

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

Professor John Angus WALKER-SMITH

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 doctor's case separately but when considering whether Professor Walker-Smith 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 and those made by Mr Miller and Miss Lindsay-Strugo on behalf of Professor Walker-Smith.

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 noted the Legal Assessor's advice that gross professional negligence can also fall within serious professional misconduct. In order for serious professional misconduct to be established on this basis the negligence has to be more than that required to give rise to civil liability and a serious departure from the expected standards of a competent medical practitioner.

The Panel has acted as an independent and impartial tribunal and exercised its own judgement on these matters. It has considered what has been adduced and submitted on behalf of Professor Walker-Smith about the standards and procedures prevailing at that time. 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; and the provisions as to research. In 2001 *Good Medical Practice*, there are provisions specific to writing reports, giving evidence and signing documents and it contains a reference to the GMC's research booklet including recording and reporting research results. The 2001 guidance is relevant only to the charge regarding Professor Walker-Smith's statement in the Lancet in 2004.

When determining whether the relevant conduct amounts to serious professional misconduct, the Panel considered all the evidence including issues of probity, honesty, medical ethics, the clinical interests of patients, the approach to research, appropriate clinical standards, Professor Walker-Smith's attitudes to those issues in his practice generally and the views of the other experienced practitioners in the relevant field.

The Panel has borne in mind the Legal Assessor's advice that Professor Walker-Smith is a man of good character, not just in the sense that he has no previous findings recorded against him by the GMC, but also in that he was professionally competent and highly regarded in his chosen field of practice at that time. It has taken into account his qualifications, experience and standing within the profession, with patients and the parents of patients, together with the impressive testimonials submitted by colleagues, patients, and associates, relevant to the question of serious professional misconduct, and in the knowledge of the findings made against him. The Panel heard positive evidence of Professor Walker-Smith's clinical ability, integrity and the respect in which he continues to be held, by witnesses called by the GMC at the fact finding stage. The Panel also heard further evidence of his good character in oral and written testimonials speaking to his many years of highly regarded practice as a clinician, researcher and teacher, with a worldwide reputation.

In considering Professor Walker-Smith'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 considered the conduct of Professor Walker-Smith at the material times, whilst he was registered as a medical practitioner and collaborating in research with Dr Wakefield. Professor Walker-Smith was employed as Professor and Head of the Department of Paediatric Gastroenterology at the Royal Free Hospital School of Medicine, a senior academic post. He also held an honorary clinical contract as a consultant with the Royal Free Hampstead NHS Trust.

Professor Walker-Smith's clinical work involved advice and treatment relating to sick children under his care and his academic work included an involvement in research projects relating to paediatric gastroenterology. The principles of research ethics and governance and in particular, the guiding principles with regard to children, require a doctor to conduct research within ethical constraints. An ethics committee, in performing its regulatory function, has a right to expect probity from applicant doctors.

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 fundamental principles of research and clinical medicine. It concluded that his actions in these areas were sufficient to amount to serious professional misconduct.

The Panel made findings of fact that Professor Walker-Smith 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 concluded that the substance was given for experimental reasons, Professor Walker-Smith having neither seen nor assessed the child between his discharge from hospital in February 1997 and his receiving Transfer Factor around December 1997. Professor Walker-Smith did not record the details relating to the substance in Child 10's medical records or give this information to the child's general practitioner. The Panel concluded that Professor Walker-Smith had acted irresponsibly in this respect and contrary to the clinical interests of the child.

The treatment of Child JS by Professor Walker-Smith arose in the context of the same research as that concerning the Lancet children. Professor Walker-Smith subjected the child to colonoscopy for the purposes of the research in which he collaborated with Dr Wakefield. Although the child had minor gastrointestinal symptoms, his main presentation was behavioural difficulties. Professor Walker-Smith deemed the colonoscopy to be "essential", but the Panel found that the procedure had not been clinically indicated. Professor Walker-Smith's conduct was contrary to the clinical interests of this child.

The Panel considered these findings in relation to Child 10 and Child JS were serious departures from the standards of a registered medical practitioner and concluded that Professor Walker-Smith's actions amounted to serious professional misconduct.

In addition to the Panel's serious findings in relation to Professor Walker-Smith's involvement in the research and his clinical care of the children, the Panel has also made findings relating to the way in which the project was subsequently written up in the Lancet paper.

The reporting in that paper of a temporal link between gastrointestinal disease, developmental regression and the MMR vaccination had major public health implications. Professor Walker-Smith did not accept that he was a senior author of the paper nor admit that he knew or ought to have known the paper had these implications or would attract intense public and media interest when it was published in February 1998. However the Panel noted that he wrote a letter to Professor Brent Taylor of the Department of Child Health at the Royal Free Hospital on 4 August 1997, following the publication of an article in the medical press in which Dr Wakefield had referred to the research results. In that letter, Professor Walker-Smith indicated his concerns about any weakening of the MMR uptake and expressed awareness of what he described as the "rapacious" press and media.

The Panel found that Professor Walker-Smith knew or ought to have known of the widespread implications of the Lancet paper and, as a senior author of the paper, had a duty to ensure that the factual information contained in the paper was true and accurate.

The Lancet paper stated that the children had been consecutively referred to the Department of Paediatric Gastroenterology of the Royal Free hospital with a history of pervasive developmental disorder and intestinal symptoms. The Panel found that this description implied to a general reader that the children had been referred to the Department of Paediatric Gastroenterology with gastrointestinal symptoms and that investigators had played no active part in the referral process. However, some of the children were not routine referrals to the gastroenterology department, in that they lacked a history of reported gastrointestinal symptoms and had been referred for investigation of the role played by the measles vaccination or the MMR vaccination in their developmental disorders. In the case of child 9, Professor Walker-Smith was 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 Professor Walker-Smith's duty to ensure that the information in the Lancet paper was accurate.

The children described in the Lancet paper were admitted as part of a project, the purpose of which was to investigate a postulated new syndrome comprising gastrointestinal symptoms and disintegrative disorder following vaccination. Professor Walker-Smith failed in his duty as a senior author to ensure that the paper stated that this was the case. He accepted that he had seen an earlier draft of the Lancet paper which included the inaccurate description of the patient population. Whilst the Panel found that his conduct was not dishonest or premeditated in that he did not write or see the final draft, it concluded that he had been irresponsible as a senior author and a senior clinician; and that as a result a misleading description of the patient population was given in the Lancet paper. This was a matter which was fundamental to the understanding of the study and the terms under which it was conducted.

In respect of the representation in the Lancet paper that investigations reported in it were approved by the Royal Free Hospital Ethics Committee, the Panel found that they were not. It concluded that although Professor Walker-Smith was not dishonest because he had no intention to deceive, he was irresponsible and in breach of his duty to ensure the information in the Lancet paper was accurate.

The scientific community and the public are entitled to expect that a senior author of a scientific paper will behave responsibly in connection with it and the Panel concluded that Professor Walker-Smith had fallen seriously short in his duty to do so.

Professor Walker-Smith made a statement in 2004 for publication in The Lancet dealing in particular with the manner in which the Lancet children had been referred. He stated that, to the best of his recollection, he did not invite any child to participate in the study. The Panel is aware of the circumstances in which this statement was made, namely when serious allegations of research misconduct had been made to the Editor of The Lancet. Professor Walker-Smith's statement although not dishonest because he had no intention to mislead, was in the case of Child 9, irresponsible and contrary to his duty to ensure that information provided by him was accurate.

Professor Walker-Smith was involved in research on young, vulnerable children, without the appropriate ethical approval; he caused them to undergo in the pursuit of that research, invasive procedures that were not in their best clinical interests; he was irresponsible in his reporting in a scientific journal of a study which he knew, or ought to have known, had major public health implications. Furthermore he caused a child to be administered Transfer Factor for experimental reasons. The Panel concluded that, 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 findings are not only collectively such as to amount to serious professional misconduct, but also when considered individually, constitute multiple separate instances of serious professional misconduct.

Accordingly the Panel finds Professor Walker-Smith guilty of serious professional misconduct.

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.

In considering what, if any, sanction to apply, the Panel was mindful at all times of the need for proportionality, that is, any direction must be in proportion to the serious professional misconduct of which the Panel found Professor Walker-Smith guilty and balance the public interest with the

doctor's interest. It must be judged in the context of the doctor's otherwise good character and other mitigating factors. The public interest includes not only the protection of patients and the public, 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. It is also in the public interest to have reputable and competent doctors in practice.

The Panel noted the submissions of GMC Counsel that the appropriate and proportionate sanction would be erasure in light of Professor Walker-Smith's serious misconduct. However the Panel accepted the Legal Assessor's advice that these submissions on behalf of the GMC were only submissions and that it was for the Panel to make up its own mind.

On Professor Walker-Smith's behalf, Defence Counsel submitted that the parents who entrusted their children to Professor Walker-Smith's care have made no complaint; Professor Walker-Smith is 73 years old; that he retired from medical practice ten years ago and would never return to providing clinical care to children. It is submitted that patients would not need protection from him, therefore the issue of protection of patients is wholly irrelevant. It was further submitted on Professor Walker-Smith's behalf that anybody looking at those findings would not expect or demand a sanction to be imposed, still less the sanction of erasure. Professor Walker-Smith's dealings with the Ethics Committee were not found to be dishonest and the testimonials emphasise his reputation for honesty and probity. In relation to personal mitigation, the testimonial letters and the oral evidence speak to the high regard in which he is held and emphasise Professor Walker-Smith's commitment to the welfare of children.

The Panel whilst in camera sought further advice from the Legal Assessor in relation to the appropriate weight to be attached to testimonials, and was referred to the case of *Meadow v GMC* [2006] EWHC 146 (Admin). The Legal Assessor advised the Panel to pay particular regard to paragraph 57 of the judgment, namely that the testimonials should be weighed in favour of the doctor and his contribution to medicine acknowledged; but it was a matter for the Panel what weight should be attached to them. However, they could not simply be ignored and any sanction must be proportionate having taken them into account. All parties were informed on the day that such advice had been given and were invited to comment - there was no dissent.

The Panel considered that Professor Walker-Smith had breached his duty to act in accordance with the clinical interests of the children. His work entailed an understanding of and an application of the principles regarding the distinctions between research medicine, with its prime purpose of testing an hypothesis, clinical medical practice undertaken with the intention of benefitting the individual patient and innovative treatment. The Panel concluded that it was incumbent upon Professor Walker-Smith to identify those very distinctions and seek the correct approvals for research projects; to carry out research projects correctly and in accordance with the permissions he had been given; and to write projects up accurately and responsibly, in order to inform and advance scientific knowledge.

The Panel's findings with regard to both the research and the clinical aspects of Professor Walker-Smith's practice constitute very serious and fundamental deficiencies.

Notwithstanding Defence submissions that a finding of serious professional misconduct on its own would be something that Professor Walker-Smith would find devastating and humbling, in view of the nature, number and seriousness of the findings the Panel considered that to conclude the case with a reprimand would be wholly inappropriate.

Professor Walker-Smith retired from the Royal Free Hospital in 2000, and it has been submitted on his behalf that he would not return to medical practice. However the public interest relates not only to the protection of patients but also to the wider interest of maintaining public confidence in the profession and maintaining the standards of the profession.

The Panel next considered under rule 31 whether it was sufficient to direct that the registration of Professor Walker-Smith 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 the imposition of conditions on his registration would not be applicable in the circumstances of this case as Professor Walker-Smith is retired from practice. Additionally, the Panel concluded that conditional registration would not mark the seriousness of such fundamental failings in his duty as a doctor.

The Panel went on to consider whether it would be sufficient to suspend Professor Walker-Smith's registration for a period not exceeding twelve months. 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 Professor Walker-Smith's actions at the material times.

The Panel considered the respect in which Professor Walker-Smith is held by the United Kingdom and international paediatric community. It has received glowing testimonials in relation to his practice as a respected eminent paediatrician, even in the light of the findings made against him and has weighed carefully those in mitigation against the failings identified in the course of undertaking Project 172-96 in collaboration with Dr Wakefield. The Panel found no evidence of harmful deep-seated or attitudinal problems and Professor Walker-Smith poses no risk of repeating behaviour. It further noted that he was and remains a well-respected doctor whose contribution to paediatric medicine has been exemplary.

In deciding what weight should be given to this considerable mitigation, the Panel considered whether the serious transgressions, which arose in respect of Professor Walker-Smith's failings, amounted to conduct being fundamentally incompatible with continuing to be a registered doctor. This is not an isolated case where a doctor departed from the proper standards. Rather, the breaches of duty relate to research and clinical areas of medical practice involving a number of children over a period of time. The nature of and background to the Panel's findings and the public interest in particular with regard to the maintenance of public confidence in research and clinical medicine was highly relevant to the Panel's consideration at this stage. The Panel concluded that Professor Walker-Smith's extensive failures in relation to the clinical care of particularly vulnerable children, his non-compliance with ethical research requirements, and the irresponsible and misleading reporting of research findings potentially having such major implications for public health, did amount to conduct being fundamentally incompatible with his remaining a registered medical practitioner.

The Panel therefore concluded that suspension was not sufficient to mark the extent of Professor Walker-Smith's serious and repeated departures from good medical practice. Therefore, with regret, the Panel determined that erasure was the only proportionate sanction appropriate in the wider public interest, including the maintenance of public trust and confidence in the profession.

Accordingly the Panel has determined that Professor Walker-Smith's name should be erased from the medical register.

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

Professor Walker-Smith is presently not subject to any interim order. 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 Miller on behalf of the doctor but will do that at the conclusion of the reading of Professor Murch's determination.