

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

Date: 24 May 2010

Dr Andrew Jeremy WAKEFIELD

Determination on Serious Professional Misconduct (SPM) and sanction:

The Panel has already given its findings on the facts and its reasons for determining that the facts as found proved could amount to serious professional misconduct.

It then went on to consider and determine whether, under Rule 29(1) of the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules Order of Council 1988, the facts as admitted or found proved do amount to serious professional misconduct and if so, what, if any sanction it should impose. It has accepted the Legal Assessor's advice in full as to the approach to be taken in this case, and has looked at each doctors' case separately but, when considering whether Dr Wakefield is guilty of serious professional misconduct, has looked at the heads of charge found proved against him as a whole. It has not confined its consideration to the heads of charge; it has also had regard to the evidence that has been adduced and the submissions made by Ms Smith on behalf of the General Medical Council. On behalf of Dr Wakefield, no evidence has been adduced and no arguments or pleas in mitigation have been addressed to the Panel at this stage of the proceedings. In fact Mr Coonan specifically submitted:

".....we call no evidence and we make no substantive submissions on behalf of Dr Wakefield at this stage." "...I am instructed to make no further observations in this case".

Nevertheless, the Panel considered the totality of the evidence in Dr Wakefield's case including the reference dated 27 October 1995, from Professor Leon Fine, the then Head of the Department of Medicine at the Royal Free Hospital, when reaching its decision at this stage, having been asked to consider that as part of Mr Coonan's submissions at Stage 1.

Serious professional misconduct has no specific definition but in *Roylance v General Medical Council* [1999] Lloyd's Rep. Med. 139 at 149 Lord Clyde, in giving the reasons of the Privy Council, said:

“Misconduct is a word of general effect, involving some act or omission which falls short of what would be proper in the circumstances. The standard of propriety may often be found by reference to the rules and standards ordinarily required by a medical practitioner in the particular circumstances...”

Lord Clyde went on to say:

“The misconduct is qualified in two respects. First, it is qualified by the word ‘professional’ which links the misconduct to the profession of medicine. Secondly, the misconduct is qualified by the word ‘serious’. It is not any professional misconduct which will qualify. The professional misconduct must be serious.”

The Panel has acted as an independent and impartial tribunal and exercised its own judgement on these matters. It has borne in mind the relevant GMC guidance at the time, namely the 1995 *Good Medical Practice* and, in so far as the findings relate to events after 1998, the 1998 *Good Medical Practice*. It has considered what has been adduced and submitted on behalf of the doctors about the standards and procedures which were prevalent at that time.

In considering Dr Wakefield's case, the Panel has also taken into account the passage of time before these matters were brought before it and the length of time this case has taken. It noted that the multiple sittings were for a variety of reasons including professional commitments of the Panel and requests from Counsel for reasons such as illnesses, accidents, unavailability of witnesses and preparation time.

The Panel has noted Dr Wakefield's previous good character and taken into account everything it has heard including his qualifications, experience and standing within the profession, with patients and the parents of patients.

The Panel considered the conduct of Dr Wakefield whilst he was registered as a medical practitioner and employed by the Royal Free Hospital Medical School in 1996 and 1997, initially as a Senior Lecturer in the Departments of Medicine and Histopathology. Later, from 1 May 1997 he was a Reader in Experimental Gastroenterology and an Honorary Consultant in Experimental Gastroenterology at the Royal Free Hospital.

The Panel has already found proved that Dr Wakefield's Honorary Consultant appointment was subject to a stipulation that he would not have any involvement in the clinical management of patients. On five occasions (child 2, 4, 5, 12 and 7) he ordered investigations on children, when he had no paediatric qualifications, and in contravention of the limitations on his appointment. The Panel considered this alone constituted a breach of trust of patients and employers alike.

In February 1996 Dr Wakefield agreed to act as an expert in respect of MMR litigation. In relation to the Legal Aid Board (LAB), the Panel found that Dr Wakefield accepted monies totalling £50,000 procured through Mr Barr, the Claimants' solicitor to pursue research. A costing proposal had been submitted by Mr Barr to the LAB containing detailed information provided by Dr Wakefield, and Dr Wakefield ought to have realised that Mr Barr would submit it to the LAB.

The costing proposal set out costs in respect of the investigation of five children. It covered each child's four-night stay in hospital with colonoscopy, MRI and evoked potential studies. Dr Wakefield admitted that the funding subsequently provided by the Legal Aid Board had not been needed for these items because these costs were borne by the National Health Service as the patients were being admitted as NHS patients.

The Panel found that Dr Wakefield had a duty to disclose this information to the Legal Aid Board via Mr Barr. It was dishonest and misleading of him not to have done so. The Panel concluded that his intention to mislead the Legal Aid Board was sufficient on its own to amount to serious professional misconduct.

The Panel also found that in respect of £25,000 of LAB monies, Dr Wakefield caused or permitted it to be used for purposes other than those for which he said it was needed and for which it had been granted. In doing so he was in breach of his duties in relation to the managing of, and accounting for, funds.

In September 1996 Dr Wakefield made an application to the Ethical Practices Sub-Committee of the Royal Free Hospital (Ethics Committee) seeking approval for a research project involving 25 children. This was approved by the sub-Committee as Project 172-96. He named himself as one of the three Responsible Consultants, thereby taking on the shared responsibility for the information given in support of his application; for ensuring that only children meeting the inclusion criteria would be admitted to the study; that conditions attached to the Ethics Committee approval would be complied with; and that children would be treated in accordance with the terms of the approval given.

In respect of Research and Ethics Committee approval, the Panel had regard to the particular ethical guiding principles with regard to conducting research on children. It rejected Dr Wakefield's overall contention that Project 172-96 was never undertaken; that all the investigations carried out on the children were clinically indicated and that the research elements of the project were covered by another Ethics Committee approval.

The Panel concluded that the programme of investigations that these children were subjected to was part of Project 172-96. It further determined that the conditions for approval and the inclusion criteria for that project were not complied with. The Ethics Committee's reliance on the probity of Dr Wakefield as a Responsible Consultant was not met.

With regard to nine of the eleven children (2,1, 3, 4, 6, 9, 5,12 and 8) considered by the Panel, it determined that Dr Wakefield caused research to be undertaken on them without Ethics Committee approval and thus without the ethical constraints that safeguard research. Ethical constraints are there for the protection both of research subjects and for the reassurance of the public and are crucial to public trust in research medicine. It was in the context of this research project that the Panel found that Dr Wakefield caused three of these young and vulnerable children, (nos. 3, 9 and 12) to undergo the invasive procedure of lumbar puncture when such investigation was for research purposes and was not clinically indicated. This action was contrary to his representation to the Ethics Committee that all the procedures were clinically indicated. In nine of the eleven children (2,1, 3, 4, 9, 5,12, 8 and 7) the Panel has found that Dr Wakefield acted contrary to the clinical interests of each child. The Panel is profoundly concerned that Dr Wakefield repeatedly breached fundamental principles of research medicine. It concluded that his actions in this area alone were sufficient to amount to serious professional misconduct.

The results of the research project were written up as an early report in the Lancet in February 1998. Dr Wakefield as a senior author undertook the drafting of the Lancet paper and wrote its final version. The reporting in that paper of a temporal link between gastrointestinal disease, developmental regression and the MMR vaccination had major public health implications and Dr Wakefield admitted that he knew it would attract intense public and media interest. The potential implications were therefore clear to him, as demonstrated in his correspondence with the Chief Medical Officer of Health and reports which had already appeared in the medical press. In the circumstances, Dr Wakefield had a clear and compelling duty to ensure that the factual information contained in the paper was true and accurate and he failed in this duty.

The children described in the Lancet paper were admitted for research purposes under a programme of investigations for Project 172-96 and the purpose of the project was to investigate the postulated new syndrome following vaccination. In the paper, Dr Wakefield failed to state that this was the case and the Panel concluded that this was dishonest, in that his failure was intentional and that it was irresponsible. His conduct resulted in a misleading description of the patient population. This was a matter which was fundamental to the understanding of the study and the terms under which it was conducted.

In addition to the failure to state that the children were part of a project to investigate the new syndrome, the Lancet paper also stated that the children had been consecutively referred to the Department of Paediatric Gastroenterology with a history of a pervasive developmental disorder and intestinal symptoms. This description implied that the children had been referred to the gastroenterology department with gastrointestinal symptoms and that the investigators had played no active part in that referral process. In fact, the Panel has found that some of the children were not routine referrals to the gastroenterology department in that either they lacked a reported

history of gastrointestinal symptoms and/or that Dr Wakefield had been actively involved in the process of referral. In those circumstances the Panel concluded that the description of the referral process was irresponsible, misleading and in breach of Dr Wakefield's duty as a senior author.

The statement in the Lancet paper that investigations reported in it were approved by the Royal Free Hospital Ethics Committee when they were not, was irresponsible.

Subsequent to the paper's publication, Dr Wakefield had two occasions on which he could have corrected the content of the Lancet paper yet both times he compounded his misconduct.

First, in a published letter in response to correspondents who had suggested that there had been biased selection of the Lancet children, Dr Wakefield stated that the children had been referred through the normal channels, a response which was dishonest and irresponsible. He provided an inaccurate statement which omitted relevant information when he knew that the description of the population in the study was being questioned by the scientific community.

Second, at a meeting of the Medical Research Council, the Chair, Professor Sir John Pattison referred to the seriousness and importance of the implications of Dr Wakefield's research and its major public health implications. At that meeting and on the issue of bias in generating the series of cases, Dr Wakefield stated that the children had come by "the standard route", a response which was dishonest and irresponsible.

Regarding the issues of conflicts of interest, Dr Wakefield did not disclose matters which could legitimately give rise to a perception of a conflict of interest. He failed to disclose to the Ethics Committee and to the Editor of the Lancet his involvement in the MMR litigation and his receipt of funding from the Legal Aid Board. He also failed to disclose to the Editor of the Lancet his involvement as the inventor of a patent relating to a new vaccine for the elimination of the measles virus (Transfer Factor) which he also claimed in the patent application, would be a treatment for inflammatory bowel disease (IBD).

Even before the publication of the Lancet Paper, eminent professionals had expressed concerns about the LAB funding to Dr Wakefield and potential conflicts of interest. Dr Wakefield rejected these views. With regard to non-disclosure to the Ethics Committee, Dr Wakefield did in evidence accept that the Legal Aid Board funding should have been disclosed, but said that his involvement in the litigation need not, especially because of his interpretation of the questions in the application form. He said no question was asked which related to that matter and therefore felt no need to disclose. In evidence to the panel he stated:

“The form is set out expecting certain answers to specific questions and no such question exists. Therefore, since it was not asked, it was not answered.”

However, given the importance of an Ethics Committee’s reliance on the probity of an applicant, the Panel determined that this was a failure by Dr Wakefield and his actions amounted to serious professional misconduct.

With regard to the non-disclosure to the Lancet the Panel accepted evidence from the Editor of the Lancet, as to the importance of this issue. The Lancet published clear guidance in relation to the conflict of interest test that the applicant should apply and the need to discuss any issues arising from it with the Editor. The Lancet test was: “Is there anything that would embarrass you if it were to emerge after publication and you had not declared it?” Dr Wakefield chose not to declare or discuss any conflict of interest with the Editor. He stated that he was able to reconcile his position, was not embarrassed by it, and was quite proud of the position he had taken on behalf of the Lancet children.

Dr Wakefield was insistent that his involvement with the new patent had not given rise to any prior need to disclose. Despite the clear terms of the patent, he did not accept that the invention was envisaged as an alternative vaccine to MMR. He acknowledged that he had envisaged the use of transfer factor for at least a proportion of the population and that he had a financial and career interest in its success, but he said that it did not cross his mind to disclose it, and even with hindsight he insisted that there was a reasonable argument, as he put it, for non-disclosure. The Panel considered that his actions and his persistent lack of insight as to the gravity of his conduct amounted to serious professional misconduct.

In relation to the administration of Transfer Factor to Child 10, the Panel noted the admitted background of Dr Wakefield’s involvement in a company set up with Child 10’s father as Managing Director, to produce and sell Transfer Factor. Around the same time, Dr Wakefield inappropriately caused Child 10 to be administered transfer factor. The Panel accepted that information as to its safety had been obtained and that the approval to administer Transfer Factor to one child was granted in the form of “Chairman’s approval”, “on a named patient basis” in a letter from Dr Geoffrey Lloyd, Chairman of the Medical Advisory Committee at the Royal Free Hospital. Nonetheless the Panel found that Dr Wakefield was at fault because the substance was given for experimental reasons, he did not cause the details to be recorded in the child’s records, or cause the general practitioner to be informed, and he did not have the requisite paediatric qualifications.

Dr Wakefield’s actions were contrary to the clinical interests of Child 10 and an abuse of his position of trust as a medical practitioner. The Panel considered these to be serious departures from the standards of a registered medical practitioner and concluded that these amounted individually and collectively to serious professional misconduct.

Dr Wakefield caused blood to be taken from a group of children for research purposes at a birthday party, which the Panel found to be an inappropriate social setting. He behaved unethically in failing to seek Ethics Committee approval; he showed callous disregard for any distress or pain the children might suffer, and he paid the children £5 reward for giving their blood. He then described the episode in humorous terms at a public presentation and expressed an intention to repeat his conduct. When giving evidence to the Panel, Dr Wakefield expressed some regret regarding his remarks. The Panel was concerned at Dr Wakefield's apparent lack of serious consideration to the relevant ethical issues and the abuse of his position of trust as a medical practitioner with regard to his conduct in causing the blood to be taken. The Panel concluded that his conduct brought the medical profession into disrepute.

Dr Wakefield defended the ethical basis for the taking of blood at a birthday party contrary to the experts who gave evidence to the Panel and who strongly condemned this action. The Panel determined that his conduct fell seriously short of the standards expected of a doctor and was a breach of the trust which the public is entitled to have in members of the medical profession. It concluded that this behaviour amounted to serious professional misconduct.

The Panel has borne in mind the principles guiding a doctor as set out in the relevant paragraphs of 1995 Good Medical Practice which relate to providing a good standard of practice and care, good clinical care, keeping up-to-date, abuse of professional position, probity in professional practice, financial and commercial dealings, and the general principles of conflict of interest, followed by particular provisions as to the way in which research must be conducted. The 1998 Good Medical Practice, relevant to Dr Wakefield's conduct at the birthday party, lists the duties of a doctor in providing a good standard of practice and care, keeping up-to-date and the issue of research and the absolute duty to conduct all research with honesty and integrity.

In all the circumstances and taking into account the standard which might be expected of a doctor practising in the same field of medicine in similar circumstances in or around 1996-1998, the Panel concluded that Dr Wakefield's misconduct not only collectively amounts to serious professional misconduct, over a timeframe from 1996 to 1999, but also, when considered individually, constitutes multiple separate instances of serious professional misconduct.

Accordingly the Panel finds Dr Wakefield guilty of serious professional misconduct.

In considering what, if any, sanction to apply, the Panel was mindful at all times of the need for proportionality and the public interest which includes not only the protection of patients and the public at large, but also setting and maintaining standards within the medical profession, as well as safeguarding its reputation and maintaining public confidence in the profession. It bore in mind that the purpose of sanctions is not punitive, although that might be their effect.

The Panel noted the submissions of GMC Counsel that the appropriate and proportionate sanction would be erasure in light of his serious and wide-ranging misconduct. However the Panel accepted the Legal Assessor's advice that this was only a submission on behalf of the GMC and it was for the Panel to make up its own mind. Dr Wakefield's counsel did not make any substantive submissions on his behalf.

The Panel went on to consider whether it should, pursuant to Rule 30(1), postpone the case. It received no submissions in this regard and so went on to determine whether it was sufficient to conclude the case without making a direction or with an admonition.

The Panel made findings of transgressions in many aspects of Dr Wakefield's research. It made findings of dishonesty in regard to his writing of a scientific paper that had major implications for public health, and with regard to his subsequent representations to a scientific body and to colleagues. He was dishonest in respect of the LAB funds secured for research as well as being misleading. Furthermore he was in breach of his duty to manage finances as well as to account for funds that he did not need to the donor of those funds. In causing blood samples to be taken from children at a birthday party, he callously disregarded the pain and distress young children might suffer and behaved in a way which brought the profession into disrepute.

In view of the nature, number and seriousness of the findings the Panel concluded it would be wholly inappropriate to conclude the case without making a direction or with a reprimand.

It next considered under rule 31 whether it was sufficient to direct that the registration of Dr Wakefield be conditional on his compliance during a period not exceeding three years with such requirements as the (Panel) may think fit to impose for the protection of members of the public or in his interests. Conditions have to be practicable, workable, measurable and verifiable and directed at the particular shortcomings identified. The Panel concluded that Dr Wakefield's shortcomings and the aggravating factors in this case including in broad terms the wide-ranging transgressions relating to every aspect of his research; his disregard for the clinical interests of vulnerable patients; his failure to heed the warnings he received in relation to the potential conflicts of interest associated with his Legal Aid Board funding; his failure to disclose the patent; his dishonesty and the compounding of that dishonesty in relation to the drafting of the Lancet paper; and his subsequent representations about it, all played out against a background of research involving such major public health implications, could not be addressed by any conditions on his registration. In addition, the Panel considered that his actions relating to the taking of blood at the party exemplifies a fundamental failure in the ethical standards expected of a medical practitioner. It concluded that conditional registration would not mark the seriousness of such fundamental failings in his duty as a doctor.

The Panel next went on to consider whether it would be sufficient to suspend Dr Wakefield's registration for a period not exceeding twelve months. Dr Wakefield has demonstrated a persistent lack of insight and has insisted in many instances on his ethical propriety: in the context of the referral process and the treatment of the children in the research project in which he was engaged; in the context of the funding of the project; with regard to the terminology of the Lancet paper; with regard to his non-declaration of interests; with regard to not acting in the best clinical interests of the Lancet children and with regard to obtaining blood from children at a birthday party.

The Panel noted that the sanction of suspension may be appropriate for conduct that falls short of being fundamentally incompatible with continued registration; where there is no evidence of harmful deep-seated or attitudinal problems; and where there is insight and no significant risk of repeating behaviour. Although these points have been set out in the GMC's *Indicative Sanctions Guidance* which was published subsequent to these events, the Panel considered that the guidance outlines the type of sanction appropriate to the gravity of misconduct and that the same principles are applicable to Dr Wakefield's actions at the material times. The Panel considers that Dr Wakefield's conduct in relation to the facts found falls seriously short of the relevant standards and that suspension would not be sufficient or appropriate against a background of several aggravating factors and in the absence of any mitigating submissions made on his behalf. Dr Wakefield's continued lack of insight as to his misconduct serve only to satisfy the Panel that suspension is not sufficient and that his actions are incompatible with his continued registration as a medical practitioner.

Accordingly the Panel has determined that Dr Wakefield's name should be erased from the medical register. The Panel concluded that it is the only sanction that is appropriate to protect patients and is in the wider public interest, including the maintenance of public trust and confidence in the profession and is proportionate to the serious and wide-ranging findings made against him.

The effect of the foregoing direction is that, unless Dr Wakefield exercises his right of appeal, his name will be erased from the Medical Register 28 days from when formal notice has been deemed to be served upon him by letter to his registered address.

Dr Wakefield is presently not subject to any interim order on his registration. The Panel will hear submissions on whether an immediate order of suspension should be imposed upon him pending the outcome of any appeal, first from Ms Smith on behalf of the General Medical Council and then from Mr Coonan on behalf of the doctor but will do that at the conclusion of the reading of all three determinations.