On 13th May 1996, Dr. Houlsby, a Consultant Paediatrician at North Tyneside General Hospital, noted some improvement in her screaming and thought that she had toddler's diarrhoea. She still lacked speech. Similar conclusions were reached at a special needs team meeting on 5th June 1996. On 21st August 1996, Heather Gate, a Senior Dietician, noted her mother's report that child 8 experienced pain on moving her bowels, that her stools were often very mucosy and sometimes foul smelling. Ms Gate thought that testing for malabsorption of fat should be undertaken. On 13th September 1996 Dr. Houlsby expressed the view to child 8's general practitioner that it was extremely unlikely that MMR was the cause of her problems.

126. On 3rd October 1996, Dr. Jelley, child 8's general practitioner, wrote to Dr. Wakefield stating that her mother had told him that a referral letter was required from him to accept child 8 "into your investigation programme", which he understood to be into

the possible effects of vaccine damage and her gastrointestinal symptoms. On 9th October 1996 Dr. Wakefield wrote to Professor Walker-Smith enclosing details of child 8 "who was referred to me with secondary autism and bowel problems". On 3rd December 1996, Professor Walker-Smith wrote to child 8's mother telling her that he had arranged for her admission for investigations, beginning with a colonoscopy, on 19th January 1996 (sic).

127. The clinical admission note of 19th January 1997 identified the problem as "developmental delay; diarrhoea since last 1 ½ years". A full clinical history included noting that she deteriorated dramatically after her febrile convulsion, two weeks after the MMR vaccine, since when she had developed screaming attacks and diarrhoea. Although her behaviour had improved in the last few months, she still did not speak. Dr. Thomson's colonoscopy report of 20th January 1997 recorded a normal appearance, except for mild increase in lymph node tissue in the terminal ileum. He noted, against plan: "Dr. Wakefield protocol". The histology report noted minimal inflammatory changes. Child 8 was seen by Dr. Berelowitz, who reported to Professor Walker-Smith on 28th January 1997 that he did not think an autistic spectrum diagnosis was merited, but was left wondering whether she had a post-vaccination encephalitis. Child 8 was discharged from the Royal Free Hospital on 28th January 1997, but it was not until 27th November 1997 that Dr. Casson sent a discharge summary to her general practitioner. He stated that the results of the investigations conducted "are not indicative of marked ongoing inflammation". The only letter from Professor Walker-Smith is one dated 14th April 1998 to Dr. Jelley recommending a therapeutic trial of an anti-inflammatory drug.

128. A striking feature of child 8's case is that there was no outpatient assessment before admission. Professor Walker-Smith's explanation, which he did not claim was based on memory of the particular case, was that a precedent had been set by the case of child 4 (with whose admission he had nothing to do, as the panel found) who had also been referred by the same general practice in the North East, and that for pragmatic reasons this far from ideal decision must have been taken. He emphasised that, on admission on 19th January 1997, child 8 would have to be assessed by a Consultant – in this case Dr. Thomson – before colonoscopy and other investigations were undertaken. He supported the decision to do so, because of the reported symptoms: screaming, abdominal pain and bouts of very loose stools, all associated with a behavioural disorder. Dr. Miller supported his view, stating that the long standing symptoms clearly required investigation and that, in the light of experience gained in the cases of other children, colonoscopy was a reasonable clinical step. Professor Rutter and Professor Booth considered that the referral was research-driven. Professor Booth also stated that the decision to admit without a prior outpatient assessment and inflammatory markers was not justified; and that, in the absence of other supportive pieces of evidence inflammatory bowel disease was present, colonoscopy was not clinically indicated.

129. The determinative findings of the panel were as follows:

> "21a. You subjected child 8 to a programme of investigations as part of the project referred to at paragraphs 2b and 2c above,
>
> Found proved. In reaching its decision that you subjected this child to the programme of investigations, the panel noted that

> no clinician at the Royal Free had seen the child at outpatients prior to her admission. Your letter to child 8's mother, dated 3 December 1996 stated, "I have had documentation concerning child 8 and I have heard that you would like us to go ahead with the investigations…I have arranged for her to be admitted…the colonoscopy will be the next day…other investigations will be arranged during the week.
>
> …
>
> d. You caused child 8 to undergo a,
>
> i. colonoscopy,
>
> Found proved
>
> iii. barium meal and follow through,
>
> Found proved
>
> Which was not clinically indicated,
>
> Found proved. The panel considered that there were minimal GI symptoms to warrant a colonoscopy at that stage. It also noted your own evidence (Day 94 B32) that if a colonoscopy was not clinically indicated, "then the barium meal and follow through is not.
>
> …
>
> j. Your conduct as set out above was contrary to the clinical interests of child 8,
>
> Found proved on the basis of the above findings."

130. Child 8's case contained a significant feature, potentially adverse to Professor Walker-Smith: that he had arranged for her admission for investigations without first assessing her, or causing her to be assessed by another consultant, at an outpatient's clinic. Given the elapse of time since her admission and the fact that he did not see her or her mother on any occasion, it is unsurprising that his recollection of circumstances was imperfect. There must have been some reason for his departure from normal practice; and the reasons that he gave were not outlandish. Ideally, the panel should have said whether it rejected them and, if so, why. Nevertheless, the panel were entitled to take the unusual arrangements for admission into account, without doing so expressly. If there had been a number of other similar instances, this pattern of admission would have been cogent evidence of a research purpose for the admissions. It is, however, the only instance in which this occurred which can be laid at the door of Professor Walker-Smith. By itself, it is no more than one piece of evidence to support the GMC's case and cannot make up for the identified deficiencies in the panel's reasoning on the remainder of the case.

131. The finding at 21d is, as in the other cases, vitiated by the lack of evidence that Dr. Miller's view was outwith the spectrum of reasonable medical opinion and the panel's failure to deal with his evidence. His view that there were clear gastrointestinal and behavioural symptoms warranting a colonoscopy cannot simply be dismissed by stating that the symptoms were "minimal" in the view of the non-expert panel. The specific reference to Professor Walker-Smith's evidence that if a colonoscopy was not clinically indicated, "then the barium meal and follow through is not" is puzzling. It is the only reference to Professor Walker-Smith's oral evidence in the findings related to the Lancet children. The natural expectation is that it would be significant and referable to this child. The point was, however, freely conceded and common ground in the cases of all of the Lancet children. It is a minor instance of the panel fixing on an insignificant bit of evidence to support a finding, when the evidence which had to be analysed to do so was not.

132. The finding at 21j stands or falls with the other findings and adds nothing to them.

Child 7

133. Because no finding of serious professional misconduct was made in relation to child 7 except that he was admitted for the purpose of unapproved research, his case can be dealt with shortly.

134. Child 7 was born on 24th February 1994 and was the brother of child 6. Before his first birthday, he suffered what was noted in his general practice records as partial complex seizures. An EEG performed in June 1995 revealed abnormality in the right frontal to central region of his brain. MMR vaccine was given in November 1995. By March 1996, his general practitioner was noting that he had problems of constipation, with occasional blood and abdominal pain. He was referred to the Royal Alexandra Hospital. On 2nd July 1996, Dr. Trounce told his general practitioner Dr. Nalletamby that the abnormality detected on the original EEG might have misled the clinicians into a diagnosis of epilepsy.

135. On 5th October 1996 Dr. Nalletamby spoke to Professor Walker-Smith asking him to see child 7. He said that he probably did not have autism, but did have convulsions "which I believe may make him eligible for your study" and bowel problems similar to those of his brother. Professor Walker-Smith arranged for an outpatient appointment, which took place on 15th January 1997. The clinical history taken by Professor Walker-Smith included a note that at 2 years he had blood and constipation which alternated with diarrhoea and mucous. On the same day, he wrote to Dr. Berelowitz stating that he was "a sibling of child 6 who is already in our protocol" and that although there were autistic features, his general practitioner had not referred the child for full investigation. On 17th January 1997 Professor Walker-Smith wrote to Dr. Nalletamby, noting the gastrointestinal symptoms identified in his clinical notes. He concluded that in view of the findings in his brother, it would be appropriate for child 7 to be investigated "particularly by colonoscopy". He said he would have other investigations "as part of the protocol".

136. Child 7 was admitted on 26th January 1997. The admission clerking note written by Dr. Dickson, a Senior House Officer, gave as the purpose of admission, "colonoscopy and investigations as part of disintegrative disorder/colitis study." He noted severe constipation and blood and alternating mucous and diarrhoea, with blood – currently

diarrhoea. Dr. Thomson's colonoscopy report of 27th January 1997 noted slight evidence of vascular abnormality in the rectum and sigmoid colon and a marked degree of lympho nodular hyperplasia in the terminal ileum. Barium meal and follow through revealed small filling defects in the terminal ileum, consistent with lymphoid nodular hyperplasia. On Professor Walker-Smith's ward round on 30th January 1997 an anti-inflammatory was suggested and, if biopsy showed inflammation, lactulose. The histology report dated 31st January 1997 revealed no significant histological abnormality. Although child 7 was discharged on 1st February 1997, Dr. Casson's discharge letter was not sent until 19th May 1997. In the interim, he had been seen at his outpatient's clinic on 16th April 1997 by Professor Walker-Smith who suggested a change in the anti-inflammatory medicine previously prescribed. Dr. Casson's discharge letter did no more than recite the procedures which had been undertaken, the results already noted and the medication prescribed by Professor Walker-Smith. Dr. Berelowitz wrote to Professor Walker-Smith on 3rd June 1997 stating his diagnosis of developmental disorder, somewhere between Asperger's and autism. Professor Walker-Smith saw child 7 on several further occasions between 1997 and 1999 and exchanged correspondence with his general practitioner.

137. There was no allegation that the colonoscopy, barium meal and follow through and lumbar puncture performed on child 7 were not clinically indicated. Charge 23g did allege that Professor Walker-Smith's conduct was contrary to his clinical interests; but the panel found that not proved, because there was evidence that the investigations were clinically indicated and were therefore in child 7's clinical interests. The only material allegation was that contained in 23a:

> "You subjected child 7 to a programme of investigations as part of the project referred to a paragraphs 2b and 2c above,
>
> Found proved. The panel is persuaded by the evidence, in particular your letter dated 17 January 1997 to the child's GP, and copied to Dr. Wakefield, which states "he will be having other investigations as part of the protocol", together with the admission clerking notes in the Royal Free Hospital notes, which record that the child is undergoing "colonoscopy and investigations as part of the disintegrative disorder/colitis study" and under the heading "Plan" it states "Autism Protocol"."

The panel went on to find that the investigations were undertaken without the approval of the Ethics Committee because he did not meet the inclusion criteria – that he had been given MMR vaccine not measles or measles/rubella vaccine and had not been diagnosed with disintegrative disorder.

138. Professor Walker-Smith's answer was that he did not admit child 7 under Project 172-96 because that project was never undertaken. The notes made by other clinicians on which the panel based its finding in paragraph 23a suggest that they had a different understanding. Two conclusions were possible: that Professor Walker-Smith had failed to make his intentions clear to other members of his clinical team, once Ethics Committee approval for 172-96 had been given; or that he did intend that child 7 should be admitted under the project, but failed to appreciate that his case did not fit

within the confines of the admission criteria, if strictly construed. Given the panel's finding that the procedures were clinically indicated and in the clinical interests of child 7, the second possibility, which is what the panel appears to have found, was open to it. It then had to consider the significance of this finding. The only ground upon which it found that the investigations lacked Ethics Committee approval was that child 7 did not meet the inclusion criteria because he had had MMR vaccination and had not been diagnosed with disintegrative disorder. Those findings were correct, but could not have justified a finding of serious professional misconduct. As far as I know the reason for including the first criterion has never been explained. The second was treated by gastroenterologists in the clinical team as shorthand for a disorder on the autistic spectrum. All that these (repeated) errors established were that Dr. Wakefield used inaccurate words to describe the conditions which he was investigating, which Professor Walker-Smith did not correct.

Child 10

139. Because the panel made no finding of serious professional misconduct in relation to child 10, except that he was admitted for the purpose of unapproved research and in relation to Transfer Factor, which I deal with separately below, his case, too, can be dealt with shortly.

140. Child 10 was born on 17th February 1993. MMR vaccine was given on 21st February 1994. On 26th October 1994, child 10's mother wrote to Dr. Thomas, his general practitioner, stating that he showed signs of some of the same problems as his sibling. On 1st May 1995 Dr. Davis, a Consultant Community Paediatrician at University Hospital Cardiff, wrote to Dr. Thomas, setting out a full behavioural history, and stating that child 10 had a number of features characteristic of autism, but that he was not in the "autistic range".

141. On 14th October 1996 Dr. Hopkins, child 10's general practitioner, referred him to Professor Walker-Smith. He gave a brief history of his condition. Professor Walker-Smith replied on 29th October 1996, saying that he would be delighted to see child 10 at his outpatient clinic. He did so on 8th November 1996. He noted that Dr. Davis had found a high measles antibody and low iron in 1995 and that he now hopped, screamed and clutched his stomach and had episodes of watery diarrhoea up to five times a day. Professor Walker-Smith wrote to Dr. Hopkins on 11th November 1996, identifying those symptoms and stating that the parents were keen that he should be investigated for "possible gastrointestinal disease". He thought that account needed to be taken of the high measles antibody.

142. Child 10 was admitted on 16th February 1997. Dr. Casson made his usual full clinical note, which included reference to deterioration, pulling his knees up and clutching his abdomen in summer 1996 and his lack of bowel control. The reason given in the endoscopy clerking sheet of the same date for the procedure was "high measles antibody, autistic clutches abdomen, ?inflammatory bowel disease". The endoscopy report of 16th February 1997 noted prominent lymphoid follicles in the colon, erythematous granular mucosa around a swollen ileo-caecal valve and minor inflammatory changes and striking lymph nodular hyperplasia in the terminal ileum. Dr. Murch's colonoscopy report of 17th February 1997 revealed clear abnormalities:

> "This colonoscopy was definitely abnormal, in probably a more striking example of the pattern seen in the cohort of the autistic children. The rectum showed definite mild abnormality, with a slightly granular mucosa and abnormal vascular pattern. Prominent lymphoid follicles could be seen throughout colon, with no other mucosal abnormality. The caecum showed an erythematous, granular mucosa around a swollen ileo-caecal valve, while the terminal ileum showed minor inflammatory change and striking lymphoid hyperplasia distally.
>
> I suspect that the biopsies will show unequivocal abnormality!"

Perhaps surprisingly, the first undated histology report did not. A second report dated 19th February 1997 found minor abnormalities: confluent lymphoid aggregates in the biopsy of the ileum and a very subtle scattering of chronic inflammatory cells within the lamina propria in the large bowel. A lumbar puncture was performed on the 17th February 1997. Child 10 was seen by Dr. Berelowitz on 18th February 1997, who diagnosed an encephalitic episode which led to some low grade generalised brain damage. Dr. Casson's discharge summary dated 17th March 1997 recited the procedures and their results and recommended anti-inflammatory medication.

143. The panel found, in paragraph 25a of its determination that Professor Walker-Smith had subjected child 10 to a programme of investigations to further Project 172-96. Its reasons referred to the introduction to the clerking notes, already cited, and two letters from other practitioners – Dr. Davis, at the University Hospital Cardiff, who had written to Professor Walker-Smith on 6th February 1997 with a description of the investigations undertaken by his team and concluding, "I would be interested to know your findings and look forward to the outcome of the research in due course"; and in Dr. Berelowitz's letter to Professor Walker-Smith of 20th February 1997 (in which he stated his diagnosis) that child 10's father had said that his mother "would not wish to participate in a research interview". The panel found that child 10 did not meet the inclusion criteria for Project 172-96, because he had been vaccinated with MMR and did not manifest disintegrative disorder. It was invited to find that the colonoscopy and lumbar puncture were not clinically indicated, but declined to do so – on the basis that there was insufficient evidence to support the charge in relation to the colonoscopy and because it accepted the evidence of Dr. Thomas that lumbar puncture was clinically indicated. It also found that Professor Walker-Smith's conduct was not contrary to the clinical interests of child 10, because there was insufficient evidence to make that finding.

144. The significance of the panel's findings to the overall case against Professor Walker-Smith is the same as in the case of child 7.

Conclusions to be drawn from the panel's findings in the Lancet children's cases

145. The panel repeatedly laid emphasis upon the circumstances in which each child was admitted for the investigations and the terms of the contemporaneous letters, in particular those from Professor Walker-Smith, leading to admission. This was a legitimate approach and led the panel to discern a pattern in the admissions: that each child was admitted to undertake a standardised programme of investigations, which were, with some exceptions, carried out. What the panel's stated reasons do not do,

however, is to justify its conclusion that the investigations were for the purposes of Project 172-96 and not for the purpose of a developing clinical project. The panel had to decide whether, as the GMC contended, the admissions were to fulfil a research programme and began when the protocol for that programme was settled; or that Dr. Wakefield began his research when the clinical team had reached sufficient agreement on a clinical protocol for children with gastrointestinal and behavioural disorders to permit them to proceed. The terms of the letters and Dr. Wakefield's participation in referrals do not, by themselves, provide the answer to that question. That required a deeper and more careful analysis than it appears to have received from the panel.

146. Both sides rightly focussed on the early admissions – children 1, 2, and 3. Careful analysis of their history does not support the panel's finding. Child 1, the first to be admitted, was only admitted after Professor Walker-Smith had changed his provisional diagnosis as a result of an abnormal blood test result. Child 2 was only subjected to neurological tests after Dr. Thomson had checked with Dr. Surtees, at Great Ormond Street, that the tests were appropriate – and what they were intended to reveal or exclude, which included metabolic disorder. (Project 172-96 only proposed testing for measles virus). Child 3's case was the only one which was consistent with the GMC's contention.

147. There were further significant anomalies in the cases of child 6 and child 12, for the reasons explained in paragraphs 80 and 119 of this judgment.

148. The fact that there are four anomalous cases out of ten (or eleven if the case of child 4 is included) should have given the panel pause for thought and did require an explanation for their conclusion that all of the children were admitted for the purpose of research. The detailed findings of the panel in the cases of the individual children did not fill the obvious gaps in its general conclusions. In no case did it address the indications in the medical notes which supported the oral evidence of the clinicians that they were undertaking a programme of diagnostic and therapeutic investigations, not research; or give adequate reasons for rejecting that account in the case of each individual child.

149. Further, the panel's finding of serious professional misconduct in respect of the Lancet children was principally founded on its conclusion that in seven of the ten cases in which it found Professor Walker-Smith at serious fault, he subjected the children to investigations which were not clinically indicated and were contrary to their clinical interests. It is not obvious from its decision that if the investigations were clinically indicated, a finding of serious professional misconduct would have been made, or justified. Its findings were as follows:

> "The children described in the Lancet paper were admitted for research purposes under a programme of investigations for Project 172-96, the purpose of which was to investigate a postulated new syndrome following vaccination. The Panel rejected Professor Walker-Smith's contention that Project 172-96 was never undertaken. It found that Professor Walker-Smith, in an application for Project 172-96, to the Royal Free Hospital Ethics Committee, was named as a Responsible Consultant and thereby took on the shared responsibility for the research governance of the application; for ensuring that only

children meeting the inclusion criteria would be admitted; that conditions attached to the Ethics Committee approval would be complied with; and that the children would be treated in accordance with the terms of the approval given. The Panel also concluded in accordance with expert evidence that Responsible Consultants who sign up to research are individually responsible and have a duty to ensure such research governance."

In respect of Child 2, 1, 3, 6, 9, 5, 12, 8, 7 and 10, the Panel found that Professor Walker-Smith subjected them to investigations as part of Project 172-96, a research project, without Ethics Committee approval, thus without the ethical constraints which safeguard research. The Panel further found that the investigations carried out on Child 2, 1, 3, 9, 5, 12 and 8 were contrary to his representations to the Ethics Committee that they were clinically indicated.

Ethical considerations are there to protect research subjects, to reassure the public and they are crucial to the public's trust in research medicine. The conditions for approval for Project 172-96 and the inclusion criteria for it were not complied with and thus the expectations of the Ethics Committee and their reliance on the probity of Professor Walker-Smith as a Responsible Consultant were not met.

In respect of the clinical care of the children, Professor Walker-Smith assessed nine of the Lancet children in the outpatients' clinic, prior to admission and all eleven children were admitted to hospital under his clinical care. The public is entitled to expect that patients entrusted to the clinical care of a doctor will be treated in accordance with their best clinical interests.

With regard to Child 2, 1, 3, 9, 5, 12 and 8, Professor Walker-Smith caused all seven of them to undergo colonoscopies that were not clinically indicated.

In respect of Child 2, 1, 3, 9, 5, 12 and 8 Professor Walker-Smith caused all seven to undergo barium meals and follow throughs which were not clinically indicated.

In respect of child 3 and 9, Professor Walker-Smith caused these two children to undergo lumbar punctures which were not clinically indicated.

In respect of Child 4, 9, 12 and 8, Professor Walker-Smith failed to record in the medical records the basis upon which their histological diagnoses were changed. He also failed to record the reason for a prescription in respect of Child 8, when the clinical histology report did not indicate a need for this medication. Good Medical Practice emphasises the need to

> record accurate and contemporaneous clinical findings and keep other colleagues well informed when sharing the care of patients. The Panel considered that this was a failing on Professor Walker-Smith's part which could lead to confusion in respect of the children's subsequent treatment.
>
> In respect of seven of the Lancet children, 2, 1, 3, 9, 5, 12 and 8, Professor Walker-Smith's conduct was contrary to their clinical interests. The Panel is concerned that Professor Walker-Smith repeatedly breached the fundamental principles of research and clinical medicine. It concluded that his actions in these areas were sufficient to amount to serious professional misconduct."

150. It is in its findings on the clinical issues in the individual cases of the Lancet children that the most numerous and significant inadequacies and errors in the determination of the panel occur. In no individual case in which the panel made a finding adverse to Professor Walker-Smith did it address the expert evidence led for him, except to misstate it. The issues to which this evidence went were of fundamental importance to the case against him. Universal inadequacies and some errors in the panel's determination accordingly go to the heart of the case. They are not curable. Unless the remainder of the panel's findings justify its conclusion that Professor Walker-Smith was guilty of serious professional misconduct, its determination cannot stand.

The Lancet paper

151. The results of the investigations into the Lancet children were written up in a paper published in the Lancet on 28th February 1988. Dr. Wakefield and Professor Walker-Smith were placed first and last in the list of authors. There was an arcane dispute about whether that meant that Professor Walker-Smith was a "senior" author, the main result of which was to permit the panel to acquit Dr. Murch of serious professional misconduct on charges arising out of the publication of the Lancet paper because, given that his name appeared second, he was not a "senior" author. For the purposes of Professor Walker-Smith's case, all that really matters is that he was identified in the first footnote to the paper as "the senior clinical investigator". On any view, he carried substantial responsibility for the contents and accuracy of the paper.

152. It was drafted by Dr. Wakefield and circulated amongst the clinicians in July 1997. Its contents were also discussed by Dr. Wakefield in an interview with the general practice magazine Pulse. This prompted the two letters from Professor Walker-Smith to Dr. Wakefield noted in paragraph 19(vi) of this judgment. It also prompted Dr. Berelowitz to write to Professor Walker-Smith on 5th August 1997. He stated that he would like to be sure that two issues were emphasised: first, because the onset of autism and disintegrative disorder always occurs at the end of the first year of life, no causal connection between vaccination and autism could yet be drawn; secondly, general practitioners and the general public should not draw strong conclusions from the paper about whether or not children should be vaccinated against measles. Finally, he proposed that the title should be amended, to substitute "Developmental disorder" for "Regressive behavioural disorder". The draft upon which he was commenting was almost certainly an undated draft headed "A new syndrome:

Regressive developmental disorder associated with ileo-colonic lympho-nodular hyperplasia, non-specific colitis and immunodeficiency". The text of this draft included the following:

> "Conclusions of clinical study: we have identified significant gastrointestinal pathology in association with developmental regression in a selected group of previously, apparently normal children. In the majority there was a clear temporal association with possible environmental triggers. Anecdotally, children who were subsequently treated with standard therapy for inflammatory bowel disease had a mild marked improvement in both behavioural and intestinal symptoms."
>
> "Conclusion…the data are not proof of a causal association between measles virus and this syndrome: however, they are significantly provocative to merit further detailed study, in particular, to either establish or refute the possible association with MMR vaccine".
>
> "Ethical approval: approval for these studies has been granted by the Ethical Practices Committee of the Royal Free Hampstead NHS Trust."

Dr. Berelowitz's comments appear to have been reflected in all subsequent drafts and in the final published article. The next draft was headed "Ileal-lymphoid-nodular hyperplasia, non-specific colitis and developmental disorder in children: a new syndrome?" A passage which dealt with the possible causal link with MMR vaccine stated

> "It is important to note that the present study does constitute proof of an association between MMR and the syndrome described: detailed viralogical studies are underway that may help to resolve this issue….If there is a causal link with the MMR then a rising incidence might be anticipated following its introduction in 1988. Despite an impression of a rise in autistic spectrum disorders, published data are inadequate to determine whether there is a rising incidence or a link with MMR. The diagnosis of autism is usually made on symptoms starting in the first year of life, when children receive MMR. Despite the striking temporal association with MMR in many of these children, this factor must be taken into consideration when examining the apparent association described."

This draft contained a revised form of words about ethical approval:

> "This clinical investigation has been approved by the Ethical Practices Committee of the Royal Free Hospital NHS Trust."

153. Professor Walker-Smith gave unchallenged evidence that this was the last draft of the paper which he saw. Dr. Murch said, again in unchallenged evidence, that there was then a meeting attended by all of the researchers and clinicians involved to discuss the

draft, which they approved. At the end of the meeting there was a discussion between Dr. Murch, Professor Walker-Smith, Dr. Thomson and Dr. Wakefield about the reference to Ethics Committee approval of "this clinical investigation", because it was a clinically driven investigation which did not require Ethics Committee approval. Dr. Murch said that Dr. Wakefield had assured them that he would liaise with the Lancet to ensure that appropriate wording was substituted. The wording in the published paper which neither Dr. Murch nor Professor Walker-Smith saw before publication was,

> "Ethical approval and consent
>
> Investigations were approved by the Ethical Practices Committee of the Royal Free Hospital NHS Trust, and parents gave informed consent."

This statement was untrue and should not have been included in the paper.

154. A temporal link between the onset of behavioural problems and MMR vaccination was noted both in the draft seen by Professor Walker-Smith and in the published paper. The draft stated,

> "In eight cases the onset of behavioural problems had been linked, temporally, with MMR vaccination, either by the parents or by the child's physician. Five of these eight had suffered an early adverse event, including rash, fever, delirium and, in three cases, convulsions. In those children in whom a precipitating event was reported by the parents, the average interval from exposure to first behavioural symptom was 6.3 days (range 1-14 days). Parents were either less clear or unclear about the timing of onset of intestinal features firstly, because children had not achieved toilet training at the time that symptoms first appeared, and secondly, because behavioural features indicative of, for example, abdominal pain only became evident to parents with time, since children were unable to communicate symptoms directly."

The published paper stated,

> "In eight children, the onset of behavioural problems had been linked, either by the parents or by the child's physician, with measles, mumps, and rubella vaccination. Five had had an early adverse reaction to immunisation (rash, fever, delirium; and, in three cases, convulsions). In these eight children the average interval from exposure to first behavioural symptoms was 6.3 days (range 1-14). Parents were less clear about the timing of onset of abdominal symptoms because children were not toilet trained at the time or because behavioural features made children unable to communicate symptoms."

The charges accurately summarised that passage as follows:

> "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."

This paraphrase was admitted and found proved.

155. The panel went on to find that Professor Walker-Smith knew that the reporting of a temporal link between the syndrome described and MMR vaccination had major public health implications and would attract intense public and media interest. Consequently, as a senior author, Professor Walker-Smith had a duty to ensure that the factual information in the paper and any information provided by him in response to queries was true and accurate. Although not formally admitted, there was, and could have been, no real issue about these propositions. It was precisely because Professor Walker-Smith and Dr. Murch were concerned about the public health implications that they wrote the letters to Dr. Wakefield and published the press release referred to in paragraph 7 of this judgment.

156. The panel then made disputed findings on the meaning of a significant part of the paper in paragraphs 29c(i) and 30, 31 and 32,

> "29….
>
> c…in the circumstances set out at paragraph 29b above, [i.e. the public health implications of the paper] and as one of the senior authors of the Lancet paper, you
>
> …
>
> i. knew or ought to have known of the importance of accurately and honestly describing the patient population,
>
> Found proved
>
> …
>
> 30a. You failed to state in the Lancet paper that the children whose referral and histories you described were part of a project, the purpose of which was to investigate a postulated new syndrome comprising gastrointestinal symptoms and disintegrative disorder following vaccination,
>
> Found proved on the basis that the children who were described in the paper were admitted under a programme of investigations under Project 172-96 for research purposes.
>
> b. Your conduct as set out at paragraph 30a was,
>
> i. dishonest,

Found not proved. The panel concluded that your actions were not premeditated and you did not intend to be deliberately dishonest. It noted that you did not write or see the final draft of the paper and considered that you had been naïve in your lack of thoroughness regarding the paper submitted to the Lancet. [Both sides accept that the reference to naivety was a reference to the conclusion of the panel and not to any evidence given by Professor Walker-Smith].

ii. Irresponsible,

Found proved. The panel considered that you as a senior author should have checked the validity or otherwise of the paper. You said you were given the second draft but did not see the final one. The panel concluded that your conduct as a senior clinician and senior author was irresponsible.

iii. Resulted in a misleading description of the patient population in the Lancet paper;

Found proved

31a. The Lancet paper stated that the children who were the subject of the paper were "*consecutively referred to the department of Paediatric Gastroenterology with a history of a pervasive developmental disorder with loss of acquired skills and intestinal symptoms (diarrhoea, abdominal pain, bloating and food intolerance)*" and subsequently described them as a "*self-referred group*",

Admitted and found proved.

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

i. A routine referral to the Gastroenterology Department in relation to symptoms which included gastrointestinal symptoms,

Found proved

ii. A routine process in which the investigators had placed no active part,

Found proved

The panel took into account the article in the Lancet (Volume 350 October 4 1997) "Writing for the Lancet" – "It is a general reader whom you are trying to reach". The panel is satisfied that a general reader would interpret the wording in 30a [in fact 31a] to mean that children were referred to the Gastroenterology Department with gastrointestinal symptoms

and that the investigators had played no active part in that referral.

32a. Contrary to paragraph 31b(i) the referrals of,

i. Child 1 as set out at paragraph 6a and 6b

Found proved

ii. Child 9 as set out at paragraphs 14a – 14c

Found proved

iii. Child 5 as set out at paragraphs 16a-16b

Found proved

iv. Child 10 as set out at paragraphs 24a and 24b

Found proved

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

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

b. Contrary to paragraph 31b(ii), the referrals, of,

i. Child 2, as set out at paragraph 4e,

Found not proved. At the end of the first assessment of the child, you said you would be happy to see the child again should the need arise. The panel accepted that you wrote to child 2's mother on 16 May 1996, offering to see child 2 again, in response to her telephone call saying that her child's symptoms had worsened.

ii. Child 9, as set out at paragraph 14a,

Found proved. The panel is satisfied that your letter to Dr. Spratt the paediatrician, asking if it was appropriate to investigate child 9 in the protocol, was tantamount to an express invitation for the child to be seen by you.

> Involved your express invitation for the child to be seen by you
>
> c. The description of the referral process in the Lancet paper was therefore,
>
> i. Irresponsible
>
> Found proved
>
> ii. Misleading
>
> Found proved
>
> iii. Contrary to your duty to ensure that the information in the paper was accurate,
>
> Found proved
>
> In reaching its decision the panel concluded that your description of the referral process as "routine" when it was not, was irresponsible and misleading and contrary to your duty as a senior author."

157. On the premise that the panel was right to find that the Lancet paper was addressed to the general reader and that it was the interpretation of the general reader which mattered, I am as well qualified as the panel to construe its meaning. Further, I am entitled to and do, apply the familiar canon of construction used by judges in construing documents: to read and construe the whole document, not just selected words. Thus construed, this paper does not bear the meaning put upon it by the panel. The phrase "consecutively referred" means no more than that the children were referred successively, rather than as a single batch, to the Department of Paediatric Gastroenterology. The words did not imply routine referral. The paragraph from which the words "a self-referred group" was taken reads:

> "We describe a pattern of colitis and ileal-lymphoid-nodular hyperplasia in children with developmental disorders. Intestinal and behavioural pathologies may have occurred together by chance, reflecting a selection bias in a self-referred group; however the uniformity of the intestinal pathological changes and the fact that previous studies have found intestinal dysfunction in children with autistic-spectrum disorders, suggests that the connection is real and reflects a unique disease process."

The general reader of that paragraph would note the author's caution about the possibility of selection bias in the self-referred group. Taken together with the comments already cited made about the temporal coincidence of the onset of symptoms and MMR vaccination in the case of eight children, the author has made it clear that this was not a routine referral. It was a referral generated by the concerns of parents about a possible link. The statement made by the panel in paragraph 32c that it was Professor Walker-Smith who had described the referral process in the Lancet

paper as "routine" was wrong. It put its stretched meaning of the wording of part of the paper into his mouth and then found that it was irresponsible and misleading. This was not a legitimate finding.

158. The findings in paragraphs 32a that the referrals of four children were not routine because the referring doctors did not mention intestinal symptoms in their referral letters was factually accurate as to the contents of the referral letters, but of no significance. In each case, Professor Walker-Smith elicited gastrointestinal symptoms at his outpatients clinic. The finding at paragraph 32a that all four children "lacked a history of gastrointestinal symptoms" is wrong unless the panel intended only to refer to the contents of the referral letters. The finding in paragraph 32b(ii) was correct, but, on its own, of little significance. (The genesis of the referral is explained in paragraphs 81 and 82 of this judgment). The panel's finding that the description of the patient population in the Lancet paper was misleading would only have been justified if its primary finding that all of the Lancet children were referred for the purposes of research as part of Project 172-96 is sustainable. Because, for the reasons which I have given, it was not, this aspect of its findings must also fall.

159. In paragraph 34 of its determination, the panel found that Professor Walker-Smith was irresponsible and in breach of his duty to ensure that the information in the paper was accurate, because it stated that investigations were approved by the Ethics Committee. This finding was justified. Professor Walker-Smith should not have allowed a paper to be published under his name without ensuring its accuracy. Whether or not that amounted to professional misconduct should have depended on the panel's view of the truthfulness and accuracy of the evidence of Dr. Murch about the meeting between him, Professor Walker-Smith, Dr. Thomson and Dr. Wakefield after the discussion between researchers and clinicians of the last draft of the paper seen by Professor Walker-Smith. If it was, Professor Walker-Smith's omission could properly have been characterised as an error of judgment: it was not misconduct for him, Dr. Murch or Dr. Thomson to invite a research colleague, Dr. Wakefield, to correct a misleading statement in the draft and leave it to him to do so. Because the panel made no finding on that issue, its reasoning is inadequate.

160. The panel made one further finding arising out of the Lancet article. In February 2004, Professor Walker-Smith, who had retired from practice in October 2000, was notified that an investigative journalist, Mr Deer, had made a number of allegations about the Lancet paper, which he had discussed with the Editor, Dr. Horton. On 18th February 2004, Dr. Wakefield, Professor Walker-Smith, Dr. Murch and Dr. Harvey attended a meeting at the Lancet offices, at which they were invited to provide a written response to the allegations for the Lancet. A meeting was convened next day by the Vice-Dean of the Medical School at the Royal Free Hospital, Professor Hodgson, who asked them to investigate and respond to the allegations. They had a day in which to do so. Professor Walker-Smith and Dr. Thomson checked the clinical notes obtained from the Royal Free Hospital's Records Department. Professor Walker-Smith's recollection was that he did not invite any child to participate in the investigations. A written response from Professor Walker-Smith was published in the Lancet for 6th March 2004, confirming that he had reviewed the medical records, that all of the children were investigated specifically and exclusively by clinical need and that to the best of his recollection he did not invite any children to participate in "our study". The panel found that it was not proved that that statement was made

dishonestly, but that it was irresponsible in one instance only – that of child 9. It clearly relied on Professor Walker-Smith's letter to Dr. Spratt of 11th September 1996. If that letter had been in the Royal Free Hospital clinical notes, this finding would have been justifiable. In fact, it was not. The panel could not reasonably have found Professor Walker-Smith to have been guilty of professional misconduct for failing to remember the terms of a letter which he had written 7 ½ years before, but which was omitted from the records which he was able to check. This finding was unjustified.

Transfer Factor and child 10

161. On 20th June 1997 Jill Thomas, a Research and Clinical nurse at the Royal Free Hospital, noted that child 10's mother had stated that his behaviour had continued to deteriorate and was somehow linked to an upsurge of measles virus. On 30th June 1997, child 10's mother telephoned Professor Walker-Smith to tell him that his behaviour had become lethargic since Easter, his sociability had worsened and his temper tantrums were very bad. She pleaded that child 10 might be allowed to try an unapproved, but harmless, drug, Transfer Factor. On 11th July 1997 she wrote to Jill Thomas, stating that his situation was desperate: their happy and affectionate little boy had "disappeared once again". Someone annotated the letter "Child 10. Prof → for your information". Professor Walker-Smith said in evidence that he read the literature provided to him by Dr. Wakefield about Transfer Factor and satisfied himself that it was a safe and appropriate treatment for child 10 to receive.

162. By a joint letter dated 23rd July 1997 Dr. Wakefield and Professor Walker-Smith wrote to Wendy Spicer, the dispensary manager at the Royal Free Hospital, telling her that they had been approached by child 10's mother who was desperate for her child to try Transfer Factor – an anti-viral therapy developed by Professor Hugh Fudenberg in California. They said that they did not know whether the treatment would work, but were aware that Professor Fudenberg had treated two children with similar symptoms with measles-specific Transfer Factor, with success in one case. They concluded:

> "After due consideration we would like to start (child 10) on measles-specific Transfer Factor and we are prepared to take full responsibility for the outcome of this treatment.
>
> The supplies of the drug are presently in our hands (Dr. Wakefield) and will be deposited with pharmacy later this week when he returns from Birmingham."

Nothing further happened until on 9th September 1997 Dr. Wakefield wrote to Dr. Geoffrey Lloyd, Chairman of the Medical Advisory Committee, a letter which has not been preserved. Dr. Lloyd replied:

> "I am prepared to give you chairman's approval for the use of Transfer Factor for the patient you referred to in your letter of 23 July, namely, (child 10). This should be used on "a named patient basis."

163. On 26th November 1997 the secretary of Dr. Jenkins, Consultant Paediatric Gastroenterologist at University Hospital Wales, under whose care child 10 came,

sent a fax message to Jill Thomas, stating that child 10's mother was anxious to start him on his new medication. A behavioural questionnaire completed by child 10's mother on 12 - 14th January 1998, stated,

> "Over Christmas + New Year we felt very optimistic about the apparent effect of Transfer Factor – there seemed to be such a noticeable change in child 10 but this week we feel pessimistic."

From this answer, the panel drew the justifiable conclusion that child 10 had taken Transfer Factor over Christmas and the New Year 1997/8.

164. In uncontradicted evidence, Professor Walker-Smith said that he had not seen the questionnaire until the hearing and had no knowledge of what had happened after September 1997.

165. On 2nd February 1998, Dr. Wakefield submitted an application to the Ethics Committee for approval of a trial of the effect of Transfer Factor. Between July and November 1998, Professor Walker-Smith and Dr. Wakefield undertook research into the safety of Transfer Factor and reported upon it to the Ethics Committee. Approval for the trial was given on 16th December 1998 and notified on 18th December 1998.

166. When it formulated the charges against Professor Walker-Smith, the GMC did not know that permission had been granted to Dr. Wakefield for the use of Transfer Factor for child 10 on "a named patient basis". Consequently, paragraph 27 of the charges accused Professor Walker-Smith of causing child 10 to be administered Transfer Factor for experimental reasons before obtaining information about its safety or ethical approval; and without recording the fact or dose of the prescription or informing child 10's general practitioner about it or recording any discussion about risks and benefits with child 10's parents in the medical records.

167. The panel's findings were as follows:

> "26a. In or about December 1997 you started child 10 on a substance called Transfer Factor,
>
> Found not proved.
>
> The panel accepted your evidence that you did not, and has seen no evidence to support this allegation."

(Paragraphs 26b – e dealt with the admitted approval of the application made in 1998).

> "27a. You inappropriately caused child 10 to be administered Transfer Factor,
>
> Found proved. The panel is persuaded that child 10 was administered Transfer Factor by the weekly diary card completed by his mother, submitted to the Royal Free Hospital in January 1998 which states, "Over Christmas and New Year we felt very optimistic about the apparent effect of Transfer

Factor…is it possible that the dose now needs to be increased?" The panel concluded that you caused the child to be administered with Transfer Factor on the basis of the letter of 23 July 1997 that you and Dr. Wakefield wrote to the dispensary manager. You informed her "that we would like to start child 10…on measles-specific Transfer Factor and we are prepared to take full responsibility for the outcome of this treatment. The supplies of the drug are presently in our hands (Dr. Wakefield)." Further, Dr. Wakefield sought permission from the Medical Advisory Committee by a letter dated 9 September 1997 for child 10 to be administered Transfer Factor on a named patient basis as is evidenced by the approval letter dated 15 September 1997 sent to him and copied to you, by its Chairman, Dr. Lloyd.

i. For experimental reasons,

Found proved. The panel is persuaded that this was experimental treatment and not given for clinical reasons, because you had not seen or assessed the child before causing him to be administered with the unlicensed drug and you stated "We do not know whether the treatment will work" in your letter to the dispensary manager of the pharmacy, dated 23 July 1997, jointly signed by you and Dr. Wakefield. You also state within the letter, "We are prepared to take full responsibility for the outcome of the treatment".

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

Found not proved. The panel has noted the letter dated 23 July 1997 to the dispensary manager from you and Dr. Wakefield, in which you refer to about 300 peer-reviewed scientific publications on the use TF and state that this substance was safe.

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

Found not proved. The panel has taken into account the letter dated 15 September 1997 from Dr. Lloyd to Dr. Wakefield and copied to you, giving chairman's approval for the use of Transfer Factor to child 10 on a named patient basis. The panel is therefore satisfied that obtaining ethical approval for a clinical trial for this child was not relevant in December 1997.

iv. Without,

a. Recording the fact of or dose of prescription in child 10's medical records,

> Found proved. Despite the application form to the Ethics Committee signed by you on 30 January 1998, stating "Anecdotally we have started one child…on an approved compassionate basis…he has tolerated therapy for one month so far", the panel noted that there is no evidence of any notes nor a recording of this child being seen
>
> b. Informing child 10's general practitioner that child 10 had been prescribed it,
>
> Found proved. The panel concluded an essential requirement of a doctor is to share information with colleagues in the ways the best serves patients' interests. The child's GP did not have knowledge of any prescription of TF other than that contained in a letter from a Consultant Community Paediatrician. You did not inform the GP nor did you arrange for someone else to do so.
>
> c. Recording in child 10's medical records the fact and nature of any discussion as to the risks and benefits of the prescription with child 10's parents,
>
> Found not proved. The panel noted your evidence that after this child was discharged from hospital on 19 February 1997, you did not see the child again and therefore had no opportunity for discussion with the parents of child 10 concerning the prescription and could not have recorded it.
>
> b. Your actions as set out above were,
>
> i. Irresponsible,
>
> Found proved
>
> ii. Contrary to the clinical interests of child 10
>
> Found proved [on the basis of the findings at 27a(i), 27a(iv)a and b]."

168. The panel's findings adverse to Professor Walker-Smith are inconsistent and unjustified. Its finding at paragraph 26a, that he did not start child 10 on Transfer Factor in December 1997 should have been an end of these charges. If he did not "start" child 10 on Transfer Factor, it is impossible to understand how he could have "caused child 10 to be administered Transfer Factor". The panel made no finding about what or who started child 10 on Transfer Factor. It dismissed a similar accusation against Dr. Wakefield.

169. There was nothing to contradict Professor Walker-Smith's evidence that he knew nothing about it until given a copy of the application to the Ethics Committee of 30th January 1998. The material relied on by the panel to find that Professor Walker-Smith had "caused" child 10 to be administered Transfer Factor did not support its

finding. All that it proved against him was that he would like to start child 10 on Transfer Factor and was prepared to take full responsibility for the outcome of the treatment. There was an unfilled gap between that statement of his wish and child 10's mother obtaining the drug to give to her son six months later. The gap was filled by the panel's finding that Professor Walker-Smith did not "start" child 10 on Transfer Factor. It did not rely on the statement in the application form of 30th January 1998, cited in paragraph 27a(iv)a to contradict its earlier finding. If it had done, it could not have borne the weight which might have been put upon it: the application named four clinicians as principal clinical investigators (Professor Walker-Smith, Dr. Thomson, Dr. Murch and Dr. Berelowitz) all or none of whom might have been referred to by the words "Anecdotally we have started one child…"

170. The panel's findings adverse to Professor Walker-Smith on the Transfer Factor issue were perverse. Miss Glynn, wisely recognising the lack of any proper foundation for those findings in the panel's reasoning, submitted, correctly, that these charges were subsidiary and should not form the real focus of this appeal. I agree, but the panel's findings do require analysis, because it went on to find that, in this respect, as in others, Professor Walker-Smith's conduct amounted to serious professional misconduct. There was no basis for that conclusion.

Child JS

171. Child JS was born on 29th November 1990. MMR vaccination was given twice in March 1992 and May 1993. His general practice records record that in June 1994, after a bout of diarrhoea lasting a week, he was referred to Dr. Green, a Senior Lecturer in Paediatrics and Child Health at Birmingham Children's Hospital, because his mother was concerned by his speech delay and possible autism. On 11th October 1994, Dr. Sriskantharajah, Senior Clinical Medical Officer at Birmingham Children's Hospital diagnosed a communication disorder in the autistic spectrum. He was then seen by a number of consultants, including Dr. Brua, a Clinical Psychologist in Worcestershire, who, settled on a diagnosis of "atypical autism" in March 1995. In early 1996, a trial of vitamin B6 treatment produced no noticeable change.

172. On 16th April 1996, child JS's mother wrote to Dr. Wakefield, following a telephone call from him, giving details of changes in his behaviour after the first and second MMR vaccinations: after the first, glazed eyes, diarrhoea and tremendous thirst; and after the second, loss of speech. On 29th April 1996, Dr. Mills, a Consultant Community Paediatrician in Worcestershire, wrote to Dr. Wakefield, copied to Professor Walker-Smith. He stated that child JS presented as a child with classical autism, which his family dated to the MMR vaccinations. Dr. Mills said that he was not keen on sanctioning detailed investigations "unless there seems to be some logic behind them". On 3rd June 1996, Dr. Mills wrote to Dr. Shore, child JS's general practitioner, noting that he had loose motions 2 – 4 times a day, but had no other gastrointestinal symptoms. He again expressed his reluctance to refer child JS "to a far flung centre for gastrological investigation and research". He arranged for child JS to be admitted to the children's ward of a local hospital, for EEG and blood and urine tests. On 23rd October 1996, Dr. Brua wrote to Dr. Mills, copied to child JS's parents, stating that his mother had said that he "seems to be losing his toileting skills" – he had started to urinate and defecate and to wet the bed at night. On 1st November 1996, he told Dr. Mills that he did not think that it was emotional or attention seeking.

173. On 6th November 1996, Dr. Wakefield wrote to Professor Walker-Smith, stating that child JS was a child "I would like to be included in our study if you consider him suitable…JS has been awarded legal aid who will pay for the investigations and this is (in) hand." On the same date, child JS's mother wrote to Dr. Mills, enclosing a copy of Project 172-96 and Dawbarns "fact sheet", the first of which had been sent to her by Dr. Wakefield. On 7th November 1996, Professor Walker-Smith replied to Dr. Wakefield, stating "If Dr. Mills and (child JS's parents) are keen for me to see JS, I would be happy to do so." On the same day, he wrote to Dr. Mills in the following terms:

> "Through Dr. Wakefield we have been looking at a group of children with autistic symptoms related to MMR vaccine and have found that a significant number of children have had gastrointestinal symptoms. When these have been present we have so far found endoscopic abnormalities in all five children we have investigated. I would be quite happy to see (child JS's parents) and to discuss the situation with them and to indicate what investigations might be appropriate and then get your advice as to the right for us to proceed…".

Dr. Mills replied on 15th November 1996, stating that he did not consider that child JS was appropriate for the investigation schedule recommended by Dr. Wakefield and that he did not think that "your research programme is appropriate for him at present". He concluded,

> "I am beginning to wonder whether you and your department are rather pressurising this family and I would request this to stop".

Professor Walker-Smith replied on 22nd November 1996,

> "…I can quite understand you feeling that it may not be appropriate for us to see (child JS) at the moment. However I would be happy to hear from you again should the position change.
>
> In relation to your last comments, I am certainly doing nothing to pressure the family to see us. In fact my department is somewhat overwhelmed by the response of parents who believe that their children have autistic and gastrointestinal symptoms following MMR. I personally had no idea that there were such large numbers of patients in the community across the country where the parents had made this association…"

On 8th January 1997, Dr. Wakefield wrote to Dr. Mills, copied to Professor Walker-Smith, expressing his indignation at the suggestion that the family were being pressurised. Dr. Mills replied on 12th February 1997, reiterating his view that the programme of investigations would not benefit child JS at present.

174. A note in child JS's general practice records of April 1997 records that he had continuing diarrhoea and behavioural difficulties. On 16th April 1997, Dr. Wakefield

wrote to Professor Walker-Smith asking him to reconsider child JS for admission and investigation. He said that his behaviour had deteriorated, that the strain on the family was enormous and that there was legal aid funding to pay for the investigation. On 23rd April 1997, Professor Walker-Smith wrote to Dr. Mills, copied to Dr. Wakefield, stating that he was writing again because he understood from Dr. Wakefield that the family were considerably distressed about child JS,

> "We have begun to have some quite remarkable success in treating children with autism and evidence of bowel inflammation with sulphasalazine [an anti-inflammatory] and related drugs. I do believe it really would be helpful for us to do these investigations in [child JS] or for me to at least see the child to assess the situation. I enclose a copy of our protocol and would be grateful if you would reconsider this issue once more."

The "protocol" was that sent to Dr. O'Connor on 6th February 1997 (to which reference is made under the heading "Facts negating the proposition paragraph (v)), not Project 172-96. As its title indicates, it was concerned with "The rationale, aims and potential therapeutic implications of the investigation of children with classic autism or the autistic spectrum disorder who have gastrointestinal symptoms". Its text set out what the study hoped to achieve:

> "The purpose of this preliminary clinical study is, firstly, to adequately and appropriately investigate the gastrointestinal signs and symptoms manifested by these children: investigation is merited on clinical grounds. It is our experience that these clinical features often have been ascribed to the inevitable consequence of behavioural abnormalities upon bowel function, and as a consequence the children have not necessarily been investigated adequately. It should be stressed, therefore, that the investigations are clinically indicated in all cases that are admitted for evaluation. The validity of this approach is borne out by the fact that most children investigated so far has significant and consistent intestinal pathology (lymphoid-nodular hyperplasia and microscopic colitis). Secondly, the purpose of the study is to seek the presence, and characterize the nature, of any intestinal and cerebral pathologies in affected children. In view of the coincident changes in both behaviour and intestinal symptoms we believe that this form of regressive autism, and perhaps other behavioural problems within the autistic spectrum, may be linked to chronic intestinal inflammation.
>
> It is our aim to investigate and institute appropriate therapeutic measures aimed at controlling the intestinal inflammation and correcting any nutritional deficiencies that may be present. The impact of these measures on behaviour will be monitored. Preliminary experience has shown that mesalazine or enteral nutrition may have significant benefit in some cases.

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

175. Dr. Mills replied on 12th May 1997, asking for details of successful treatments. Professor Walker-Smith replied on 29th May 1997:

> "The success that we have had with treating autistic children is an unexpected secondary aspect of our study, we had expected improvement with the gastro-intestinal symptoms with use of 5 ASA derivatives and salazopyrine, but we had not expected the parents to tell us that there had been such an improvement in behaviour. We are in fact with the help of Dr. Mark Berelowitz, planning a further study to analyse the successes but our work at the moment has been to provide a diagnostic service to determine the gastro-enterological manifestations of these children….
>
> My own position in this work is entirely responsive, when I transferred from Barts to the Royal Free I was quite sceptical about the research work of Dr. Andy Wakefield, but since I came here it is absolutely obvious to me that there is a large unmet need of children with autism who have a variety of GI symptoms ranging from quite mild symptoms to quite major ones. The unexpected outcome of this research has led us to being very interested in the treatment of these drugs…
>
> I am myself not soliciting for patients to be referred to us, but I am reacting to the parent's requests."

176. On 5th July 1997, child JS's mother wrote to Dr. Wakefield, copied to Dr. Mills, asking for him to refer her son "for tests to see if there is any way he can be helped following the devastating damage caused by his MMR injection in 1992". She said that he had a history of diarrhoea, but that, because he had no communication, she could not tell where his discomfort lay. Dr. Mills would not refer child JS to Professor Walker-Smith under the National Health Service Scheme. Following this rebuff, his mother wrote to Dr. Wakefield in a letter which has not been preserved. It was passed to Professor Walker-Smith who responded, on 14th July 1997, saying that he would be happy to see child JS as a private outpatient. His personal assistant made an appointment for JS to be seen by Professor Walker-Smith, on a private basis, at his outpatient ward round on 13th July 1997. He made his usual detailed clinical note, which included a history of diarrhoea aged 2, but not since. On 31st July 1997, he wrote to Dr. Shore, child JS's general practitioner, setting out his clinical history and observing that he was a child within the autistic spectrum "who does have…currently some rather minor gastrointestinal symptoms". He said that he was a child "who would be suitable to have investigation by colonoscopy etc." and enclosed details of the protocol (the same document as was sent to Dr. Mills on 23rd April 1997). He wrote in similar vein to Dr. Mills, who wrote to child JS's parents, asking them how they wished him to proceed.

177. Difficulty was experienced in arranging funding for admission. On 10th November 1997, Professor Walker-Smith wrote to Rachel Lewis, Deputy Contracts Manager at the Royal Free Hospital, stating,

> "I think it is essential that this child does have a colonoscopy. This kind of service is just not available elsewhere for children with autism and for the special investigations which Dr. Wakefield can offer."

178. Child JS was admitted on 12th November 1997. The endoscopy clerking sheet records the reason for the procedure as "colonoscopy on Friday. For autism. Referred by Dr. Mills from Worcester." The admission clerking note of 13th November 1997 states the reason as,

> "Elective admission for colonoscopy
>
> Probs
>
> 1. Autism
>
> 2. Intermittent diarrhoea
>
> Without blood, but with occasional mucous."

The endoscopy report, misheaded "Endoscopy clerking sheet" dated 13th November 1997, records the reason for the procedure as: "Autistic" and Dr. Thomson's findings as

> "an ↑ vascularity in recto-sigmoid area to SPL. Flexure
>
> ? ↑ granularity around caecum, +/− ↑ vascularity
>
> Lympho-nodular hyperplasia of TI".

The histology report, added on 21st November 1997, noted no active inflammation in the ileum, but patchy changes in the colon, lymphoid aggregates in the caecum and active cryptitis in the transverse and sigmoid colonoscopy, characterized in the histology report itself as "of a mild patchy non-specific acute colitis". At his ward round on 14th November 1997, Dr. Thomson suggested anti-inflammatory treatment. The discharge summary dated 27th November 1997, set out the findings noted above. A handwritten amendment in Professor Walker-Smith's writing stated:

> "Histology revealed active inflammation of the distal colon with patchy active cryptitis (with eosinophils neutrophils) and crypt abscesses formation. There was lymphoid-nodular hyperplasia of the terminal ileum."

179. Professor Walker-Smith saw child JS again on 28th January 1998 and wrote to Dr. Mills on 6th February 1998, telling him that child JS did in fact have evidence significant of inflammation histologically, which he specified; and that he had suggested a therapeutic trial of an anti-inflammatory drug. There is no suggestion in the hospital records that Professor Walker-Smith saw child JS again.

180. The GMC's case was that Professor Walker-Smith subjected child JS to a colonoscopy in reaction to parental pressure and for the purpose of his and Dr. Wakefield's research into a purported association between gastrointestinal and autistic symptoms and the MMR vaccine. Professor Walker-Smith's answer was that parental pressure did play a part in him seeing the child but not in the decision to perform a colonoscopy. That was taken to investigate child JS's gastrointestinal condition, with a view to diagnosing whether he had an inflammatory bowel disease and, if so, begin a therapeutic regime. His explanation for "lowering the threshold" was that which he had stated in correspondence to Dr. Mills, in particular in his letter of 29th May 1997: the success which he had had with treating autistic children with gastrointestinal symptoms, both on those symptoms and on their behaviour. Dr. Miller supported his decision, in the light of child JS's symptoms and of the experience which Professor Walker-Smith had gained (by the time of the publication of the Lancet paper, in forty cases). Professor Booth concluded, without hesitation, that the colonoscopy was a research investigation "not (sic) having seen the correspondence that led up to the admission".

181. The determinative findings of the panel were as follows:

> "36a. You subjected child JS to a colonoscopy,
>
> Found proved. The panel noted the letter to the Deputy Contracts Manager of the Royal Free Hospital on 10 November 1997 where you stated that "It is essential that this child has a colonoscopy".
>
> i. In reaction to parental pressure,
>
> Found not proved. There was insufficient evidence to find that the colonoscopy was undertaken as a direct consequence of parental pressure and it accepts you evidence that it was not.
>
> ii. Without any proper consideration to your duty to treat him in accordance with his best interests,
>
> Found proved. The panel noted that the parent's concern was regarding the child's presenting with behavioural difficulties rather than GI symptoms because the child was at the time well-nourished and had improved bowel motions. A colonoscopy was undertaken without proper consideration of his current clinical presentation.
>
> iii. For the purposes of yours and Dr. Wakefield's research into a purported association between gastrointestinal symptoms, autistic symptoms and the MMR vaccine,
>
> Found proved. The panel noted the letter dated 6th November 1996 from Dr. Wakefield to you stating that "This is a child I would like to be included in our study…" together with the letter dated 7 November 1996 from you to the Community Paediatrician stating, "Through Dr. Wakefield we have been

> looking at a group of children with autistic symptoms related to MMR vaccine and have found that a significant number of children have had gastrointestinal symptoms." You wrote to the Deputy Contracts Manager of the Royal Free Hospital on 10 November 1997, saying "I think it is essential that this child does have a colonoscopy. This kind of service is just not available elsewhere for children with autism and for the special investigations which Dr. Wakefield can offer" and the panel also noted the admission note dated 13 November 1997 which notes an "elective admission for colonoscopy".
>
> …
>
> v. Which was not clinically indicated,
>
> Found proved. The panel concluded that subjecting the child to a colonoscopy was not clinically indicated as his main presentation was behavioural difficulties and you accepted his GI symptoms were "rather minor" in your letter to the Community Paediatrician on 31 July 1997. In your evidence to the panel you accepted that you did "lower the threshold" in relation to this child. (Day 96 p15)
>
> b. Your conduct as set out above was contrary to the clinical interests of child JS,
>
> Found proved on the basis of the above findings."

182. The GMC's case on the Heads of Charge set out in paragraph 36a(i) and (iii) was internally inconsistent: it is unlikely that child JS would have been admitted for the purpose of a joint research project in reaction to parental pressure unless, perhaps, as no one suggested, the parents' principal interest was in obtaining damages from the manufacturers of the MMR vaccine. As child JS's mother's letter to Dr. Wakefield dated 5th July 1997 made clear, although she felt that he had been damaged by MMR vaccine, her purpose in seeking Dr. Wakefield's help was to "explore every possibility to help our son" who, otherwise, "has no future at all – other than being sedated and confined to an institution". The panel sensibly resolved this contradiction by finding this aspect of the charge not proved.

183. Its finding that the colonoscopy was "for the purpose of yours and Dr. Wakefield's research" is odd and the reasons given for it unsustainable. It is odd, because, as was common ground, no neurological investigations (MRI scan, EEG or lumbar puncture) had been carried out routinely since February 1997 and there is no evidence in the transcript of the medical notes which I have of laboratory analysis of biopsies for measles virus. (There is a document headed "Ward Protocol: Investigation of Enteritis/Disintegrative Disorder" which provides for the taking of research specimens of blood and urine, but no report of any laboratory analysis of them). In those circumstances, it is difficult to understand how "research" into the purported association between gastrointestinal and autistic symptoms and MMR vaccine could have been furthered by this colonoscopy. If child JS had been admitted at the end of 1996, the references to the letters of 6th and 7th November 1996 might have been

apposite; but he was not admitted until 12th November 1997. The reference to the "special investigations which Dr. Wakefield can offer" in Professor Walker-Smith's letter to the Deputy Contracts Manager of 10th November 1997 is not borne out by the hospital records. This was a loose end which required to be tied down before a finding adverse to Professor Walker-Smith on this issue could reasonably be made.

184. There was evidence to support the panel's findings that the decision to perform a colonoscopy was not clinically indicated and/or in the best or clinical interests of child JS, some of which was noted by the panel in its determination: the lack of serious gastrointestinal symptoms and Professor Walker-Smith's admission that he did "lower the threshold" in relation to child JS. However, before reaching those conclusions, the panel had to decide whether or not to reject the evidence of Dr. Miller as being outwith the spectrum of reasonable medical opinion. As in the case of the other children it did not do so. In this instance, Professor Booth's firm view that this was research appears to have been based on the correspondence. As in the case of several of the other children, the correspondence is equivocal, but in this child's case, supports Professor Walker-Smith's case that his purpose was clinical investigation and treatment. His letters to Dr. Mills of 23rd April 1997 and 9th May 1997 are of particular significance: unless Professor Walker-Smith deliberately misrepresented his perception of the outcome of the investigation and treatment of earlier children and his own state of mind, they were the letters of a clinician who believed that he had discovered something of therapeutic value for his patients. He may, or may not, have been wrong about that; but the letters exclude the proposition that his purpose was research. The terms of the letters are reinforced by the five page explanation of the protocol under which Professor Walker-Smith and his team were operating, which was sent both to Dr. Mills and to Dr. Shore.

185. For the reasons explained above, child JS's case did not fit into the pattern for which the GMC contended. At worst, it was an individual example of a procedure undertaken for genuine but ill-founded clinical reasons. Even that finding required the rejection of Dr. Miller's evidence; and by itself, it could amount to no more than an error of clinical judgment, insufficient to support a finding of serious professional misconduct. It is puzzling that any charge was brought – against Professor Walker-Smith alone – in respect of child JS. In the event, the charge gave rise to an inadequately reasoned conclusion of serious professional misconduct which, on the evidence available to the panel, was wrong.

Conclusion

186. For the reasons given above, both on general issues and the Lancet paper and in relation to individual children, the panel's overall conclusion that Professor Walker-Smith was guilty of serious professional misconduct was flawed, in two respects: inadequate and superficial reasoning and, in a number of instances, a wrong conclusion. Miss Glynn submits that the materials which I have been invited to consider would support many of the panel's critical findings; and that I can safely infer that, without saying so, it preferred the evidence of the GMC's experts, principally Professor Booth, to that given by Professor Walker-Smith and Dr. Murch and by Dr. Miller and Dr. Thomas. Even if it were permissible to perform such an exercise, which I doubt, it would not permit me to rescue the panel's findings. As I have explained, the medical records provide an equivocal answer to most of the questions which the panel had to decide. The panel had no alternative but to decide

whether Professor Walker-Smith had told the truth to it and to his colleagues, contemporaneously. The GMC's approach to the fundamental issues in the case led it to believe that that was not necessary – an error from which many of the subsequent weaknesses in the panel's determination flowed. It had to decide what Professor Walker-Smith thought he was doing: if he believed he was undertaking research in the guise of clinical investigation and treatment, he deserved the finding that he had been guilty of serious professional misconduct and the sanction of erasure; if not, he did not, unless, perhaps, his actions fell outside the spectrum of that which would have been considered reasonable medical practice by an academic clinician. Its failure to address and decide that question is an error which goes to the root of its determination.

187. The panel's determination cannot stand. I therefore quash it. Miss Glynn, on the basis of sensible instructions, does not invite me to remit it to a fresh Fitness to Practice panel for redetermination. The end result is that the finding of serious professional misconduct and the sanction of erasure are both quashed.