

General Medical Council

Regulating doctors
Ensuring good medical practice
28 January 2010

Drs Wakefield, Walker-Smith and Murch,

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

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

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

The Panel has accepted in full the advice of the Legal Assessor as to the approach to be taken. The three doctors have nothing to prove, the burden of proof is on the GMC throughout. If the Panel were not sure beyond reasonable

doubt, the sub-head of charge was found not proved in favour of the doctor, in accordance with the criminal, as opposed to the civil, standard of proof.

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

The Panel received no further advice whilst deliberating.

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

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

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

The Panel accepts the expert advice that amongst the responsibilities of a Responsible Consultant, is the requirement to conduct research within ethical constraints, and report it responsibly, accurately and fairly. At no stage should a

doctor take any action that is contrary to the clinical interests of the patient involved.

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

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

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

Due to the large number of charges in this case, it has been agreed by all parties that the full determination should be handed down, but the Panel has asked me to summarise and announce the main findings of fact. This is only an attempt to summarise the findings and is not to be treated as the findings themselves or the determination.

Dr Andrew Wakefield:

At all material times you were employed at the Royal Free Hospital School of Medicine as a Senior Lecturer then Reader in Experimental Gastroenterology and as an honorary consultant at the Royal Free Hospital with no involvement in the clinical management of patients.

Legal Aid Board

In 1996 you were involved in advising Richard Barr, a solicitor acting for those alleged to have suffered vaccine damage from MMR, as to research required to establish that the vaccine was causing injury. He had public funding from the Legal Aid Board to pursue litigation against the manufacturers of the vaccine. The Panel has found proved that you provided a costing proposal to Richard Barr for a research study for testing a selected number of MR and MMR vaccinated children and that you sent him a protocol giving details of that research study which you knew or ought to have known Mr Barr required for submission to the Legal Aid Board. The protocol described a study on children who had been vaccinated with MMR or MR vaccine, had disintegrative disorder, and gastrointestinal symptoms.

On 22 August 1996 the Legal Aid Board agreed to provide a maximum cost of £55,000 to fund the items included in the costing proposal and this was paid in two instalments of £25,000 each in 1996 and 1999. The Panel found that you did not use the second instalment as it was intended. The cost of treating the children in the programme as detailed by you had actually been met by the NHS. The investigations were deemed clinically indicated and not for research purposes. You failed to tell the Legal Aid Board (via Mr Barr) that the cost would be met by the NHS and the Panel found this conduct to be dishonest. You used the second instalment to further your research generally but the Panel found the dishonesty charge in this respect not proved because it considered that you had not kept the funds for personal gain. However, it did find that you had failed, even by 1999, to account accurately for the funds provided and you breached your duty in managing finances.

Research and Ethics Committee approval

You signed an application to the Ethical Practices Sub-Committee of the Royal Free Hampstead NHS Trust (the Ethics Committee) which was submitted on or about 16 September 1996. The application was allocated a reference 172-96. It named you, Professor Walker Smith and Dr Murch as Responsible Consultants and it sought approval for a project involving 25 children entitled "A new paediatric syndrome; enteritis and disintegrative disorder following measles/rubella vaccination" It described a programme of investigations including invasive gastrointestinal and neurological tests to be carried out on children who had been vaccinated with the measles or measles/rubella vaccine and had

manifested disintegrative disorder and had symptoms of intestinal disease or dysfunction.

The application 172-96 indicated that all the procedures including lumbar puncture, Electro encephalogram (EEG), evoked responses or evoked potentials (ER/EP), colonoscopy, barium meal and follow through, MRI scan of the brain, and a variety of blood and urine tests were clinically indicated, that is to say the children would have undergone these investigations whether or not the research was conducted. The Panel found that the application indicated you would be responsible for arranging a number of procedures including MRI and EEG although the Panel found not proved that you would be responsible for arranging the lumbar punctures.

The Chairman of the Ethics Committee raised reservations about the intensive regime of investigations the children would have to undergo in a letter of October 1996 which was sent to Professor Walker Smith and forwarded to you and Dr Murch for comment. Following reassurances from Professor Walker Smith that the children would have undergone the investigations even if there were no trial, and that five children had already been investigated on a clinical needs basis, Ethics Committee approval was granted on 18 December 1996 with conditions set out in a letter dated 7 January 1997, addressed to Professor Walker Smith and forwarded by him to you on 9 January 1997. The conditions included:

- that no child enrolled before 18 December 1996 could be in the trial
- that the Ethics Committee would have to be informed and give approval to any proposed amendments to your application which had a bearing on the treatment of the children
- a copy of the consent form and information sheet given to parents would be lodged in the notes of each patient

These conditions were accepted in a letter from Professor Walker Smith and copied to you on 9 January 1997.

The Panel found that you, as a Responsible Consultant had a duty to ensure that the information in support of the application was accurate, that only children who met the stated inclusion criteria could be admitted to the study and that you complied with the conditions as set out by the Ethics Committee. Notwithstanding that yours was a shared rather than a sole responsibility and that you could not be held responsible for factors outside your knowledge or control, the Panel was satisfied that these duties were within the parameters of a named Responsible Consultant. You also had a duty to declare to the Ethics Committee any matter which could legitimately give rise to a perception of "conflict of interest" but the Panel found that you did not. It also found that Project 172-96 document was substantially the same as the protocol sent to the Legal Aid Board. Your involvement with the Legal Aid Board and receipt of funding for part of the project from the Legal Aid Board were disclosable interests which you failed to disclose.

You accepted during the course of your evidence that you should have disclosed the funding from the Legal Aid Board and additionally the Panel found that your involvement with that body should have been disclosed. Your non-disclosure was contrary to your duties as a Responsible Consultant and deprived the Ethics Committee of information material to its considerations of the ethical implications of Project 172-96.

Where the Panel has found that you caused a child to undergo the programme of investigations for research purposes, it was on the basis of your involvement with parents and/or GPs and other doctors of these children prior to their referral to the Royal Free. This acted as a catalyst for the children's referral and subsequent admissions and investigations under the protocol.

The Panel went on to consider matters relating to the referral and admission process and subsequent investigations at the Royal Free Hospital of each of the children separately and summarises the findings as follows:

Child 2 – This child did not meet the inclusion criteria in that he had been vaccinated with MMR and had been enrolled into the project before 18 December 1996. You caused this child to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research. By ordering an EEG and an EP you were in contravention of the limitations on your honorary consultant appointment, that is, to have no clinical role with patients. You failed in your duties as a Responsible Consultant and your conduct was contrary to the clinical interests of this child.

Child 1 – This child did not meet the inclusion criteria in that he had been vaccinated with MMR not measles or measles rubella vaccine, he had been admitted to hospital with an established diagnosis of autism not disintegrative disorder and had been enrolled on the project before 18 December 1996. You caused this child to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research. You failed in your duties as a Responsible Consultant and your conduct was contrary to the clinical interests of this child.

Child 3 – This child did not meet the inclusion criteria in that he had been vaccinated with MMR not measles or measles rubella vaccine, he had been admitted to hospital with a diagnosis of autism spectrum disorder not disintegrative disorder and had been enrolled on the project before 18 December. You caused this child to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research. You failed in your duties as a Responsible Consultant and your conduct was contrary to the clinical interests of this child. The Panel also found that you caused this child to undergo a lumbar puncture which was not clinically indicated, contrary to your representations to the Ethics Committee.

Child 4 – This child did not meet the inclusion criteria in that he had not been diagnosed with disintegrative disorder and he had been enrolled on the project before 18 December. You caused this child to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research. The Panel also found that you exposed Child 4 to an unnecessary neurophysiology investigation and by ordering an EEG and an EP you were in contravention of the limitations on your honorary consultant appointment, that is, to have no clinical role with patients. You failed in your duties as a Responsible Consultant and your conduct was contrary to the clinical interests of this child.

Child 6 – This child did not meet the inclusion criteria in that he had been admitted to hospital with a diagnosis of Aspergers' Syndrome not disintegrative disorder and had been enrolled on the project before 18 December, and had been vaccinated with MMR. You caused this child to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research. You failed in your duties as a Responsible Consultant.

Child 9 – This child did not meet the inclusion criteria in that he had a form of autism and had not manifested disintegrative disorder, he had been enrolled on the project before 18 December, and had been vaccinated with MMR. You caused this child to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research. You caused Child 9 to undergo a lumbar puncture which was not clinically indicated, contrary to your representations to the Ethics Committee. You failed in your duties as a Responsible Consultant and your conduct was contrary to the clinical interests of this child.

Child 5 – This child did not meet the inclusion criteria in that he had been referred to hospital with “autism and disturbed behaviour” and had not manifested disintegrative disorder, he had been enrolled on the project before 18 December, (his first admission was on 1 December 1996) and he had been vaccinated with MMR. You caused this child to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research. You ordered an EEG investigation and the Panel rejects your explanation of that role as purely administrative. You did not have the requisite paediatric qualifications to do so and you were in contravention of the limitations on your honorary consultant appointment, that is, to have no clinical role with patients. You failed in your duties as a Responsible Consultant and your conduct was contrary to the clinical interests of this child.

Child 12 – This child did not meet the inclusion criteria in that he had not been diagnosed with disintegrative disorder, and he had been vaccinated with MMR. You caused this child to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research. You signed the forms for ordering an EEG investigation and for other

neurophysiological investigations. You did not have the requisite paediatric qualifications to do so and you were in contravention of the limitations on your honorary consultant appointment, that is, to have no clinical role with patients. You caused him to undergo a lumbar puncture which was not clinically indicated and contrary to your representations to the Ethics Committee. You failed in your duties as a Responsible Consultant and your conduct was contrary to the clinical interests of this child.

Child 8 – This child did not meet the inclusion criteria in that she had not been diagnosed with disintegrative disorder and that she had been vaccinated with MMR. You caused this child to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research. You failed to ensure a copy of a consent form and information sheet was lodged in her hospital notes. Your conduct was contrary to the clinical interests of this child and you failed in your duty as a Responsible Consultant.

Child 7 – This child did not meet the inclusion criteria in that he had not been diagnosed with disintegrative disorder and he had been vaccinated with MMR. You ordered an EEG and other neurophysiological investigations. You did not have the requisite paediatric qualifications to do so and you were in contravention of the limitations on your honorary consultant appointment, that is, to have no clinical role with patients. Your conduct was contrary to the clinical interests of this child and you failed in your duty as a Responsible Consultant.

Child 10 – This child had not been diagnosed with disintegrative disorder, there were no references to gastrointestinal symptoms in his referral, and he had been vaccinated with MMR. You failed to ensure a copy of the consent form or information sheet was placed in his notes. However, the Panel found it not proved that you caused this child to undergo a lumbar puncture but did find that you failed in your duty as a Responsible Consultant.

The Lancet Paper

The investigations on the children were written up in a scientific paper entitled “Ileal-Lymphoid Nodular Hyperplasia, Non-specific colitis and Pervasive Developmental Disorder in Children” which was published in the Lancet Journal on 28 February 1998 and referred to as “the Lancet Paper”. The Panel rejected your objections that this was not a “scientific” paper. You admitted that you knew that the Lancet paper report of a temporal link between MMR vaccination and gastrointestinal disease and developmental regression would have major public health implications and would attract intense public and media interest. The Panel found that, as a senior author of the paper, you had a duty to ensure that the factual information in the paper and provided by you in response to queries, was true and accurate. Furthermore you should have disclosed any matters which could legitimately give rise to a perception of a conflict of interest. The Panel found that you failed to state that the children in the Lancet paper were

part of a project to investigate a postulated new syndrome. The Lancet paper did not describe this fact at all. The Panel found your conduct in this respect to be dishonest and irresponsible. Your conduct resulted in a misleading description of the patient population in the Lancet paper.

The Lancet paper stated that the children 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...” and were later referred to in the paper as “self-referred”. The Panel found that you knew or ought to have known that such a description implied a routine referral to the gastroenterology department in relation to gastrointestinal symptoms and a routine process in which the investigators played no part.

The Panel found that the referrals of Child 1, 9, 5 and 10 did not constitute routine referrals to the gastroenterology department in relation to intestinal symptoms as the referring doctors referred the children for investigation of the role played by the measles vaccination or the MMR vaccination into their developmental disorders and did not report any history of gastrointestinal symptoms. Further, the referrals of Child 2, 9, 5 and 12 included active involvement in the referral process by you. The description of the referral process in the Lancet was therefore irresponsible, misleading, and contrary to your duty to ensure that the information in the Lancet paper was accurate.

In a letter to the Lancet dated 2 May 1998, in response to the suggestion of previous correspondents that there was a biased selection of patients in the Lancet article, you stated that the children had all been referred through the normal channels on the merits of their symptoms and the Panel found this statement to be dishonest and irresponsible.

On 23 March 1998 at a scientific meeting at the Medical Research Council, you were asked about the issue of bias in generating the series of cases, including the 12 children of the Lancet paper and you stated that all patients reviewed so far had come through GPs or paediatricians by “the standard route”. The Panel found that you were dishonest and irresponsible in making this statement and that it was contrary to your duty to ensure the information provided by you was true and accurate. The Panel has borne in mind that this was an important meeting to consider the implications of your published research and that you knew your response to the question was factually wrong.

The Lancet paper stated that the investigations reported were approved by the Ethical Practices Committee of the Royal Free Hospital NHS Trust (the Ethics Committee) when in fact you did not have ethical approval for the investigations of the children as they did not meet the inclusion criteria. The statement that you made in the Lancet was therefore irresponsible.

You have admitted that around June 1997 you filed for a patent with the Patent Office. You were one of the inventors for a vaccine for the elimination of measles virus and for the treatment of IBD. Your involvement in the MMR litigation, receipt of funding for part of the project 172-96 and involvement in the patent constituted a disclosable interest which could have given rise to a legitimate perception of a conflict of interest which you did not disclose to the editor of the Lancet. The Panel found this to be contrary to your duties as a senior author of the Lancet paper.

Transfer Factor

On 2 February 1998 you submitted an application to the Ethics Committee seeking approval for a trial which involved studying the effect of "transfer factor" in children with autistic enteropathy, naming you as the Principal Scientific investigator and Professor Walker Smith as a Principal Clinical investigator. The application was referenced as Project 22-98. You admitted that around the same time, you were involved in a proposal to set up a company called Immunospecifics Biotechnologies Ltd to specialise in the production, formulation and sale of Transfer Factor. You have also admitted that the proposed CEO of the company was the father of Child 10 and you wrote to this effect to the finance officer of the Royal Free Hospital School of Medicine on 26 February 1998. A proposal drafted by the father of Child 10 was submitted to the Royal Free in March 1998 seeking funding for a clinical trial of Transfer Factor in the treatment of IBD and pervasive developmental disorder and for research into using Transfer Factor as an alternative measles-specific vaccine. You were to be the Research Director and the father of Child 10 was to be the Managing Director. It was proposed that the equity would be shared between a number of parties including the Managing Director and yourself.

Between July and November 1998 you and Professor Walker-Smith undertook research into the safety of Transfer Factor and Project 22-98 was approved by the Ethics Committee on 16 December 1998.

The Panel found that you inappropriately caused Child 10 to be administered Transfer Factor for experimental reasons without causing to be recorded in his medical notes the fact of, or dose of, the prescription and without causing the child's GP to be informed that it had been prescribed. The Panel is aware that you and Professor Walker-Smith had written to the Dispensary Manager to inform her that "we are prepared to take full responsibility for the outcome of this treatment." You did not have the requisite paediatric qualifications and your actions were contrary to the clinical interests of Child 10 and an abuse of your position of trust as a medical practitioner.

The Birthday Party

Prior to 20 March 1999, at your son's birthday party you caused blood to be taken from a group of children to use for research purposes. You admitted during the course of your evidence they were paid £5 each for doing so. On 20 March 1999 you gave a presentation to the MIND Institute in California and described the incident at your son's party in humorous terms and expressed an intention to obtain research samples in a similar way in the future. Despite your explanation that you did not consider it unethical to obtain blood in this way, the Panel found that it was unethical and that you did not have ethical approval for such an undertaking. It also found that you caused blood to be taken in an inappropriate social setting and you showed a callous disregard for the distress and pain that you knew or ought to have known the children involved might suffer. You abused your position of trust as a medical practitioner and your conduct in the presentation to the MIND Institute was such as to bring the medical profession into disrepute.

Having found these facts proved, the Panel went on to consider, whether your admissions and the Panel's findings, taken collectively, would be insufficient to support a finding of serious professional misconduct. In your case it found that the facts would not be insufficient and therefore your case will proceed to the next stage, under Rule 28. Evidence will be adduced and submissions made in respect of whether you are guilty of serious professional misconduct and if so what if any sanction should be imposed on your registration.

The sanctions available to the Panel are a warning, conditional registration for a period of up to three years, suspension for up to a year or erasure from the medical register.

Professor Walker-Smith:

At the material time you were the Professor of Paediatric Gastroenterology employed by the Royal Free School of Medicine with an honorary clinical contract with the Royal Free Hampstead NHS Trust.

Research and Ethics Committee approval

An application to the Ethical Practices Sub-Committee of the Royal Free Hampstead NHS Trust (the Ethics Committee) was submitted on or about 16 September 1996 and allocated a reference 172-96. It named you, Dr Wakefield and Dr Murch as Responsible Consultants and it sought approval for a project involving 25 children entitled "A new paediatric syndrome; enteritis and disintegrative disorder following measles/rubella vaccination" It described a programme of investigations including invasive gastrointestinal and neurological tests to be carried out on children who had been vaccinated with the measles or measles/rubella vaccine and had manifested disintegrative disorder and had symptoms of intestinal disease or dysfunction.

The application 172-96 indicated that all the procedures including lumbar puncture, Electro encephalogram (EEG), evoked responses or evoked potentials (ER/EP), colonoscopy, barium meal and follow through, MRI scan of the brain, and a variety of blood and urine tests were clinically indicated, that is to say, part of normal patient care and that the children would have undergone these investigations whether or not the research was conducted.

The Chairman of the Ethics Committee raised reservations about the intensive regime of investigations the children would have to undergo in a letter of October 1996 which you forwarded to Dr Wakefield and Dr Murch for comment. You replied to him on 11 November 1996, informing him that the children would have undergone the investigations even if there were no trial, and that five children had already been investigated on a clinical needs basis. Ethics Committee approval was granted on 18 December 1996 with conditions set out in a letter to you, dated 7 January 1997, which you accepted in a letter dated 9 January 1997 and forwarded to Dr Wakefield on the same date. The conditions included:

- that no child enrolled before 18 December 1996 could be in the trial
- that the Ethics Committee would have to be informed and give approval to any proposed amendments to your application which had a bearing on the treatment of the children
- a copy of the consent form and information sheet given to parents would be lodged in the notes of each patient

The Panel found that you, as a Responsible Consultant had a duty to ensure that the information in support of the application was accurate, that only children who met the stated inclusion criteria could be admitted to the study and that you

complied with the conditions as set out by the Ethics Committee. Notwithstanding that yours was a shared rather than a sole responsibility and that you could not be held responsible for factors outside your knowledge or control, the Panel was satisfied that these duties were within the parameters of a named Responsible Consultant.

Where the Panel has found that you subjected a child to undergo the programme of investigations for research purposes, it was on the basis of your decisions to admit the children to the Royal Free for the purpose of investigation under the protocol of Project 172-96. Some of these children were not seen or assessed in outpatients prior to their admission.

The Panel went on to consider matters relating to the referral and admission process and subsequent investigations at the Royal Free Hospital of each of the children separately and summarises the findings as follows:

Child 2 – This child did not meet the inclusion criteria in that he had been vaccinated with MMR and had been enrolled into the project before 18 December 1996. Child 2 was admitted to hospital on or about 1 September 1996 and the Panel was satisfied that notwithstanding your partial absence during the admission dates, this child was admitted under your clinical care. You subjected this child to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research. You caused Child 2 to undergo a colonoscopy and barium meal and follow through which were not clinically indicated. You failed in your duties as a Responsible Consultant and your conduct was contrary to the clinical interests of this child.

Child 1 – This child did not meet the inclusion criteria in that he had been vaccinated with MMR, he had been admitted to hospital with an established diagnosis of autism not disintegrative disorder and had been enrolled on the project before 18 December 1996. The child's GP referral letter of 17 May 1996 made no mention of gastrointestinal symptoms. The child was admitted to the Royal Free on 21 July 1996 under your clinical care, notwithstanding that you were not present at the time and underwent a colonoscopy, MRI scan, EEG and a variety of blood and urine tests. On re-admission on 23 October 1996, you caused him to undergo a lumbar puncture and barium meal and follow through, which were not clinically indicated. You subjected this child to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research. The Panel also concluded that your reliance on the view's of this child's mother that there was a link between autism, immunisation and bowel inflammation, was inappropriate in making a decision to undertake a colonoscopy. You failed in your duties as a Responsible Consultant and your conduct was contrary to the clinical interests of this child.

Child 3 – This child did not meet the inclusion criteria in that he had been vaccinated with MMR, he had been admitted to hospital with a diagnosis of

autism spectrum disorder not disintegrative disorder and had been enrolled on the project before 18 December. You subjected this child to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research. You caused him to undergo investigations, including colonoscopy and a lumbar puncture which were not clinically indicated. You failed in your duties as a Responsible Consultant and your conduct was contrary to the clinical interests of this child.

Child 4 – This child did not meet the inclusion criteria in that he had not been diagnosed with disintegrative disorder and he had been enrolled on the project before 18 December 1996. The child was admitted on 29 September 1996 under your clinical care, for research purposes without ethical approval, but the Panel accepted in this case that you did not see this patient until your ward round of 3 October 1996 and so found not proved that you selected this child or subjected him to investigations. However it found that as a Responsible Consultant you had a duty to ensure adequate research governance and that you had joint responsibility for overseeing the overall process governing the project. You diagnosed this child as having colitis and prescribed treatment but did not record any explanation in his records even though the diagnosis was contrary to the histology meeting assessment on 4 October 1996.

Child 6 – This child did not meet the inclusion criteria in that he had been admitted to hospital with a diagnosis of Aspergers' Syndrome not disintegrative disorder and had been enrolled on the project before 18 December 1996, and had been vaccinated with MMR. You subjected this child to a programme of investigations for research purposes without having Ethics Committee approval for such research. You failed in your duties as a Responsible Consultant, but the Panel found that, despite this child being subject to the programme there was insufficient evidence to make a finding that the investigations were contrary to his clinical interests.

Child 9 – This child did not meet the inclusion criteria in that he had a form of autism and had not manifested disintegrative disorder, he had been enrolled on the project before 18 December 1996, and had been vaccinated with MMR. He was admitted to hospital under your clinical care in November where he underwent a colonoscopy, barium meal and follow-through, and blood and urine tests. He was re-admitted in December, and underwent an MRI scan, an EEG and a lumbar puncture. You subjected this child to undergo a programme of investigations for research purposes without having Ethics Committee approval for such research. You caused Child 9 to undergo a lumbar puncture, colonoscopy and barium meal and follow through which were not clinically indicated, contrary to your representations to the Ethics Committee. You failed in your duties as a Responsible Consultant and your conduct was contrary to the clinical interests of this child.

Child 5 – This child did not meet the inclusion criteria in that he had been referred to hospital with “autism and disturbed behaviour” and had not manifested disintegrative disorder and he had been enrolled on the project before 18 December 1996. He had been vaccinated with MMR. The child was admitted to the Royal Free under your clinical care, on 1 December 1996 and underwent a colonoscopy, a barium meal and follow through and other investigations and on his re-admission in January 1997 he underwent a repeat barium meal and follow through and a lumbar puncture which were not clinically indicated, contrary to your representations to the Ethics Committee. You subjected this child to the programme of investigations without Ethics Committee approval and in respect of his second admission to hospital, you failed to ensure any consent form was lodged in his medical notes. Your conduct was contrary to the clinical interests of this child and you failed in your duties as a Responsible Consultant.

Child 12 – This child did not meet the inclusion criteria in that he had not been diagnosed with disintegrative disorder, and he had been vaccinated with MMR. He was admitted to hospital on 5 January 1997 under your clinical care and underwent a variety of investigations. The Panel found that you subjected this child to a programme of investigations for research purposes without having Ethics Committee approval for such research. You caused Child 12 to undergo a colonoscopy and barium meal and follow through which were not clinically indicated. In this child’s case, the Panel accepts that you indicated this child should not undergo a lumbar puncture but the Panel found that by admitting him for investigations under Project 172-96, your conduct was contrary to the clinical interests of this child and you failed in your duties as a Responsible Consultant.

Child 8 – This child did not meet the inclusion criteria in that she had not been diagnosed with disintegrative disorder and she had been vaccinated with MMR. You subjected her to a programme of investigations as part of the project despite no clinician having seen her in outpatients prior to her admission. Contrary to the conditions set out by the Ethics Committee, you did not lodge a copy of the consent form in her medical notes. You caused her to undergo a colonoscopy and barium meal and follow through which were not clinically indicated, contrary to your representations to the Ethics Committee. Your conduct was not in the clinical interests of this child and you failed in your duty as a Responsible Consultant.

Child 7 – This child did not meet the inclusion criteria in that he was not diagnosed with disintegrative disorder, and he had been vaccinated with MMR. The child was admitted under your clinical care on 27 January 1997 and you subjected him to a programme of investigations for research purposes without having Ethics Committee approval for such research. Contrary to the conditions set out by the Ethics Committee, you did not lodge a copy of the consent form in her medical notes. You failed in your duty as a Responsible Consultant although the Panel accepts that the investigations that this child underwent were clinically indicated.

Child 10 – This child did not meet the inclusion criteria in that he did not manifest disintegrative disorder, there were no references to gastrointestinal symptoms and he had been vaccinated with MMR. He was admitted to the Royal Free in February 1997 and you subjected this child to a programme of investigations for research purposes without having Ethics Committee approval for such research. You failed to ensure a copy of the consent form or information sheet was placed in his notes. You failed in your duty as a Responsible Consultant. The Panel found that you caused this child to undergo a lumbar puncture and colonoscopy although it accepts that these were clinically indicated.

Child JS – This child was admitted under your clinical care on 12 November 1997 and you subjected him to a colonoscopy without any proper consideration to your duty to treat him in accordance with his best interests. The Panel also found it was for the purpose of your and Dr Wakefield's research into the purported association between gastrointestinal symptoms, autistic symptoms and the MMR vaccine, without it being clinically indicated. Your conduct was contrary to the child's clinical interests.

Transfer Factor

On 2 February 1998 Dr Wakefield submitted an application to the Ethics Committee seeking approval for a trial which involved studying the effect of "transfer factor" in children with autistic enteropathy, naming himself as the Principal Scientific investigator and you as a Principal Clinical investigator. The application was referenced as Project 22-98.

Between July and November 1998 you and Dr Wakefield undertook research into the safety of Transfer Factor and Project 22-98 was approved by the Ethics Committee on 16 December 1998.

The Panel found that you inappropriately caused Child 10 to be administered with Transfer Factor without recording the fact of or dose of the prescription in his medical notes and without informing the child's GP that it had been prescribed. The Panel is aware that you and Dr Wakefield had written to the Dispensary Manager to inform her that "we are prepared to take full responsibility for the outcome of this treatment". It is persuaded that the treatment was experimental in that you stated in the same letter, "we do not know whether the treatment will work" and moreover this child had not been seen or assessed by you before being administered an unlicensed drug. The Panel concluded your actions were irresponsible and contrary to the clinical interests of Child 10.

The Lancet Paper

The investigations on the children were written up in a scientific paper entitled "Ileal-Lymphoid Nodular Hyperplasia, Non-specific colitis and Pervasive

Developmental Disorder in Children” which was published in the Lancet Journal on 28 February 1998 and referred to as “the Lancet Paper”. The Panel found that you knew or ought to have known that the Lancet paper report of a temporal link between MMR vaccination and gastrointestinal disease and developmental regression, would have major public health implications and would attract intense public and media interest. The Panel found that, as a senior author of the paper, you had a duty to ensure that the factual information in the paper and provided by you in response to queries was true and accurate. The Panel found that you failed to state that the children in the Lancet paper were part of a project to investigate a postulated new syndrome comprising disintegrative disorder and gastrointestinal symptoms following vaccination. However the Panel accepted that you had not seen a final draft of the paper and concluded you had not been deliberately dishonest. It considered that you had been naïve in your lack of thoroughness regarding the paper.

The Lancet paper stated that the children 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...” and were later referred to in the paper as “self-referred”. The Panel found that you knew or ought to have known that such a description implied a routine referral to the gastroenterology department in relation to symptoms including gastrointestinal symptoms and a routine process in which the investigators played no part.

However, the Panel found that the referrals of Child 1, 9, 5 and 10 did not constitute routine referrals to the gastroenterology department in relation to intestinal symptoms as the referring doctors referred the children for investigation of the role played by the measles vaccination or the MMR vaccination into their developmental disorders and did not report any history of gastrointestinal symptoms. Further, the referral of Child 9 involved your express invitation for the child to be seen by you. The description of the referral process in the Lancet was therefore irresponsible, misleading, and contrary to your duty to ensure that the information in the Lancet paper was accurate.

In a response by you published in the Lancet on 6 March 2004, you stated that no children were invited to participate in the study and that, to the best of your recollection, you did not invite any children to participate. The Panel found that these statements were irresponsible and in respect of child 9, contrary to your duty to ensure the information was accurately presented. However the Panel did not find that you had been dishonest. The statement to the Lancet paper in respect of there being ethical approval was also found to be irresponsible and contrary to your duty to ensure accurate information.

Having found the facts proved, the Panel went on to consider whether Professor Walker-Smith's admissions and its findings, taken collectively, would be insufficient to support a finding of serious professional misconduct. In Professor

Walker-Smith's case it found that the facts would not be insufficient and therefore his case will proceed to the next stage, under Rule 28. Evidence will be adduced and submissions made in respect of whether he is guilty of serious professional misconduct and if so, what, if any, sanction should be imposed on his registration.

The sanctions available to the Panel are a warning, conditional registration for a period of up to three years, suspension for up to a year or erasure from the medical register.

Dr (now Professor) Murch:

At all material times you were a Senior Lecturer in Paediatric Gastroenterology employed by the Royal Free Hospital School of Medicine with an honorary consultant contract with the Royal Free Hampstead NHS Trust.

Research and Ethics Committee approval

An application to the Ethical Practices Sub-Committee of the Royal Free Hampstead NHS Trust (the Ethics Committee) was submitted on or about 16 September 1996 and allocated a reference 172-96. It named you, Dr Wakefield and Professor Walker-Smith as Responsible Consultants and it sought approval for a project involving 25 children entitled "A new paediatric syndrome; enteritis and disintegrative disorder following measles/rubella vaccination." It described a programme of investigations including invasive gastrointestinal and neurological tests to be carried out on children who had been vaccinated with the measles or measles/rubella vaccine and had manifested disintegrative disorder and had symptoms of intestinal disease or dysfunction.

The application 172-96 indicated that all the procedures including lumbar puncture, Electro encephalogram (EEG), evoked responses or evoked potentials (ER/EP), colonoscopy, barium meal and follow through, MRI scan of the brain, and a variety of blood and urine tests were clinically indicated, that is to say, part of normal patient care and that the children would have undergone these investigations whether or not the research was conducted.

The Chairman of the Ethics Committee raised reservations about the intensive regime of investigations the children would have to undergo in a letter of October 1996 which was forwarded to you and Dr Wakefield for comment. Professor Walker-Smith's reply, copied to you, informed him that the children would have undergone the investigations even if there were no trial, and that five children had already been investigated on a clinical needs basis. Ethics Committee approval was granted on 18 December 1996 with conditions set out in a letter to Professor Walker-Smith, dated 7 January 1997, which he accepted on 9 January 1997. The conditions included:

- that no child enrolled before 18 December 1996 could be in the trial
- that the Ethics Committee would have to be informed and give approval to any proposed amendments to your application which had a bearing on the treatment of the children
- a copy of the consent form and information sheet given to parents would be lodged in the notes of each patient

The Panel found that you, as a Responsible Consultant had a duty to ensure that the information in support of the application was accurate, that only children who met the stated inclusion criteria could be admitted to the study and that you

complied with the conditions as set out by the Ethics Committee. Notwithstanding that yours was a shared rather than a sole responsibility and that you could not be held responsible for factors outside your knowledge or control, the Panel was satisfied that these duties were within the parameters of a named Responsible Consultant.

The Panel went on to consider matters relating to the investigations at the Royal Free Hospital of each of the children separately and summarises the findings as follows:

Child 2 – This child did not meet the inclusion criteria in that he had been vaccinated with MMR and had been enrolled into the project before 18 December 1996. On 2 September 1996 you carried out a colonoscopy on this child and you accepted that you had a responsibility to ensure it was clinically indicated by reference to his clinical history and presenting symptoms. The Panel found that it was not clinically indicated, contrary to your representations to the Ethics Committee. The Panel found that Child 2 underwent the programme of investigations for research purposes and you failed to comply with your duties as a Responsible Consultant. Whilst the Panel accepts that you could not be held responsible for factors outwith your knowledge and expertise, you had joint responsibility for overseeing the overall process governing the project. Your conduct was contrary to the clinical interests of this child.

Child 1 – On 22 July 1996 you attempted to carry out a colonoscopy on this child and the Panel found that this failed attempt and his subsequent colonoscopy were carried out for research purposes, for which there was no ethical approval and which were not clinically indicated. He did not fit the inclusion criteria in that he had been vaccinated with MMR and he was admitted to hospital with an established diagnosis of autism, and was enrolled into the programme of investigations before 18 December 1996. The Panel found that you failed in your duties as a Responsible Consultant and your conduct was contrary to the clinical interests of Child 1.

Child 3 – This child did not meet the inclusion criteria in that he had been vaccinated with MMR, he had not been diagnosed with disintegrative disorder and had been enrolled into the project before 18 December 1996. The Panel found that he underwent the programme of investigations for research purposes, and that you failed in your duty as a Responsible Consultant to ensure adequate research governance. Whilst the Panel accepts you could not be held responsible for factors outwith your knowledge and expertise, nevertheless you had joint responsibility for overseeing the overall process governing the project.

Child 4 – This child did not meet the inclusion criteria in that he had not been diagnosed with disintegrative disorder and he had been enrolled into the project before 18 December 1996. You carried out a colonoscopy on this child which the Panel found was not clinically indicated, contrary to your representations to the

Ethics Committee. The Panel found that Child 4 underwent the programme of investigations for research purposes and you failed in your duty as a Responsible Consultant. Your conduct was contrary to the clinical interests of this child.

Child 6 – This child did not meet the inclusion criteria in that he had been admitted to hospital with a diagnosis of Aspergers' Syndrome, he had been enrolled into the project before 18 December 1996, and had been vaccinated with MMR. The Panel found that he underwent the programme of investigations for research purposes, and that you failed in your duty as a Responsible Consultant.

Child 9 – This child did not meet the inclusion criteria in that he had a form of autism and had not manifested disintegrative disorder, he had been enrolled into the project before 18 December 1996 and had been vaccinated with MMR. The Panel found that he underwent the programme of investigations for research purposes, and that you failed in your duty as a Responsible Consultant.

Child 5 – This child did not meet the inclusion criteria in that he had not manifested disintegrative disorder and he had been enrolled on the project before 18 December 1996. He had been vaccinated with MMR. You carried out a colonoscopy on this child which the Panel found was not clinically indicated, contrary to your representations to the Ethics Committee. In respect of Child 5's second admission to hospital you failed to ensure a copy of the consent form was lodged in his clinical notes. The Panel found that he underwent the programme of investigations for research purposes. You failed in your duty as a Responsible Consultant and your conduct was contrary to the clinical interests of this child.

Child 12 – This child did not meet the inclusion criteria in that he had not been diagnosed with disintegrative disorder, and he had been vaccinated with MMR. He was admitted to hospital in January 1997 and underwent a variety of investigations and The Panel found that he underwent the programme of investigations for research purposes. You carried out a colonoscopy which was not clinically indicated, contrary to your representations to the Ethics Committee. Your conduct was contrary to the clinical interests of this child and you failed in your duties as a Responsible Consultant.

Child 8 – This child did not meet the inclusion criteria in that she had not been diagnosed with disintegrative disorder and she had been vaccinated with MMR. The Panel found that she underwent the programme of investigations for research purposes and you failed to include a copy of the consent form in her medical notes. The Panel found that you failed in your duty as a Responsible Consultant.

Child 7 – This child did not meet the inclusion criteria in that he was not diagnosed with disintegrative disorder, and he had been vaccinated with MMR.

The Panel found that he underwent the programme of investigations for research purposes for which there was no ethical approval and contrary to the conditions set out by the Ethics Committee, you did not lodge a copy of the consent form in his medical notes. You failed in your duty as a Responsible Consultant.

Child 10 – This child did not meet the inclusion criteria in that he did not manifest disintegrative disorder, there were no references to gastrointestinal symptoms and he had been vaccinated with MMR. You carried out a colonoscopy on Child 10, although the Panel accepted it may have been clinically indicated. You failed to ensure a copy of the consent form was lodged in his clinical notes. The Panel found that he underwent the programme of investigations for research purposes and you failed in your duty as a Responsible Consultant although it accepts that there is insufficient evidence to support the allegation that the investigations undergone by the child were contrary to his clinical interests.

The Lancet Paper

The investigations on the children were written up in a scientific paper entitled "Ileal-Lymphoid Nodular Hyperplasia, Non-specific colitis and Pervasive Developmental Disorder in Children" which was published in the Lancet Journal on 28 February 1998 and referred to as "the Lancet Paper". The Panel accepted that you were not a senior author and therefore could not be held responsible for the information contained therein to be true and accurate. However, it found proved that you did not have ethical approval for the investigations carried out on the children, as listed above. In accepting that you were not a senior author of the paper, it also accepted that you could not be held responsible for the statement regarding ethical approval within that paper.

Having found the facts proved, the Panel went on to consider whether your admissions and its findings, taken collectively, would be insufficient to support a finding of serious professional misconduct. In your case it found that the facts would not be insufficient and therefore your case will proceed to the next stage, under Rule 28. Evidence will be adduced and submissions made in respect of whether you are guilty of serious professional misconduct and if so what if any sanction should be imposed on your registration.

The sanctions available to the Panel are a warning, conditional registration for a period of up to three years, suspension for up to a year or erasure from the medical register.