FITNESS TO PRACTISE PANEL
21 MARCH – 24 APRIL 2012
7th Floor, St James's Buildings, 79 Oxford Street, Manchester, M1 6FQ

Name of Respondent Doctor: Dr Jean Anne MONRO

Registered Qualifications: MRCS 1960 Royal College of Surgeons of England, LRCP 1960 Royal College of Physicians of London, MB BS 1960 University of London

Area of Registered Address: Hertfordshire

Reference Number: 0552174

Type of Case: New case of impairment by reason of misconduct

Panel Members: Ms E Samupfonda, Chairman (Lay)
Dr A Vaidya (Medical)
Mrs M Bamford (Lay)

Legal Assessor: Mr D Smith

Secretary to the Panel: Mr A Chan

Representation:
GMC: Mr Jeremy Donne QC, instructed by GMC Legal

Doctor: Dr Monro was present and represented by Mr Angus Moon QC, instructed by Nabarro LLP

ALLEGATION

"That being registered under the Medical Act 1983, as amended:

1. Since 1988 you have worked as the Medical Director of the Breakspear Hospital, ~~Hemel Hempstead~~ latterly the Breakspear Clinic, a private ~~day care~~ hospital specialising in environmental medicine and chronic fatigue disorders; **Admitted and Found Proved**

2. On or about 9 January 2009 Doctor's Data laboratory of Illinois, USA, reported the analysis of pre- and post-DMSA provoked urine samples obtained from Patient HB on 5 January 2009; **Admitted and Found Proved**

3. In a letter to HB's general practitioner ('GP') on 2 April 2009 referring to Dr G's letter dated 12 February 2009 and HB's urine toxic metal analyses you advised that HB should embark on a programme of chelation therapy as soon as possible to remove the lead from his body; **Admitted and Found Proved**

4. You did not

   i. measure HB's blood lead concentration, **Admitted and Found Proved**

   ii. refer HB to a specialist in toxicology or lead poisoning, **Admitted and Found Proved**

   iii. seek the advice of the National Poisons Information Service; **Admitted and Found Proved**

5. You did not explain to HB or his GP that

   i. the DMSA challenge test alone has no demonstrated benefit in the diagnosis of lead toxicity compared with analysis of HB's blood lead concentration, **Admitted and Found Proved**

   ii. the challenge test had been performed using a substantially greater dose of DMSA than was either necessary or appropriate; **Admitted and Found Proved**

6. You did not advise HB or his GP

   i. of the possible complications from chelation therapy, **Admitted and Found Proved in relation to HB's GP. Found Proved in relation to HP.**

   ii. that chelation therapy is available free of charge from the National Health Service if clinically required; **Admitted and Found Proved in relation to HB's GP. Found Proved in relation to HP.**

7. HB received chelation therapy at the Breakspear Hospital subsequent to you being notified by the GMC of his GP's complaint against you; **Admitted and Found Proved**

8. The amount of sodium calcium edetate administered to HB during his course of chelation therapy was substantially below the BNF recommended dose for patients with lead poisoning; **Admitted and Found Proved**

9. Your treatment recommendation at 3 above was

   i. made despite a provoked urine sample alone not being an appropriate test upon which to base a diagnosis of lead poisoning or toxicity, **Found Proved**

   ii. made despite you not having specialist training or expertise in

a. clinical toxicology, **Admitted and Found Proved**

b. the investigation and treatment of lead poisoning, **Admitted and Found Proved**

iii. based on inadequate evidence, **Found Proved**

iv. potentially harmful; **Found Proved**

10. Your conduct described in paragraphs 3,4, 5, 6, 7, 8 and 9 above was not in the best interests of the patient. **Found Proved in relation to paragraphs 3, 4 (in its entirety), 5 (in its entirety), 6(i) and 9 (in its entirety). Found Not Proved in relation to paragraphs 6(ii) and 7.**

And that by reason of the matters set out above your fitness to practise is impaired because of your misconduct."

Determination on facts

"Dr Monro:

At the outset of these proceedings, the Panel acceded to an unopposed application made by Mr Donne, on behalf of the General Medical Council (GMC), to replace the word 'performing' in paragraph 5(i) of the allegation with the words 'analysis of'.

Following this amendment, Mr Moon, on your behalf, made a number of admissions in relation to the amended allegation and the Panel announced the following paragraphs as admitted and found proved: Paragraphs 2, 3, 4 (in its entirety), 5 (in its entirety), 6(i) and 6(ii) in respect of not advising HB's GP, 7, 8 and 9(ii)(a).

During the course of the proceedings, Mr Donne made a further application to amend the allegation. He applied to replace the words 'Hemel Hempstead' in paragraph 1 of the allegation with the words 'latterly the Breakspear Clinic' and to remove the words 'day care' from that same charge. These proposed amendments were not opposed by Mr Moon and the Panel acceded to the application. Mr Moon, on your behalf, then admitted paragraph 1 as amended and the Panel announced it as being admitted and found proved.

After making his closing submissions on the facts, Mr Moon made a further admission on your behalf, namely, paragraph 9(ii)(b), which the Panel announced as being admitted and found proved.

The Panel has considered the outstanding paragraphs of the allegation separately. In doing so it has considered all of the evidence adduced in this case including your own oral evidence, the oral evidence from witnesses called by the GMC and by you, the documentary evidence placed before it, and the submissions of both Counsel.

The Panel has accepted the Legal Assessor's advice that the burden of proof rests with the GMC and that proof is to the civil standard.

At the outset of this determination, the Panel acknowledged that this is a complex and technical case concerning a specialised branch of medicine. This case concerns the alleged use of inappropriate methods by you, together with a former colleague, to diagnose and treat lead toxicity in a patient, HB.

The Panel's assessment of witnesses

The Panel has heard evidence of fact from Drs A and B, HB's General Practitioners. It also heard from Dr C, Consultant Chemical Pathologist and regards all three as credible and reliable witnesses.

Expert witnesses

Expert witnesses have been called by both sides. The GMC called two experts, Professor D, a Consultant Clinical Pharmacologist who holds a Chair in the University of Birmingham Medical School. He is the Director of the Birmingham unit of the National Poisons Information Service; the second witness, Professor E is not a clinician as he is not medically qualified, but holds a doctorate and an NHS post as a Consultant Clinical Toxicologist at King's College Hospital. He is also a visiting Professor in Analytical Toxicology at the University of Loughborough and an Honorary Professor of Analytical Toxicology at Queen Mary College, University of London.

Professor F was called on your behalf. Professor F is not a clinician but is Emeritus Professor of Medicinal Chemistry at the University of Sunderland, holds a PhD, Faculty of Medicine from the University of London and is, by election, a member of the Royal Institute of Chemistry. His main area of expertise is medicinal chemistry and, since 1997, has been heavily involved in the, "*emerging complex, chronic multi-system conditions (largely environmental) as a scientific advisor to many different groups of people*".

The Panel's assessment of the experts

The Panel accepted the Legal Assessor's advice that, "*An expert [is]…a witness who has acquired by study or experience sufficient knowledge of the subject to render his opinion of value in resolving the issues before the Panel. An investigation of the methods used by the witness in arriving at his opinion may be pertinent. If he does possess the necessary competence his evidence of opinion is admissible; the fact that an expert witness may have been discredited will go to the weight of the evidence, not to its admissibility*". It has considered the experience and background of all three experts and the manner in which they dealt with matters relevant to the charges of the allegation. The Panel was impressed by both Professors D and E, and

regards their opinions, based as they were, on substantial experience in both research and practice, as persuasive.

Although the Panel acknowledges that Professor F is an expert in his own field of medicinal chemistry, his professed expertise in the field of lead toxicity is limited. He stated in evidence that, prior to this case, he had no experience of lead toxicity. Further, he stated that he does not seek to compare his depth of knowledge with that of Professors D and E. He accepted that lead toxicity is a heavily researched area with in excess of 20,000 published papers in the last two or three decades alone; he admitted that he had only read, "*a big handful compared with the total*". The Panel has also noted that Professor F made an elementary mistake in preparing his evidence - his misinterpretation of some of the figures in table 1 in the learned article of Perrine Hoet et al entitled, "Clinical Evaluation of Lead Mobilization Test Using the Chelating Agent DMSA, Clinical Chemistry 52:1 88-96 (2006)". This served to undermine his professed expertise in the field of lead toxicity. The Panel has noted that Professor F's evidence is based solely on his interpretation of academic literature and does not derive from practical and direct experience in the field. The Panel could not give weight to his conclusions and opinions where they conflicted with those of the other experts.

The Panel's treatment of your evidence

The Panel noted that Mr Moon conceded on your behalf that you do not have specialist training or expertise in clinical toxicology or in the investigation and treatment of lead poisoning. However, it was argued on your behalf, and you asserted in your evidence, that you are an expert in the field of environmental medicine. Mr Moon invited the Panel to treat you as an expert in this field. In assessing whether it should do so, the Panel considered the following factors:

1. you do not have any formal recognised (by the GMC) qualification or training in occupational medicine within which the specialty of environmental medicine falls;

2. you have not produced any learned papers in the specialty you assert although you have been involved in some research in the area of environmental medicine;

3. you have not produced evidence of any post-qualifying experience or certificates in environmental medicine or in treating body burdens of lead, though you stated you have attended a variety of courses and received training.

The Panel has been presented with no evidence to substantiate your claim that you are an expert in environmental medicine and was not provided with your CV. Whilst the Panel acknowledges that you said in evidence that you are a fellow of the American Academy of Environmental Medicine and have a Diploma of an International Board in Environmental Medicine, it rejects your evidence and

Mr Moon's argument that this makes you an expert in environmental medicine. In the circumstances, the Panel has treated your evidence as equiDnt to any other witness appearing before a Panel.

Expert academic literature

The Panel has been presented with numerous academic papers from each party in support of its own case. The Panel has read and considered these articles in full and the arguments propounded by the authors. The Panel has reserved comment on these articles unless otherwise necessary in this determination. As a general comment, however, the Panel appreciates that mutually exclusive interpretations supporting opposing views have been presented.

The Panel's findings

Paragraph 1 as amended:

> "Since 1988 you have worked as the Medical Director of the Breakspear Hospital, ~~Hemel Hempstead~~ latterly the Breakspear Clinic, a private ~~day care~~ hospital specialising in environmental medicine and chronic fatigue disorders"

has been admitted and found proved

Paragraph 2:

> "On or about 9 January 2009 Doctor's Data laboratory of Illinois, USA, reported the analysis of pre- and post-DMSA provoked urine samples obtained from Patient HB on 5 January 2009"

has been admitted and found proved.

Paragraph 3:

> "In a letter to HB's general practitioner ('GP') on 2 April 2009 referring to Dr G's letter dated 12 February 2009 and HB's urine toxic metal analyses you advised that HB should embark on a programme of chelation therapy as soon as possible to remove the lead from his body"

has been admitted and found proved.

Paragraph 4:

> "You did not"

Paragraph 4(i):

> "measure HB's blood lead concentration"

has been admitted and found proved.

Paragraph 4(ii):

"refer HB to a specialist in toxicology or lead poisoning"

has been admitted and found proved.

Paragraph 4(iii):

"seek the advice of the National Poisons Information Service"

has been admitted and found proved.

Paragraph 5:

"You did not explain to HB or his GP that"

Paragraph 5(i) as amended:

"the DMSA challenge test alone has no demonstrated benefit in the diagnosis of lead toxicity compared with analysis of HB's blood lead concentration"

has been admitted and found proved.

Paragraph 5(ii):

"the challenge test had been performed using a substantially greater dose of DMSA than was either necessary or appropriate"

has been admitted and found proved.

Paragraph 6:

"You did not advise HB or his GP"

Paragraph 6(i):

"of the possible complications from chelation therapy"

has been admitted and found proved in respect of not advising HB's GP. Has been found proved in respect of not advising HB.

In finding this fact proved, the Panel noted your evidence that you had assumed that Dr G, a former colleague at the Breakspear Clinic, had advised HB of the possible complications from chelation therapy. However, in looking at HB's medical

records for the period in which Dr G saw him, the Panel could not find any reference to any advice given by Dr G of the possible complications of chelation therapy. Further, even if your assumption had been correct, the Panel considers that it would have been good practice for you to ensure that HB was again advised of the complications when you took over his care, particularly so given that more than six months had elapsed between Dr G's treatment recommendation and the actual chelation therapy taking place. The Panel considers that, as HB's treating physician at the time, it was incumbent upon you to advise him of the complications.

Further, the Panel noted your evidence that you told HB that, "*in general, it is a completely safe procedure in our hands. The second thing is I did say to him that we would be providing him with the nutrients that are required for replenishment*." The Panel has also had regard to the brochure entitled "Chelation Therapy" which is readily available at the Breakspear Clinic, a copy of which had been obtained by HB. Professor D stated that this brochure, "*is a helpful adjunct because patients often forget what they have been told in a consultation, so to have a booklet is an excellent idea as long as it is up-to-date and accurate*." However, he pointed out that, "*it does not mention the adverse effects of sodium calcium edetate at all when given intravenously, so HB could not have been informed about the potential adverse effects because it is not mentioned*."

You also stated in your evidence that, "*should [patients] require any further information about any of the things that we were proposing for them it was available to them. It is also on our notice boards that such information is available*." The Panel regards this to be insufficient in that it transfers responsibility to patients.

In all the circumstances, therefore, whilst it was helpful of you to have informed HB of potential nutrient depletion, this does not itself sufficiently alert patients to the potential complications of chelation therapy.

Paragraph 6(ii):

> "that chelation therapy is available free of charge from the National Health Service if clinically required"

has been admitted and found proved in respect of not advising HB's GP. Has been found proved in respect of not advising HB.

In finding this fact proved, the Panel considered your evidence that HB had a copy of the brochure. It was pointed out to the Panel that, within the introduction section of the brochure, it states,

> "*Chelation therapy is the standard treatment used in the UK National Health Service (NHS) for acute metal poisoning.*"

It was submitted on your behalf that this statement amounted to advice that chelation therapy was available free of charge on the NHS if clinically required. The

Panel considers that the statement in the brochure does not make this sufficiently clear; it is merely a statement informing a reader that chelation therapy is used in the NHS. Further, the Panel recognises that there are some clinical services which, although offered by the NHS, are not free of charge. The Panel considers that it would require a sophisticated patient to understand that the statement in the brochure indicates that chelation therapy is free of charge on the NHS.

Further, the Panel noted that, when you were asked a direct question as to whether your clinic would normally advise patients of the availability of treatment on the NHS if they were clinically indicated, you stated that chelation therapy was, "*suggested to his doctor",* and that, *"if his doctor wished to refer him, she was at liberty to do so, but, you know, it was her choice as to whether this should be pursued, and it was also the choice of the two doctors on the PCT Panel who decided to fund his treatment at the Breakspear rather than fund his treatment with the national poisons centre."*

The Panel considers that you were vague in answering the question and appeared to place the responsibility on HB's GP, Dr A. The Panel has heard from Dr A that, at that time, she did not know what chelation therapy was. You have admitted that you did not inform Dr A that chelation therapy is available free of charge. On the contrary, you advised that an extra contractual referral was required. It therefore could not have been possible for Dr A to have informed HB that it was available free of charge.

Paragraph 7:

> "HB received chelation therapy at the Breakspear Hospital subsequent to you being notified by the GMC of his GP's complaint against you"

has been admitted and found proved.

Paragraph 8:

> "The amount of sodium calcium edetate administered to HB during his course of chelation therapy was substantially below the BNF recommended dose for patients with lead poisoning"

has been admitted and found proved.

Paragraph 9:

> "Your treatment recommendation at 3 above was"

Paragraph 9(i):

> "made despite a provoked urine sample alone not being an appropriate test upon which to base a diagnosis of lead poisoning or toxicity"

has been found proved

In finding this fact proved, the Panel considered the ten factors you identified in your evidence upon which you relied in making your recommendation that HB embark upon a programme of chelation therapy as soon as possible. You dispute the allegation that it was made on the provoked urine sample alone. The Panel considered the letters to HB's GP, dated 2 April 2009 and 12 February 2009, informing the GP that HB should undergo chelation therapy and noted that none of the ten factors you identified as being pertinent to your decision in recommending chelation therapy was mentioned in either of these letters.

The Panel has noted Professor D's evidence in respect of urine samples as being a measure of lead toxicity. He stated that there is no national or international reference value for post provocation urine samples. He further stated that, "*you cannot use [it], even if you believe the provocation test has some value"*, as *"it could lead to misinterpretation."* He was of the opinion that, *"you have to measure the blood lead concentration."* He sought support for his opinion by reference to the American College of Medical Toxicology Position Statement on Post-Chelator Challenge Urinary Metal Testing, 31 March 2010, which states that,

> "*it is, therefore, the position of the American College of Medical Toxicology that post-challenge urinary metal testing has not been scientifically validated, has no demonstrated benefit, and may be harmful when applied in the assessment and treatment of patients in whom there is concern for metal poisoning*."

Professor D stated that those practising in the United Kingdom would share the same view as this. He told the Panel that, "*we have debated this topic in the UK within the National Poisons Information Service, which includes all clinical toxicologists practising in the UK, and we are completely supportive of this document*."

Furthermore, the report from Doctor's Data providing the results of the post-urine test notes that, "*reference ranges are representative of a healthy population under non-challenge or non-provoked conditions. No safe reference levels for toxic metals have been established*."

Paragraph 9(ii):

> "made despite you not having specialist training or expertise in"

Paragraph 9(ii)(a):

> "clinical toxicology"

has been admitted and found proved.

Paragraph 9(ii)(b):

"the investigation and treatment of lead poisoning"

has been admitted and found proved

Paragraph 9(iii):

"based on inadequate evidence"

has been found proved

In finding this fact proved, the Panel again considered your ten factors. All the experts agreed that the combination of HB's symptoms were the classic non-specific symptoms of myalgic encephalomyelitis (ME) or chronic fatigue syndrome (CFS). In addition, the Panel noted that it was not presented with any blood lead level (BLL) or urine lead level readings prior to the commencement of HB's chelation treatment in 2010. The DNA adducts and the Biolab report you relied upon, were obtained nine and 11 years earlier in 2001 and 1999 respectively and were of no clinical diagnostic use.

With regard to the results of the Doctor's Data tests, the Panel accepted Professor D's view that, based on those results, there is no reasonable body of medical opinion that would support a diagnosis of lead toxicity. His view was unaffected by HB's history of potential environmental exposure to lead over the preceding decade, nor was his opinion tempered by HB's reported symptoms.

The Panel accepts that, whilst the ten factors may have been present and that the history of HB demonstrates that there was the potential for lead exposure, there was no independent or conclusive evidence to indicate that he in fact suffered from lead toxicity. You did not conduct the basic blood test which would have contributed to the assessment of levels of HB's lead toxicity. The Panel considers that none of the factors you identified, either taken individually or collectively, demonstrated that HB had lead poisoning; therefore, your recommendation that HB should embark on a programme of chelation therapy was based on inadequate evidence.

Paragraph 9(iv):

"potentially harmful"

has been found proved

In finding this fact proved, Professor D said that the predominant side effect of the chelating agent calcium disodium EDTA, is impairment of kidney performance, depending on the dose administered. He acknowledged that the low dose actually administered was unlikely to have had this effect. The Panel also noted that when a

blood lead concentration was measured prior to the extra contractual referral being sought, it revealed that he had a BLL of 2.9 µg/dL, which is not indicative of a high body burden of lead. Professor D stated that if chelation therapy using calcium disodium EDTA was embarked upon with a BLL of 2.9 µg/dL, then the risk was that it, "*would certainly produce zinc depletion, because that is characteristic with sodium calcium edetate, and if there is no lead there, then it would chelate zinc and excrete it*."

Paragraph 10:

> "Your conduct described in paragraphs 3,4, 5, 6, 7, 8 and 9 above was not in the best interests of the patient"

has been found proved in respect of paragraphs 3, 4 (in its entirety), 5 (in its entirety), 6(i) and 9 (in its entirety). Found not proved in respect of paragraphs 6(ii) and 7.

In determining whether your conduct was not in the best interest of HB in respect of the paragraphs in this head of charge, the Panel recognised that it had to first interpret 'best interests'. In doing so, the Panel noted Mr Moon's submission that, 'best interests' is a concept encompassing medical, emotional and all other welfare issues. He referred to the cases of R-B (A Patient) v The Official Solicitor [2000] Lloyd's Law Report: Medical 87 and Re SL (Adult Sterilisation [2000] Lloyd's Law Report: Medical 339. Mr Moon argued that you acted in HB's best interests in this wide sense.

The Panel has considered the advice of the Legal Assessor, Mr Smith, who stated that the cases identified by Mr Moon are of limited assistance since, "*the Panel's task is to judge whether, from a purely medical point of view, the chelation treatment was or was not in HB's interests. It is right in so doing to take account of HB's own wishes since his consent, far from being withheld, was gladly forthcoming. It cannot, however, be regarded as the deciding factor since chelation is treatment and treatment needs to be advised on medical grounds. "*

The Panel accepted Mr Smith's advice and has thus made the following findings under head of charge 10.

Paragraph 3

In finding paragraph 10 proved in respect of paragraph 3, the Panel noted Professor D's evidence that, *"no clinical toxicologist in the UK would treat a patient with this blood lead level concentration [2.9 µg/dL] with DMSA or sodium calcium edetate."* He went further and told the Panel that he is, *"aware of all the evidence for intervention in published and reputable journals to suggest that intervention with chelation should not be less than a concentration of 50."* He pointed out that he has "*read the alternative medicine literature and I am aware of patients being treated at*

very low concentrations" but does not consider them to be reasonable opinions as "*they give no support…that their intervention made any difference*."

The Panel accepts Professor D's evidence in respect of this matter.
It also notes that HB was a patient who suffered from numerous non-specific symptoms and was strongly motivated to find a cure for his CFS. Whilst HB was not a witness at these proceedings, it was adduced in evidence that he had researched and found your clinic. At a consultation at the Breakspear Clinic, chelation therapy was suggested to HB and he clearly wanted this treatment. However, notwithstanding what HB wanted, there was no objective or clinical indication that HB should embark upon such a programme. The Panel considers that you should not have intervened and chelated HB and it was therefore not in his best interest for you to have done so.

Paragraph 4(i)

In finding paragraph 10 proved in respect of paragraph 4(i), the Panel accepted Professor D's evidence that, *"HB had a variety of non-specific symptoms and he had a normal urine lead concentration. We do not have the advantage at that stage of having a blood lead concentration but we know later it was 2.9 micrograms per decilitre, so it is important when you are trying to discover the cause of non-specific symptoms to have all the relevant tests available that are easily available…that [blood lead concentration] would have been very informative because it would have told the clinicians concerned that this patient had a minimal body burden of lead and, therefore, the provocation test would not have been misinterpreted as it was."*

In light of Professor D's evidence, it was not in HB's best interests not to measure his blood lead concentration.

Paragraph 4(ii)

In finding paragraph 10 proved in respect of paragraph 4(ii), the Panel noted your evidence. You told the Panel that, *"I do not think that a toxicologist might have done anything for him, and I had the evidence of that in this hearing."* You went on, *"toxicologists seem to think that there is a threshold at which lead has an effect. In my opinion, lead has effects in the form of a continuum and that is not compatible with a threshold. You cannot have a threshold where a poison suddenly becomes not a poison."*

The Panel does not accept your evidence in this regard. As you do not have specialist training or expertise in clinical toxicology or in the investigation and/or treatment of lead poisoning, the Panel considers that you should have referred HB to a specialist who would have provided HB with complete advice.

Paragraph 4(iii)

The Panel's reasons for finding for paragraph 10 proved in respect of paragraph 4(iii) are the same as its reasons for finding paragraph 10 proved in respect of paragraph 4(ii). In

addition to those reasons, it noted Professor D's evidence that where a physician, who is not a specialist and is considering, for example, the results obtained from Doctor's Data, then that physician, "*should telephone the National Poison Information Service and discuss it with one of the consultants, which is precisely why the Department of Health funds the National Poisons Information Service to provide this expert advice*."

Paragraph 5(i)

In finding paragraph 10 proved in respect of paragraph 5(i), the Panel first considered the proposition that the DMSA challenge test alone has no demonstrated benefit in the diagnosis of lead toxicity. If it considered that there was no demonstrated benefit, then it should go on to consider whether you explained this to either HB or his GP.

In respect of the first issue, the Panel noted the following learned articles:

- Perrine Hoet et al – Clinical Evaluation of Lead Mobilization Test Using the Chelating Agent Dimercaptosuccinic Acid, Clinical Chemistry 52:1 88-96 (2006);

- Dilshad Ahmed Khan et al – Evaluation of Lead Body Burden in Occupational Workers by Lead Mobilization Test, Vol 59, No 6 June 2009;

- Walter J Crinnion, ND – The Benefits of Pre- and Post-challenge Urine Heavy Metal Testing: Part 1, Alternative Medicine Review, Vol 14, No 1 2009 and Part 2, Alternative Medicine Review, Vol 14, No 2 2009.

The Panel is aware that there are different interpretations of the value of lead mobilisation tests (LMT) as an indicator of body burden of lead. However, the very strong evidence of Professors D and E, and the footnote of the Doctor's Data laboratory, would indicate that this is not a reliable method of establishing a body burden of lead as there is no post-challenge reference data available against which this can be measured. Indeed, the position paper published by the American College of Medical Toxicology states,

> "*Currently, available scientific data do not provide adequate support for the use of post-challenge urine metal testing as an accurate or reliable means of identifying individuals who would derive therapeutic benefit from chelation.*"

Mr Moon submitted that, "*the essence of those articles is to extol the virtues of the post-challenge urine test and to point out the limitations of the blood lead tests. Blood lead tests were done by the authors, but it is nowhere suggested in those articles that they* ***have*** *to be done*" (Mr Moon's emphasis). The Panel has responded to Mr Moon's invitation to read all these articles carefully. That the authors do not state explicitly that BLL tests should be carried out is not to infer by default that they should ***not*** be carried out; nor is it to be inferred that LMTs alone have a sufficient diagnostic value. The Panel considers that LMTs are a contributive test and not a definitive diagnostic tool. It therefore concluded that the DMSA challenge test alone has no demonstrated benefit in the diagnosis of lead toxicity.

Given this finding, it follows that it was not in HB's best interests not to have explained to him the limited value of a DMSA challenge test alone. Similarly, it follows that it was not in HB's best interests that you did not explain this to his GP, who needed to be informed of the proposed therapy in order to advise him appropriately and treat him if necessary.

Paragraph 5(ii)

The Panel noted that you admitted paragraph 5(ii). The Panel is of the view that the fact that you did not explain to HB or his GP that the challenge test had been performed using a substantially greater dose of DMSA than was either necessary or appropriate could not have been in his best interest.

Paragraph 6(i)

In finding paragraph 10 proved in respect of paragraph 6(i), the Panel finds it axiomatic that not to advise either HB or his GP of the possible complications of chelation therapy was not in his best interests.

Paragraph 6(ii)

In finding paragraph 10 not proved in respect of paragraph 6(ii), the Panel finds that it is of no relevance to HB's welfare that this advice was not given.

Paragraph 7

The Panel could not find paragraph 10 proved in respect of paragraph 7 as there is no conduct alleged which can be regarded as not being in HB's best interests.

Paragraph 8

In finding paragraph 10 proved in respect of paragraph 8, the Panel noted that the dose administered was equiDnt to 30 mg/kg, which, according to Professor D, was substantially less than recommended for treating lead toxicity. He told the Panel that the British National Formulary recommends a dose of 80 mg/kg per day over five consecutive days. The Panel considers that, given there was no need to chelate HB it could not have been in his best interests to embark upon this therapy regardless of the low dose.

Paragraph 9(i), (ii)(a) & (b), (iii) & (iv)

Given that the Panel has found paragraph 9 proved in its entirety, it is axiomatic that your conduct was not in HB's best interests.

Having reached findings on the facts, the Panel will now invite further evidence and submissions from both Counsel as to whether, on the basis of the facts found proved, your fitness to practise is impaired by reason of your misconduct."

Determination on impaired fitness to practise

"Dr Monro:

The Panel has considered under Rule 17(2)(k) of the General Medical Council (Fitness to Practise) Rules Order of Council 2004 whether, on the basis of the facts found proved, your fitness to practise is impaired. In doing so, it has taken account of all the evidence adduced at the first stage, including your own oral evidence and all the documentary evidence. It has also considered the submissions of both Counsel.

Mr Donne, on behalf of the General Medical Council (GMC), submitted that your fitness to practise is impaired by reason of your misconduct. In respect of misconduct, he reminded the Panel that it has found proved that you,

- practised beyond your competence;
- utilised inappropriate and ineffective tests to make a diagnosis;
- recommended and conducted inappropriate and potentially harmful treatment.

Mr Donne also submitted that patient HB was placed at risk of harm in a variety of ways, including,

- side effects of unnecessary and/or inappropriate tests and treatment;
- the loss of or delay in other diagnostic opportunities; and
- the raising of hope that could not, on the evidence, have been fulfilled by the treatment provided. Although he accepted that HB experienced an amelioration of his symptoms following treatment, [this was] no doubt due to placebo (sic).

Mr Donne further submitted that damage was undoubtedly caused to the standing of the profession by the conflict that arose between HB and his "orthodox" medical advisors, Drs A, B and C, as well as by the undermining of trust in conventional diagnostic techniques.

Mr Donne submitted that you breached the following paragraphs of *Good Medical Practice* (November 2006):

- 2(b) and (c);
- 3(a), (b), (c) and (i);
- 12; and
- 14(c), (d), (e) and (f);

and, in the light of this, a finding of misconduct is inevitable and required in the public interest.

In respect of the issue of impairment, Mr Donne argued that the facts found proved, notwithstanding that they relate to a single patient, are to be considered in the context that they are representative of your practice over a considerable number of years and are reflected in the protocols of the Breakspear Clinic.

He reminded the Panel that she states, "*unequivocally that she is simply an adherent to an acceptable body of medical practice and opinion and in truth she is an adherent to a comparatively marginal and aberrant body of opinion.*" Mr Donne stated that, whilst complementary or alternative medicine is not, per se, outside accepted practice, its adherents must ensure they practise safe, evidence-based medicine that is truly in the patient's interests. He submitted, therefore, that you have no insight into your failings. He also argued that, given the views held by you which are deeply entrenched, the Panel cannot be sure that the conduct is, "*highly unlikely to be repeated*."

Furthermore, Mr Donne submitted that the level of criticism levelled against you by experts called on behalf of the GMC is of a magnitude that it requires intervention to maintain professional standards and public confidence in the profession. He concluded his submissions by reminding the Panel of Professor D's evidence that a doctor, *"must do no harm*".

Mr Moon, on your behalf, stated that, in respect of the issue of misconduct, it is only the facts which the Panel has found proved which can be considered. As to the nature of the misconduct, he directed the Panel to the cases of Meadow v GMC [2006] EWCA CIV 1390 and Calhaem v GMC [2007] EWHC 2606 (Admin). Mr Moon argued that your case concerns the treatment of one patient which was judged not to be in that patient's best interests. He submitted that it is rare that cases like this would amount to misconduct. He provided four points to support this submission:

1. that the Panel's findings relate to one patient;

2. that even on the Panel's findings, you are not a doctor who has embarked upon a course which was entirely unsupported by others; there was, he submitted, support for some of the things which you did;

3. that there is absolutely no evidence that HB was harmed. Mr Moon pointed out that all the evidence is to the effect that HB improved following treatment and suffered no ill effects following treatment. He reminded the Panel that this was treatment which HB wanted and referred the Panel to paragraph 3(d) of *Good Medical Practice* (November 2006).

4. that HB did not complain to the GMC and is a strong supporter of your treatment.

In addition to those four points, Mr Moon reminded the Panel that it has heard that Dr G was the subject of a complaint to the GMC and an allegation that his fitness to practise was impaired. Mr Moon stated that Dr G was the clinician who originally

recommended the chelation treatment and he was permitted by the GMC to take voluntary erasure. Mr Moon told the Panel that voluntary erasure is only available in cases in which the GMC considers that the doctor's conduct is not likely to give rise to a finding of impairment. Mr Moon submitted that the Case Examiners must therefore have considered that his conduct would not give rise to a finding of impairment and that this Panel may find that relevant to your case. The Panel will return to this later.

In respect of the issue of impairment, Mr Moon submitted that you have been in medical practice for over 50 years. He stated that there have been no findings of misconduct against you during this long career, which suggests that your fitness to practise is not impaired. In addition, he told the Panel that, whilst you did proceed with the chelation therapy, it is clear that you felt that you had HB's best interests at heart and there is no evidence to suggest that you acted other than in good faith.

As to the future, Mr Moon stated that, in light of the Panel's findings, you will undertake to cease pre and post challenge urine testing and will cease to provide chelation therapy.

Furthermore, Mr Moon contended that the Panel may consider that this is one of those cases in which a doctor should be given a very clear warning to comply with Good Medical Practice. He submitted that a warning, together with the Panel's findings, will satisfy the public interest.

So far as Mr Moon's submissions related to Dr G's voluntary erasure, the Panel has paid no regard to those circumstances since it has received no evidence and it considers that, in any case, such material would have been irrelevant and, therefore inadmissible. The Panel bore in mind the Legal Assessor's warning, given in his advice at the first stage, that speculation has to be avoided at all costs.

Whilst the Panel has borne in mind counsel's submissions, the decision as to whether your fitness to practise is impaired is one for it alone to reach, exercising its own judgement.

The Panel has already given a detailed determination in relation to the facts of this case and it has taken those matters into account in its finding on impairment.

Throughout its deliberations, the Panel has borne in mind that its primary responsibility is to protect the public interest. This includes not only the protection of patients, but also the maintenance of public confidence in the profession, and the declaring and upholding of proper standards of conduct and behaviour.

In determining whether your fitness to practise is impaired, the Panel applied the test referred to by Mr Smith, the Panel's Legal Assessor, as outlined by Cranston J in the case of Cheatle v GMC [2009] EWHC 645 (Admin), where at paragraph 19, he states that,

"Whatever the meaning of impairment of fitness to practise, it is clear from the design of section 35C that a panel must engage in a two-step process. First, it must decide whether there has been misconduct…Then it must go on to determine whether, as a result, fitness to practise is impaired. Thus it may be that despite a doctor having been guilty of misconduct, for example, a Fitness to Practise Panel may decide that his or her fitness to practise is not impaired."

In line with the above approach, the Panel first considered whether your actions constituted misconduct. In so doing, the Panel recognised that this case concerns the inappropriate methods used by you to diagnose and treat lead toxicity. You advised patient HB that he should embark on a programme of chelation therapy to remove lead from his body. You did not measure HB's blood lead concentration, nor refer him to a specialist in toxicology or lead poisoning nor seek the advice of the National Poisons Information Service. Further, you failed to explain to HB or his GP that the DMSA challenge test alone has no demonstrated benefit in the diagnosis of lead toxicity compared with analysis of blood lead concentration, or that the challenge test had been performed on HB using a substantially greater dose of DMSA than was either necessary or appropriate. In addition, you did not advise HB or his GP of the possible complications of chelation therapy.

The Panel has already determined that your recommendation that HB should embark on a programme of chelation therapy was made;

- despite a provoked urine sample alone not being an appropriate test upon which to base a diagnosis of lead poisoning or toxicity;

- despite you not having specialist training or expertise in clinical toxicology or in the investigation and treatment of lead poisoning;

- based on inadequate evidence; and was potentially harmful to HB. The Panel has found that your conduct in this regard was not in HB's best interests.

In determining whether your action amounts to misconduct, the Panel has considered paragraphs 2 and 3 of *Good Medical Practice* (November 2006).

Paragraph 2 states,

"*Good clinical care must include:*

…
(b) providing or arranging advice, investigations or treatment where necessary
(c) referring a patient to another practitioner, when this is in the patient's best interests."

Paragraph 3 states,

> "*In providing care you must:*
>
> *(a) recognise and work within the limits of your competence*
> *(b) prescribe drugs or treatment, including repeat prescriptions, only when you have adequate knowledge of the patient's health, and are satisfied that the drugs or treatment serve the patient's needs*
> *(c) provide effective treatments based on the best available evidence…*
> *(i) consult and take advice from colleagues, when appropriate…*"

The Panel is of the opinion that, in recommending a potentially harmful treatment to HB, you acted beyond the level of your qualifications, competence and expertise. As highlighted above, you failed to perform adequate diagnostic tests and did not advise HB or his GP of the complications of such treatment. The Panel considers that, in this respect, you have breached fundamental tenets of the profession and concludes that your errors amount to misconduct.

The Panel next considered whether, as a result of your misconduct, your fitness to practise is currently impaired. In doing so, the Panel noted paragraph 32 of Meadow, which states,

> "*In short, the purpose of [fitness to practise] proceedings is not to punish the practitioner for past misdoings but to protect the public against the acts and omissions of those who are not fit to practise. The FTPP thus looks forward not back. However, in order to form a view as to the fitness of a person to practise today, it is evident that it will have to take account of the way in which the person concerned has acted or failed to act in the past.*"

Paragraph 22 of Cheatle, which states,

> "*the context of the doctor's behaviour must be examined. In circumstances where there is misconduct at a particular time, the issue becomes whether that misconduct, in the context of the doctor's behaviour both before the misconduct and to the present time, is such as to mean that his or her fitness to practise is impaired. The doctor's misconduct at a particular time may be so egregious that, looking forward, a panel is persuaded that the doctor is simply not fit to practise medicine without restrictions, or maybe at all. On the other hand, the doctor's misconduct may be such that, seen within the context of an otherwise unblemished record, a Fitness to Practise Panel could conclude that, looking forward, his or her fitness to practise is not impaired, despite the misconduct.*"

In determining whether your fitness to practise is impaired, the Panel noted your dual role at the Breakspear Clinic; you are the Medical Director and a clinician. As such, the Panel considers that you have a duty to provide good medical care to all of your patients. When you took over the care of HB from Dr G, you had every

opportunity to review HB's case and it was your responsibility to consider whether chelation therapy was clinically indicated. However, you did not do this and without carrying out a blood lead level test, you proceeded to support an application for extra-contractual funding so that you could embark on a programme of chelation therapy.

Mr Donne's submission that it is implicit in your evidence that your conduct in regard to HB is representative of your practice in the field of heavy metal toxicity; that, "*It is not a one-off mistake, this is the way she works*", requires careful scrutiny. The GMC has produced evidence concerning only one patient on one occasion. While you have steadfastly sought to justify proceeding to undertake chelation therapy on what you have consistently maintained were adequate test results, in the absence of evidence of other patients similarly treated, the Panel is unable to extrapolate and to conclude that this is representative of your methods of your practice generally.

Another important factor to be taken into consideration about which the Panel heard evidence, was the role of the Primary Care Trust (PCT). The application for extra-contractual funding for the treatment was originally refused following tests at NHS hospitals which indicated that the blood and urine (pre and post) lead levels were all within the normal range. On appeal, however, the PCT approved the proposed treatment stating, "*due to conflicting evidence on clinical effectiveness of this particular treatment, the Panel have decided on this occasion to approve the request*." The decision by the PCT to commit NHS funding for the treatment must, therefore, mitigate to a degree any criticism that would otherwise attach to your acting beyond your competence and the other findings of facts determined by this Panel.

HB was happy with your treatment and did not support the proceedings brought against you. He did not agree that the treatment was not in his best interests.

The Panel took into account that you produced some evidence to support your views, that you have been a medical practitioner for over 50 years and there has been no adverse finding against you by your regulatory body.

Furthermore, the Panel considers that your appearing before your regulatory body would in itself have had a salutary effect upon you. It has also noted that, through Mr Moon, you have freely and unequivocally undertaken to this Panel that you will cease to carry out pre and post challenge testing of urine and will cease to provide chelation therapy. This is a factor which has played a significant part in this Panel's decision at this stage. Congruent with current authority (Cheatle), the Panel looks forward and not back.

The Panel has had regard to the wider public interest and to whether public confidence in the profession would be undermined if a finding of impairment were not made in the circumstances of this case.

The Panel does not condone your misconduct; it is on the cusp of a finding of impairment. However, the Panel determines, on balance, in the light of all the recent authorities, all the circumstances which have been drawn to its attention, and the context, there is insufficient evidence to lead to a judgement that your fitness to practise is impaired.

The Panel will now invite submissions as to whether a warning should be imposed in this case."

Determination on a Warning

"Dr Monro:

Having found that your fitness to practise is not impaired, the Panel has considered whether to impose a warning on your registration. In doing so, it has taken into account the submissions of both Counsel.

Mr Donne, on behalf of the General Medical Council (GMC), submitted that a warning would be appropriate in your case. In making this submission, he reminded the Panel that it has made a finding of misconduct; that your misconduct was on the cusp of a finding of impairment; that you have accepted that a warning would be appropriate; and that you have undertaken not to carry out urine challenge testing and chelation therapy. He also suggested that the undertaking which you offered should be expressed in the formal warning.

Mr Moon, on your behalf, accepted that a warning would be appropriate.

In making its decision, the Panel has given detailed consideration to the GMC's Guidance on Warnings. Consistent with that guidance, it has applied the principle of proportionality.

Paragraph 11 of the guidance is particularly relevant:

> "*Warnings allow the GMC to indicate to a doctor that any given conduct, practice or behaviour represents a departure from the standards expected of members of the profession and should not be repeated. They are a formal response from the GMC in the interests of maintaining good professional standards and public confidence in doctors…*"

The Panel's earlier determination makes clear that you breached fundamental tenets of the profession and *Good Medical Practice*. Whilst it has determined that your fitness to practise is not impaired, it did consider that your misconduct is on the cusp of a finding of impairment. The Panel also noted that you have accepted that a warning would be appropriate in the circumstances. It has further considered your previous good history and the fact that you have undertaken not to carry out pre and post urine challenge testing and chelation therapy.

In deciding whether to issue a warning, the Panel has balanced your interests with the public interest and concluded that the need to uphold and declare standards of conduct and behaviour and to maintain public confidence in the profession outweighs your own interests.

The Panel considers that the public interest would not be served if it concluded your case without the imposition of a warning. In all the circumstances, the Panel has determined that it is appropriate and proportionate to impose a formal warning as follows:

"Dr Monro

In April 2009, you advised HB that he should embark on a programme of chelation therapy to remove lead from his body. You did not measure HB's blood lead concentration, refer him to a specialist in toxicology or lead poisoning or seek the advice of the National Poisons Information Service. Further, you did not explain to HB or his GP that the DMSA challenge test alone has no demonstrated benefit in the diagnosis of lead toxicity compared with analysis of HB's blood lead concentration or that the challenge test had been performed using a substantially greater dose of DMSA than was either necessary or appropriate. In addition, you did not advise HB or his GP of the possible complications from chelation therapy. Your recommendation that HB should embark on a programme of chelation therapy was made despite a provoked urine sample alone not being an appropriate test upon which to base a diagnosis of lead poisoning or toxicity; made despite your not having specialist training or expertise in clinical toxicology or in the investigation and treatment of lead poisoning; based on inadequate evidence; and potentially harmful to HB. The Panel has found that your conduct in this regard was not in HB's best interests.

This conduct and behaviour does not meet the standards required of a registered medical practitioner and breaches provisions of *Good Medical Practice*. It is misconduct which undermines the public's confidence in the profession and risks bringing the profession into disrepute. The required standards are set out in *Good Medical Practice* (November 2006), namely, paragraphs 2 and 3. Whilst this misconduct in itself is not so serious as to require any restriction on your registration, it is necessary in response to issue this formal warning.

Further, you must not carry out any procedures which are inconsistent with the unequivocal guarantee that you have publicly given to this Panel, namely pre and post urine challenge testing and chelation therapy. Failure to comply with your guarantee may be regarded in its own right as giving rise to an allegation of further misconduct."

This warning will be published on the List of Registered Medical Practitioners (LRMP) for a period of five years and will be disclosed to any person enquiring about your fitness to practise history. After five years, the warning will cease to be published on LRMP. It will however be kept on record and disclosed to employers on request.

That concludes this case."

Confirmed

Date: Chairman: Ms Evis Samupfonda