FITNESS TO PRACTISE PANEL
11 JANUARY – 5 MARCH 2010
27 MARCH 2010; 10-11 APRIL 2010
6 – 10 & 27 – 29 SEPTEMBER 2010
Regent's Place, 350 Euston Road, London, NW1 3JN

Name of Respondent Doctor:	Dr Robert Theodore Henri Kees TROSSEL
Registered Qualifications:	Artsexamen 1980 Universiteit te Leiden
Registration Number:	6049460
Type of Case:	New case of impairment by reason of: misconduct; caution and conviction
Panel Members:	Professor B Gomes da Costa, Chairman (Lay) Mrs M Bamford (Lay) Dr S Pande (Medical) Mrs S Pond (Lay) Ms E Tessler (Lay)
Legal Assessor:	Mr R Hay (Days 1 – 41 & 47 - 49) Mr D Mason (Days 42 - 46)
Secretary to the Panel:	Ms J Hazell (Days 1 to 46) Mr A Elliott (Days 47 – 49)

Representation:
GMC: Mr Tom Kark, Counsel, instructed by Field Fisher Waterhouse, represented the General Medical Council.

Doctor: Dr Trossel was present and was represented by Mr Robert Jay, QC, instructed by Eastwoods Solicitors.

ALLEGATION

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

1. At all material times you were a medical practitioner with consulting rooms at 57a New Cavendish Street, London, 15a Wimpole St, London and in Rotterdam, Holland;
Amended to read: At all material times you were a medical practitioner with consulting rooms at 57a Wimpole St, London and in Rotterdam, Holland;
Admitted as amended and found proved.

Patient A

2. On or about ~~17~~ **10** August 2004 you had a consultation in Rotterdam with Patient A,
Admitted, as amended, and found proved

i. Patient A suffered from Secondary Progressive Multiple Sclerosis (MS),
Admitted and found proved

ii. During the consultation you purported to inject a substance said to contain stem cells into Patient A,
Admitted and found proved

iii. Your actions in paragraph ii. above were,

a. Unjustifiable on the basis of the available scientific or clinical medical evidence,
Found proved

b. Inappropriate,
Found proved

c. Not in the best interests of the patient,
Found proved

d. Exploitative of a vulnerable patient;
Found proved

Patient B

3. In January 2006 you met at your consulting rooms Patient B (a journalist) purportedly for a consultation in relation to his suffering from Hodgkins' Disease,
Admitted and found proved

i. He gave you a history consistent with a diagnosis of Hodgkins' disease in 2004, followed by a course of chemotherapy and remission. He also described how a recent scan had shown that the disease had returned to his liver;
Admitted and found proved.

4. During the consultation you did not,

i. Question the patient appropriately about his past medical history,
Found proved

ii. Question the patient appropriately about his current symptoms,
Found not proved

iii. Perform a physical examination,
Found proved

iv. Undertake an adequate assessment of the case before giving the patient advice;
Found proved

5. During the consultation you made the following assertions,

i. That chemotherapy would be an ineffective treatment for the patient's tumours,
Found not proved

ii. That there were benefits to the use of 'Vitamin B17 (Laetrile)' both intravenously and orally in the patient's circumstances,
Found not proved

iii. That there was 'a good chance' that 'Aqua Tilis Therapy' would be an effective remedy for the patient's illness,
Admitted and found proved.

iv. That 'Aqua Tilis Therapy' had cured people with cancer such as that suffered by the patient,
Admitted and found proved.

v. That the inventor of the MRI (Magnetic Resonance Imaging) machine had made a 'therapeutic' MRI machine;
Admitted and found proved.

6. Your statements as set out at 5.i., ii., iii., iv. and v. were,

i. False,
Found proved in relation to 5iii., 5iv. and 5v

ii. Misleading,
Found proved in relation to 5iii., 5iv. and 5v

iii. Dishonest,
Found not proved in relation to 5iii., 5iv. and 5v

iv. And in respect of the statements set out at 5.i., ii., iii. and iv. unjustifiable on the basis of the available scientific or clinical medical evidence;
Found proved in relation to 5iii and 5iv.

7. You did not contact other health professionals purportedly undertaking the care of the patient either during or following your consultation. This was unprofessional; **Amended to read:**

7a. You did not contact other health professionals purportedly undertaking the care of the patient either during or following your consultation.
Admitted and found proved

7b. This was unprofessional;
Found not proved

Patient C

8. On or about 12 January 2006 you had a consultation in Rotterdam with Patient C,
Admitted and found proved

i. Patient C suffered from Secondary Progressive Multiple Sclerosis (MS), **Admitted and found proved**

a. During the consultation you,

i. Purported to inject a substance said to contain stem cells into Patient C,
Admitted and found proved

ii. Advised that he undergo 'Aqua Tilis' Treatment,
Admitted and found proved

b. Your actions in paragraph a. above were,

i. Unjustifiable on the basis of the available scientific or clinical medical evidence,
Found proved

ii. Inappropriate,
Found proved

iii. Not in the best interests of the patient,
Found proved

iv. Exploitative of a vulnerable patient;
Found proved

Patient D

9. On or about 16 February 2006 you had a consultation in Rotterdam with Patient D,

Admitted and found proved.

i. Patient D suffered from Multiple Sclerosis (MS),
Admitted and found proved.

ii. During the consultation you,

a. Purported to inject a substance said to contain stem cells into Patient D,
Admitted and found proved.

b. Advised that he undergo 'Aqua Tilis' Treatment,
Admitted and found proved.

iii. Your actions in paragraph 9.ii. above were,

a. Unjustifiable on the basis of the available scientific or clinical medical evidence,
Found proved

b. Inappropriate,
Found proved

c. Not in the best interests of the patient,
Found proved

d. Exploitative of a vulnerable patient;
Found proved

Patient E

10. On or about 10 May 2006 you had a consultation in Rotterdam with Patient E,

i. Patient E suffered from Secondary Progressive Multiple Sclerosis (MS),
Admitted and found proved

ii. During the consultation you purported to inject a substance said to contain stem cells into Patient E;
Found not proved

11. Your actions in paragraph 10.ii. above were,

a. Unjustifiable on the basis of the available scientific or clinical medical evidence,
Found not proved

b. Inappropriate,
Found not proved

c. Not in the best interests of the patient,
Found not proved

d. Exploitative of a vulnerable patient;
Found not proved

Patient F

12. On 16 May 2006 Patient F attended a consultation with you at your consulting rooms at 15a Wimpole St, London,
Amended to read: On 16 May 2006 Patient F attended a consultation with you at your consulting rooms at **57a** Wimpole St, London,
Admitted, as amended, and found proved

i. Patient F suffered from Multiple Sclerosis,
Admitted and found proved

ii. During the consultation you recommended electromagnetic therapy followed by stem cell therapy to take place in Holland;
Found proved

13. Your recommendations as set out in paragraph 12.ii. above were,

i. Unjustifiable on the basis of the available scientific or clinical medical evidence,
Found proved

ii. Inappropriate,
Found proved

iii. Not in the best interests of the patient,
Found proved

iv. Exploitative of a vulnerable patient;
Found proved

14. Following the consultation you sent Patient F a letter dated 19 May 2006 together with other literature in which the following claims were made,
Admitted and found proved

i. That 600 patients had been treated with Stem Cell Therapy of whom 75% had reported some degree of improvement,
Admitted and found proved

ii. That the PMC clinic had treated 60 people with MS in 2005 and that as a result of their treatment 10% were out of their wheelchair and 80% had received a significant improvement to their health,
Admitted and found proved

iii. That you personally had treated "approximately 120 patients over the last year and a half of which half had MS and 10% were now walking out of a wheelchair. Another 80% have had had a 'proven significant clinical benefit",
Admitted and found proved

iv. That Assaidi Aqua Tilis Therapy had caused the improvement or complete removal of the symptoms of 'many patients',
Admitted and found proved

v. That the following diseases (among others) were treatable effectively with Core Blood Stem Cell Therapy: heart disease, stroke, Alzheimer's, and other neurological diseases like MS, ALS and spinal cord lesions as well as a number of other serious conditions and diseases,
Found proved

vi. That you had achieved 'spectacular results' with core blood stem cell treatments;
Admitted and found proved

15. The claims made in your letter and in the accompanying literature provided by you,

i. Exaggerated the benefits of the treatment proposed for Patient F,
Found proved

ii. Were unsupported by scientific or substantial clinical evidence,
Found proved

iii. Were misleading,
Found proved

iv. Were dishonest,
Found not proved

v. Exploited the patient's vulnerability,
Found proved

vi. Failed to warn the patient of the potential risks of stem cell therapy;
Found proved

Patient G

16. On or about 30 May 2006 you had a consultation in Rotterdam with Patient G,

i. Patient G suffered from Secondary Progressive Multiple Sclerosis (MS),
Admitted and found proved

ii. During the consultation you purported to inject a substance said to contain stem cells into Patient G;
Found not proved

17. Your actions as set out in paragraph 16.ii. above were,

i. Unjustifiable on the basis of the available scientific or clinical medical evidence,
Found not proved

ii. Inappropriate,
Found not proved

iii. Not in the best interests of the patient,
Found not proved

iv. Exploitative of a vulnerable patient;
Found not proved

Patient H

18. Patient H attended your clinic in Rotterdam on 7 August 2006 where you injected her with a substance which you claimed to be 'placenta injection',
Admitted and found proved.

i. Patient H suffered from Primary Progressive Multiple Sclerosis (MS),
Admitted and found proved

ii. You claimed that this injection would increase the effectiveness of the stem cell therapy you intended to give her,
Found not proved

iii. On 8 August Patient H again attended your clinic where you arranged for her to have an infusion of what you claimed to be vitamin C in order purportedly to 'flush out' a bladder infection,
Admitted and found proved

iv. You then purported to inject a substance said to contain stem cells into Patient H; **Admitted and found proved**

19. Your claims and actions as set out in paragraph 18. above were,

i. Unjustifiable on the basis of the available scientific evidence,

Found proved in relation to 18(iii) and (iv)

ii. Inappropriate,
Found proved in relation to 18(iii) and (iv)

iii. Not in the best interests of the patient,
Found proved in relation to 18(iii) and (iv)

iv. Exploitative of a vulnerable patient;
Found proved in relation to 18(iii) and (iv)

Patient I

20. Patient I suffered from Secondary Progressive Multiple Sclerosis (MS),
Admitted and found proved.

i. Patient I attended your clinic on 7 August 2006 where she was, within your knowledge, injected with a substance which you had previously claimed to be a 'placenta injection',
Admitted and found proved

ii. You claimed that this injection would increase the effectiveness of the stem cell therapy you intended to give her,
Found not proved

iii. On 8 August Patient I again attended your clinic where you arranged for her to have an infusion of what was claimed to be
vitamin B,
Found not proved

iv. You then purported to inject a substance said to contain stem cells into Patient I;
Found proved

21. Your claims and actions as set out in paragraph 20. above were,

i. Unjustifiable on the basis of the available scientific or clinical medical evidence,
Found proved in relation to 20(i) and (iv)

ii. Inappropriate,
Found proved in relation to 20(i) and (iv)

iii. Not in the best interests of the patient,
Found proved in relation to 20(i) and (iv)

iv. Exploitative of a vulnerable patient;
Found proved in relation to 20(i) and (iv)

Patient J

22. Patient J suffered from Secondary Progressive Multiple Sclerosis (MS),
Admitted and found proved

i. In about July/August 2006 approximately 12,500 Euro were paid on Patient J's behalf to PMC Clinic of which you were a Director in respect of proposed stem cell treatment to be provided by you in Rotterdam,
Found not proved

ii. On 4 September 2006 you had a consultation at your clinic in Rotterdam with Patient J, and her husband and daughter in relation to the stem cell treatment which had previously been offered,
Found proved

iii. During the consultation you gave assurances about the safety and efficacy of the stem cells you had intended to use,
Found proved

iv. On request you provided to Patient J a Certificate of Analysis in respect of the stem cells you had intended to use in her treatment. The certificate of analysis stated that the cells were not intended for use in humans;
Admitted and found proved

23. Your offer of treatment by means of stem cell therapy was,

i. Unjustifiable on the basis of the available scientific or clinical medical evidence,
Found proved

ii. Inappropriate,
Found proved

iii. Not in the best interests of the patient,
Found proved

iv. Exploitative of a vulnerable patient;
Found proved

24. In respect of each patient A, B, C, D, E, F, G, H, I, and/or J in offering to treat the patient by stem cell therapy in the manner proposed, you,

i. Failed to make the care of the patient your first concern,
Found proved in relation to patients A, C, D, F, H, I and J

ii. Failed to respect the rights of the patient to be fully involved in the decision about their care,
Found proved in relation to patients A, C, D, F, H, I and J

iii. Abused your position as a doctor;
Found proved in relation to patients A, C, D, F, H, I and J

25. You injected the following patients with RNA material manufactured by Regeneresen, which you knew to contain Bovine Brain and Spinal Cord live cells and prior to doing so you failed to obtain informed consent: Patient C, Patient D, Patient H and Patient I.
Found proved

Police Caution

26. i. On 26 June 2007 at Stansted Airport in Essex you committed the offence of making off without payment for a service contrary to Section 3(1) and 4 of The Theft Act 1978,
Admitted and found proved

ii. On 16 August 2007 you were formally cautioned by the police for the offence and you admitted your guilt and agreed to repay £472.50 to NCP Car Parks,
Admitted and found proved

iii. You failed to notify the GMC of the police caution;
Admitted and found proved

Conviction

27. On 17 February 2009 you were convicted in the Court of First Instance of the Court District of Antwerp of the following offences taking place between 9 October 2006 and 26 January 2007,
Admitted and found proved

i. Failing to comply with the statutory provision that every removal and transplant of tissues, cells and organs must be carried out by a physician at a hospital as laid down by the Belgian Hospital Act of 23 December 1963 by removing or transplanting stem cells at a place which was not a recognised Hospital,
Admitted and found proved

ii. The illegal practice of medicine in Belgium by assisting Mr Q who failed appropriately to notify the Ministry of Public Health in Belgium of his intention to perform medical services namely the carrying out of stem cell treatments;
Admitted and found proved

28. And upon your conviction you were sentenced as follows,

i. Five months imprisonment which was suspended for three years,
Admitted and found proved

ii. A fine of four thousand Euros;'
Admitted and found proved

And that by reason of the matters set out above your fitness to practise is impaired because of your misconduct, caution and conviction.
Found proved in relation to misconduct and caution
Found not proved in relation to conviction

DETERMINATION ON FINDINGS OF FACTS (HANDED DOWN ON 11 APRIL 2010)

1. This is a resumed hearing of Dr Trossel's case, which began on 11 January 2010, and was adjourned on 5 March 2010.

2. At the outset of the hearing on 11 January 2010 Mr Robert Jay, QC, made the following admissions on Dr Trossel's behalf and the Panel found them proved:

   Paragraphs 1(as amended); the stem of 3; 3(i); 5(iii), (iv) and (v); 7(a)(as amended); the stem of 8; 8(i); 8(i)(a)(ii); the stem of 9; 9(i); 9(ii)(a) and (b); 10(i); the stem of 12 (as amended); 12(i); the stem of 14; 14(i), (ii), (iii), (iv) and (vi); 16(i); the stem of 18 (as amended); 18(i), (iii) and (iv); the stem of 20 and 20(i); the stem of 22 and 22(iv); 25; 26 and 27 in their entireties.

3. During the course of the hearing the Panel acceded to an unopposed application made by Mr Tom Kark, QC, on behalf of the General Medical Council (GMC), under Rule 17(3) of the General Medical Council (Fitness to Practise) Rules Order of Council 2004, that the date in the stem of paragraph 2 be amended to read "10 August 2004". It also acceded to an application made by Mr Kark under the same Rule to include an additional charge (number 25) as follows:

   "25. You injected the following patients with RNA material manufactured by Regeneresen, which you knew to contain Bovine Brain and Spinal Cord live cells and prior to doing so you failed to obtain informed consent: Patient C, Patient D, Patient H and Patient I."

4. As a consequence of this amendment, the original paragraphs 25 to 27 were renumbered to 26, 27 and 28.

5. In the course of the hearing Mr Jay made further admissions on behalf of Dr Trossel , which were as follows: the stem of paragraph 2 (as amended); paragraphs 2(i), 2(ii) and 8(i)(a)(i). Accordingly, the Panel found them proved.

6. During the course of closing submissions, the Panel, of its own motion, under Rule 17(3) amended paragraph 19(i) to include the words “or clinical medical” after the word “scientific” so as to make the wording consistent throughout.

7. In determining the outstanding paragraphs of the allegation, the Panel has considered all of the evidence adduced in this case and has had regard to the submissions made by Mr Kark and those made by Mr Jay.

8. The Panel has borne in mind that the burden of proof rests on the GMC and that the civil standard of proof applies, that is to say, proof on the balance of probabilities.

The GMC’s case

9. This case involves Dr Trossel’s treatment of nine patients at the Preventief Medisch Centrum (PMC) in Rotterdam between August 2004 and August 2006. During this period Dr Trossel was Director of the PMC. The Panel has heard that these patients suffered from Secondary Progressive Multiple Sclerosis (MS). It is said that Dr Trossel offered stem cell therapy by injection to each of these patients and that he administered a substance said to contain stem cells to seven of them.

10. At an early stage Mr Jay had indicated that, where an allegation relating to the purported injection of stem cells had not been admitted, this was because Dr Trossel denied giving the injections.

11. Mr Kark, in his final submissions, did not contend that the injections were of substances other than stem cells.

12. In the cases of two of the patients, Dr Trossel advised that they also undergo Aqua Tilis Therapy (‘Aqua Tilis’).

13. The GMC’s case is that Dr Trossel’s actions in offering stem cell therapy and/or Aqua Tilis were unjustifiable on the basis of the available scientific or clinical medical evidence, inappropriate, not in the best interests of patients and were exploitative of vulnerable patients. Further, it is said that in offering to treat patients by stem cell therapy in the manner proposed, Dr Trossel failed to make the care of patients his first concern; he failed to respect the rights of patients to be fully informed in the decision about their care and he abused his position as a doctor.

14. Patient B was a freelance journalist, undertaking an investigation into complementary and alternative therapies, offered by doctors and others treating cancer. As part of his investigation, he saw Dr Trossel at his consulting rooms in London. He posed as a patient suffering from Hodgkin’s Disease. The GMC’s case is that, in the course of the consultation, Dr Trossel made a number of assertions which were false, misleading, dishonest and unjustifiable on the basis of the available scientific or clinical medical evidence. It is further said that Dr Trossel did not contact other health

professionals purportedly undertaking the care of Patient B either during or following the consultation, and that this was unprofessional.

Applicable standard of conduct

15. Mr Jay conceded that this Panel has jurisdiction in this case by virtue of the fact that Dr Trossel was, and still is, registered with the GMC. However, he contends that what he describes as the 'Dutch dimension' should be taken into account, given that the treatment was administered in the Netherlands. Mr Jay submits that standards of professional conduct in the Netherlands may be different from those applicable in the UK. In particular, he says that, at the relevant time, stem cell treatment was not unlawful in the Netherlands, although it was so in the UK, unless licensed.

16. Mr Kark has submitted that the standards of conduct are those applicable to a doctor registered with the GMC. The Panel has been referred to the case of *R on the application of the Singapore Medical Council v General Medical Council and Shorvon 2006 EWHC 3277.* The Panel has concluded that UK registered Doctors, wherever they carry out their duties, must conform to the standards required by the GMC; these are set out in the publication "Good Medical Practice" and are not subject to qualification.

Expert evidence

17. The GMC called two experts in this case - Professor L and Dr M. Although no expert witnesses have been called on behalf of Dr Trossel, the Panel has in mind that Dr Trossel does not have to prove anything.

18. The Panel heard substantial evidence from Professor L, who described the nature of MS; information regarding the nature of autoimmunity; a summary of the available evidence regarding the relationship between dental amalgam and MS; a summary of the current status of stem cells as a potential therapy for MS and an analysis of the information on Dr Trossel's treatment of the nine patients with MS. He also gave his opinion as to whether Dr Trossel's offer of treatment by means of stem cell therapy for each of these patients was justifiable on the basis of the available scientific or clinical medical evidence. In addition, Professor L gave evidence in relation to Aqua Tilis.

19. Professor L is a Consultant Neurologist and is an acknowledged international authority on MS. He has been treating patients with MS for over 30 years and has been actively involved in research relating directly to MS since 1975. He has published some 650 original or review articles on MS. He leads a Medical Research Council funded clinical trial, testing stem cell therapy on MS patients using cells derived from autologous bone marrow transplantation. Although Professor L is not an expert in the pure science of stem cells, he has wide experience in the field of MS and the current research in associated therapies and trials.

20. The Panel finds the evidence given by Professor L to be authoritative and cogent.

21. Dr M is a principal in general practice and a part time NHS homeopathic consultant physician, with a general interest in complementary medicine. In his general practice, he has treated a number of patients suffering from Hodgkin's Disease. Dr M's evidence related specifically to Dr Trossel's consultation with Patient B, Vitamin B17 (Laetrile), Hodgkin's Disease and Aqua Tilis. The Panel found his evidence to be cogent.

22. Dr Trossel accepted that he has no background in neurology or haematology and that he was not an expert in stem cell research. However, he pointed to his extensive experience in the Netherlands of live cell therapy. He further accepted that he had had no involvement with stem cell therapy until the early 2000s, when he was introduced to this form of "treatment" by S V R and L B, the directors of the US-based company BioMark, a commercial supplier of stem cells. In 2004 Biomark was renamed Advanced Cell Therapeutics (ACT). ACT remained under the control of S V R and L B, neither of whom were medical practitioners. The only medically qualified member of ACT's management team was Dr V, a General Practitioner. She had qualified as recently as 2001. Dr Trossel accepted that Dr V was not a leader in the field of stem cell research, although she appeared to him to be "very knowledgeable".

Stem cell therapy - unjustifiable on the basis of the scientific or clinical medical evidence

23. In his evidence Professor L maintained that there was no scientific basis or evidence for the use of umbilical cord stem cells in patients with secondary progressive MS. He was well acquainted with the scientific and clinical medical literature relating to the use of stem cells and to the treatment of MS. He had been unable to find any published material evaluating clinical trials of the use of umbilical cord stem cells in this context. Further, in respect of allogeneic stem cells (stem cells from a donor, which Dr Trossel was injecting into patients), Professor L knew of no studies which had shown efficacy and/or safety for this as a treatment for MS. He considered that the rationale for the treatment Dr Trossel used was without foundation for the following reasons:-

- There is no convincing evidence that human umbilical cord stem cells injected subcutaneously or intravenously into a random patient without any attempt at matching donor and recipient will survive in numbers sufficient to achieve clinical efficacy. Many cells do not survive and also if not matched, could be subject to immune rejection and therefore even less likely to survive.

- There is no evidence that human umbilical cord stem cells delivered to a remote site can reach the brain and spinal cord.

- There is no logic to the suggestion that human umbilical cord stem cells, injected into an MS patient subcutaneously over the site of an assumed area of tissue damage are preferentially able to access the

adjacent lesion by comparison with cells injected at a remote location or intravenously.

- There is no evidence in humans that umbilical cord stem cells, however delivered, reach the lesions of MS and influence clinical features of the disease.

- There is no evidence from adequate clinical trials in humans that umbilical cord stem cells, however delivered, affect the pathological processes involved in causing local tissue damage in MS.

- There is no evidence that unstimulated stem cells, however delivered, and of whatever origin, differentiate into neurones, astrocytes and oligodendrocytes; and integrate with surviving tissue in sufficient numbers required to repair or re-myelinate the brain and spinal cord in chronic progressive MS.

- There are no reported clinical trials or persuasive evidence that any such treatment yet makes a significant impact on the level of disability or course of advanced secondary MS.

- There was some published theoretical scientific research on animals. In particular, reference was made to the Pluchino papers (2003 and 2005). These concerned laboratory experiments on mice. Professor L commented also that the work of Pluchino and his associates related in principle to animals in the relapsing remitting stage of MS. It was, therefore, not relevant at the secondary progressive stage of the disease and in any event it was not applicable to the treatment of MS in humans. In short, these experiments on mice fell far short of the necessary scientific or medical basis for embarking on allogeneic stem cell treatment on MS in humans.

24. Professor L concluded that there was no evidence of efficacy, or indeed safety, upon which any responsible medical practitioner could rely in embarking on allogeneic stem cell treatment in MS patients in 2004, 2005 and/or 2006, the dates specified in the allegation.

25. Professor L accepted that these conclusions were subject to one important caveat. This was in relation to what he described as the “medical pioneer”. He pointed out, that at some stage, the pioneer had to take a first step; that it was not irresponsible to do so; but in doing so, he must take it from a position of “considerable caution”. Further, that he is in a position of special responsibility, acting as he does beyond the boundaries of current knowledge.

26. There were a number of over-riding criteria and obligations for a medical pioneer. Before undertaking a pioneering procedure, he must inform himself of the relevant scientific background; his knowledge would need to be at a level greater than that expected of a general medical practitioner and he must ensure that a proper infrastructure is in place to facilitate follow up. Further, he

must be clear in his explanation to the patient of the procedure to ensure that he obtains a truly informed consent. There is a duty to explain fully, and perhaps more than once, the nature of the treatment and the scientific and clinical medical evidence upon which it is based.

27. Professor L's evidence was that the medical pioneer is in a very privileged position, which carries significant responsibilities. For a clinical trial, it would be necessary for any responsible practitioner to carry out a physical assessment of the patient, pre and post-treatment. The Panel finds that it would be most unusual in any pioneering treatment involving MS patients for there not to be a physical examination of the patient at the beginning and at intervals throughout the course of the treatment. Further, it would be necessary for the follow up to be for a minimum period of six months; indeed, a longer period would usually be more appropriate. Professor L's own practice in his experimental work is to evaluate the patient for a period of two to five years following treatment.

28. The Panel finds that Dr Trossel did not have the necessary knowledge of the science and the research background to stem cell therapy upon which to embark on such treatment. By his own admission, he was neither an expert in stem cell therapy nor did he have the appropriate specialist knowledge in neurology. Dr Trossel's basis for proceeding was informed by anecdotal and aspirational information, including scientific research that had been carried out only on animals. In regard to the use of stem cell therapy on patients, Dr Trossel relied on telephone conversations with S V R, L B and Dr V. Dr Trossel's evidence was that in the light of these conversations there was "no reason not to give [stem cell therapy] a try". The Panel finds this explanation to be inadequate and unacceptable.

29. The nature of the follow-up work described by Dr Trossel was wholly unsatisfactory. In particular, there was no post-treatment physical examination of UK patients, save for observation during the hour immediately subsequent to treatment; Dr Trossel relied solely on the patients' subjective impressions given over the telephone, in many instances, to persons other than a qualified medical practitioner; some enquiries were made once only; others were made at intervals, over a maximum period of some 18 months. The follow-up procedure was inconsistent and inadequate. Moreover, the scoring system on which Dr Trossel's follow-up was predicated was statistically flawed and was fundamentally unsound.

30. The Panel is satisfied, in the light of Dr Trossel's description of his practice, that this follow-up did not produce data which yielded valid and reliable clinical medical evidence.

31. Further, the Panel finds that the number of cells Dr Trossel injected into patients was inadequate. They were far fewer in number than Professor L considered necessary to have any positive therapeutic effect, whatever their quality. In this context, one sample of stem cells was submitted for analysis by Dr Trossel to Dr X. He held a PhD in neuroscience and was the Director of an

independent research establishment. The cells in the sample were found to be viable and of good quality, with no contamination. However, the Panel finds this to be of no relevance to the allegation.

Aqua Tilis (aka "electromagnetic therapy")

32. The transcript of Dr Trossel's consultation with Patient B records that he described Aqua Tilis as treatment in a steam room involving a "therapeutic MRI machine". Dr Trossel stated that this therapy had been developed by Mr Ei, whom he described as "the inventor of the diagnostic MRI machine".

33. In May 2006 Dr Trossel sent to Patient F publicity material in which it was said that: "Aqua Tilis is an electromagnetic frequency, for the direct repair, growth and stimulation of nerve cells… The patient is surrounded by a specific water vapour called Aqua Tilis. It enters the body through the skin pores … Heart rate and blood pressure are under constant control… The "Ei" Aqua Tilis therapy stops the progression of a number of diseases … it removes damaged cells and causes to replace(sic) them by new cells. ... Positive effects have also been observed with diseases such as multiple sclerosis. In several types of cancer … definitely positive effects were seen… Many patients whose clinical symptoms either improved or disappeared (among which a number of cases without recovery prospects) prove the validity of the concept and the efficacy of this therapeutic technology."

34. Dr M's evidence was that, prior to this case, he had never heard of Aqua Tilis. Furthermore, although he had commissioned a formal search of the literature by a specialist librarian, no published evidence about Aqua Tilis had been found. Moreover, there is no published evidence to support Dr Trossel's assertion that Aqua Tilis can cure cancer. He was sceptical about Dr Trossel's notion that the therapy could "peel off the cancer cells".

35. Professor L's evidence was that prior to this case he, too, had never heard of Aqua Tilis. He was not aware of any literature on the subject and, as a specialist in MS, he thought it improbable that, had there been any, he would have missed it. He did not agree with Dr Trossel's assertion, expressed to Patient D, that Aqua Tilis could dissolve sclerotic plaque.

36. The evidence of both experts was that MRI is a purely diagnostic, not a therapeutic procedure.

37. In the light of the experts' evidence, the Panel finds that Aqua Tilis has no scientific or clinical medical justification in the treatment of MS and/or Hodgkin's Disease.

The Patients

38. The Panel has found that Dr Trossel's treatment and/or offers of stem cell therapy and/or Aqua Tilis lacked the necessary scientific and clinical medical justification. It therefore follows that such treatment or offers of treatment can be neither appropriate nor in the best interests of the patient.

39. The Panel finds that the patients (other than Patient B, the investigative journalist) were suffering from incurable conditions which were serious, deteriorating and life changing. They were desperate to find some relief for their disease and were prepared to raise large sums of money in the hope that the treatment offered would alleviate their symptoms. The Panel therefore finds these patients to be vulnerable.

40. The Legal Assessor's advice was that the meaning of the verb "to exploit" is to take advantage of a person unfairly and, in the context of this case, that this was tantamount to an allegation of dishonesty. However, in this case, the Panel concludes that there may be exploitation without dishonesty. In deciding whether Dr Trossel was dishonest, the Panel has considered his state of mind at the time, taking into account his evidence about what he did and why he did it, and his actual belief at the time. In the light of this, the Panel has found that his actions were not dishonest.

41. Dr X, in his evidence, described the positive effect of stem cell therapy on one patient of his close acquaintance. Notwithstanding this positive outcome, the Panel has found that there was scant, if any, prospect of alleviation of the patients' MS symptoms by stem cell therapy and/or Aqua Tilis. The Panel has therefore concluded that, by his claims and/or actions, although not acting dishonestly, Dr Trossel, was taking unfair advantage of vulnerable patients and was therefore exploitative of them.

Patient A

42. Paragraph 2(iii)(a) has been found proved.
The Panel's reasons for this are set out above in the section entitled "Stem cell therapy …"**.**
Paragraphs 2(iii)(b), (c) and (d) have been found proved for the reasons set out above in the section entitled "The Patients".

Patient B

43. Paragraph 4(i) has been found proved.
Although there were some inconsistencies in Patient B's evidence, the Panel found him to be a largely credible witness. The Panel is satisfied that Dr Trossel did not question him appropriately about his past medical history. Dr Trossel should have asked him questions about that, given that this was the first consultation. Dr Trossel's evidence was that he understood that Patient B had had chemotherapy treatment at a polyclinic, which explained why Patient B had written "No" under the heading "hospital admissions" on the form he had completed in respect of his history. However, Dr Trossel had not recorded this explanation in Patient B's notes. The Panel did not find Dr Trossel's evidence on this point to be credible.

44. Paragraph 4(ii) has been found not proved.
The Panel has reached its decision in the light of Dr Trossel's notes of the consultation, which list the patient's then current symptoms.

45. Paragraph 4(iii) has been found proved.
The Panel has found that Dr Trossel did not carry out a physical examination, although he felt Patient B's wrists. In broad terms Dr Trossel's evidence was that he attempted to examine Patient B but that he did not get very far because Patient B was "off-standish", albeit there is no record in the patient's notes to that effect.

46. Paragraph 4(iv) has been found proved.
Dr M emphasised the importance of examining the patient to establish a "baseline" to assess the progression of the disease and to find out if there was anything else wrong before giving advice to the patient. The Panel finds that before advising Patient B, Dr Trossel should have seen his MRI scan, his medical records, or a report from his treating consultant. Dr Trossel suggested a blood test, which Patient B declined. That test alone, without further supporting evidence, would have been an insufficient basis on which to give advice to the patient.

47. Paragraph 5(i) has been found not proved.
The transcript of the consultation with Patient B records Dr Trossel as saying: "The total group of people diagnosed with Hodgkin's – there is a 50/50 chance, so the other 50% they are obviously not so responsive to chemotherapy… and 10 per cent is still … have the option to choose … per cent chance. It is always your choice." Patient B understood this to mean that there was about a 10% prospect of a successful response to chemotherapy. Dr M offered a similar interpretation.

48. Paragraph 5(ii) has been found not proved
Although in Patient B's newspaper article there is reference to Vitamin B17 (Laetrile), this does not appear in the transcript of the consultation. The evidence of both Dr Trossel and Patient B was that the topic of Vitamin B17 had been raised by Patient B after the recording had ended. The Panel has accepted Dr Trossel's evidence that he advised Patient B that he had not given Vitamin B17 intravenously to patients and that he would need to look into it.

49. Paragraphs 6(i) and 6(ii) have been found proved in relation to 5(iii), 5(iv) and 5(v) in that the statements were false and misleading.
The Panel has interpreted the word "false" to mean that the statement is not true, even though the person asserting it believes it to be so. It has interpreted the word "misleading" to mean that a person may be misled if a statement is untrue, even though the person asserting it believes it to be true.

50. In respect of 5(v), it is a matter of record that Mr Ei was not the inventor of the MRI machine; Sir P M and Dr L are credited with this.

51. Paragraph 6(iii) has been found not proved in relation to 5(iii), 5(iv) and 5(v).
The Panel has found that the statements Dr Trossel made were false and misleading. However, it is not satisfied that when Dr Trossel made the

statements, he realised them to be untrue. Therefore, the Panel is not satisfied that Dr Trossel was acting dishonestly.

52. Paragraph 6(iv) has been found proved in relation to 5(iii) and 5(iv).
The Panel's reasons for this are set out above in the section entitled 'Aqua Tilis.'

53. Paragraph 7(b) has been found not proved.
Patient B accepted that he did not provide Dr Trossel with the details of his GP or oncologist. Further, that he told Dr Trossel that he was going away to think about the treatment recommended. The Panel has also heard that a sticker placed over Patient B's notes was a reminder to Dr Trossel's secretary to chase this matter up. The Panel therefore does not find it unprofessional that Dr Trossel did not contact other health professionals purportedly undertaking the care of Mr Patient B either during, or following, the consultation.

Patient C

54. Paragraph 8b in its entirety in relation to 8(i)(a)(i) and (ii) has been found proved.
The Panel's reasons in relation to 8(i)(a)(i) are set out above in the section entitled **"**Stem cell therapy …" and "The Patients".
The Panel's reasons in relation to 8(i)(a)(ii) are set out above in the sections entitled "Aqua Tilis…" and "The Patients".

Patient D

55. Paragraph 9(iii) in its entirety has been found proved in relation to paragraphs 9(ii)(a) and 9(b)
The Panel's reasons in relation to 9(ii)(a) are set out above in the sections entitled **"**Stem cell therapy …" and "The Patients".
The Panel's reasons in relation to 9(ii)(b) are set out above in the sections entitled "Aqua Tilis…" and "The Patients".

Patient E

56. Paragraph 10(ii) has been found not proved.
Patient E's evidence was that she was uncertain about who injected her; she agreed that it could have been a female doctor. The evidence of one of the Doctors at the clinic, Dr O, was that Patient E was her patient; that it was she, Dr O, who had completed the ACT patient report and therefore it was probable that it was she who administered the stem cells.

57. Consequent upon the Panel's finding at paragraph 10(ii), paragraph 11 in its entirety and 24 in relation to this patient have been found not proved.

Patient F

58. Paragraph 12(ii) has been found proved.
The Panel reached this decision in the light of Patient F's letter dated 27 May 2006 ("to whom it may concern"), her statement to the GMC dated 12

September 2008, which have been admitted in evidence, together with Dr Trossel's letter to her dated 19 May 2006.

59. Paragraph 13 in its entirety has been found proved.
The Panel's reasons in relation to 12(ii) are set out above in the section entitled "Aqua Tilis…" and "The Patients".

60. Paragraph 14(v) has been found proved.
The Panel finds no meaningful distinction between the wording of paragraph 14(v) and that contained in the literature sent to Patient F on 19 May 2006 under the heading "What diseases are treated with cord blood stem-cell therapy?"

61. Paragraphs 15(i) and (ii) have been found proved.
The Panel finds that Dr Trossel accepted at their face value and without further investigation the claims made on the ACT website and those made by Dr V. It further finds that the repetition of such claims by Dr Trossel constituted unjustifiable exaggeration, since they were unsupported by scientific or clinical medical evidence.

62. Paragraph 15(iii) has been found proved.
The Panel has adopted the same meaning of the word "misleading" as that set out above. It is satisfied that Dr Trossel believed them to be true.

63. Paragraph 15(iv) has been found not proved.
The claims made by Dr Trossel were contrary to the facts. He based them on Dr V's assurances about recent progress in stem cell therapy and his own interpretation of inadequate follow-up data. However, Dr Trossel believed them to be true.

64. Paragraph 15(v) has been found proved.
The Panel's reasons for this finding are set out in the section above entitled "Stem cell therapy", "Aqua Tilis…" and "The Patients".

65. Paragraph 15(vi) has been found proved.
Dr Trossel's letter to Patient F dated 19 May 2006 describes stem cell therapy as being "a new procedure" and that there had been no reports of "significant adverse side effects". However, Dr Trossel did not refer to any potential risks that might arise from this therapy. It was a new procedure and the long-term risks were unknown. Dr Trossel should have given this advice when offering the patient treatment.

Patient G

66. Paragraph 16(ii) has been found not proved.
Patient G's evidence was that she identified Dr Trossel as the person who injected her. However, she could not recollect whether or not a physical examination had taken place, even though there are written notes of such an examination. Dr Q, a retired neurologist, and part time member of staff at PMC, was called on behalf of the Defence. His evidence was that the notes of

the physical examination of Patient G and the recording of the administration to her of the stem cells were in his handwriting. The Panel therefore finds that it was probably Dr Q who had administered the stem cells.

67. Consequent upon the Panel's finding at paragraph 16(ii), paragraph 17 in its entirety and 24 in relation to this patient have been found not proved.

Patient H

68. Paragraph 18(ii) has been found not proved.
Patient H agreed that, when recommending placenta injection, Dr Trossel probably said that it *"might"* (rather than *"would")* increase the effectiveness of the stem cell therapy.

69. Paragraph 19 in its entirety has been found proved in relation to the stem of paragraph 18 and paragraph 18(iii).
In respect of the stem of paragraph 18, Professor L had no knowledge of the use of placenta injections in the treatment of patients with MS. The Panel finds that Dr Trossel's action in this regard was unjustifiable on the basis of the available scientific or clinical medical evidence. It was therefore inappropriate, not in the best interests and exploitative of a vulnerable patient.

70. Regarding 18(iii), Dr Trossel's evidence was that in order to render stem cell therapy effective it was necessary first to cure the patient's bladder infection in order to avoid diversion of stem cells to the infection site. Moreover, use of antibiotics would further dissipate the intended effect of stem cells. Hence, the preferential use of vitamin C, which would not have any undermining effect.

71. Professor L's evidence was that the most appropriate way to treat a bladder infection was by using antibiotics. He conceded that one method of reducing the risk of infection could be to acidify the urine, for example, by the administration of vitamin C, although he did not recognise this as an orthodox medical therapy for the treatment of a bladder infection. Even if vitamin C had been an appropriate treatment for a bladder infection, there was no opportunity for this to take effect before the administration of the stem cells, which occurred immediately after the vitamin C infusion.

72. Paragraph 19 in its entirety has been found proved in relation to paragraph 18(iv).
The Panel's reasons for this are set out in the sections above entitled "Stem cell therapy…" and "The Patients".

Patient I

73. Paragraph 20(ii) has been found not proved.
Patient I's evidence was that she was 100% sure that she had received an email from Dr Trossel concerning placenta stem cells and that it stated that this treatment "would benefit" her. However, Patient I's evidence on this point was not borne out by the contents of Dr Trossel's email to her dated 7 August 2006 which, although making reference to a placenta pre-treatment injection, does not refer to any benefits.

74. Paragraph 20(iii) has been found not proved.
Although Patient I's evidence was that she was clear that she had received an infusion of vitamin B, there is no mention of vitamin B in her medical records. The Panel has accepted Dr Trossel's evidence that had vitamin B been administered, it would have been recorded in the patient's medical records. Accordingly, the Panel is not satisfied that this paragraph has been found proved to the requisite standard.

75. Paragraph 20(iv) has been found proved.
The Panel accepts Patient I's evidence that Dr Trossel injected her with a substance said to contain stem cells.

76. Paragraph 21 in relation to 20(i), has been found proved in its entirety for the same reasons as set out in the case of Patient H.

77. Paragraph 21 in relation to 20(iv) has been found proved in its entirety.
The Panel's reasons for its decision are set out in the sections above entitled "Stem cell therapy…" and "The Patients".

Patient J

78. Paragraph 22(i) has been found not proved.
The evidence is that the sum of approximately 12,500 Euro was paid on Patient J's behalf to ACT and not to PMC.

79. Paragraph 22(ii) has been found proved.
Mr K contacted ACT directly as a result of the article in New Pathways. He received literature and an application form from ACT and a request that blood test results be sent to both ACT and to PMC, in Rotterdam, where the proposed treatment was to take place. The results were sent in about August 2006. An appointment was arranged for stem cell treatment to be administered, the fee of approximately 12, 500 Euros having been paid in advance to ACT. The Panel finds that the making of an appointment at the PMC for stem cell therapy amounted to an offer of treatment by Dr Trossel.

80. Paragraph 22(iii) has been found proved.
The Panel finds that on 4 September 2006 Dr Trossel stated that, prior to the Newsnight programme, he had been satisfied as to the safety and efficacy of the stem cells that ACT had supplied and which he had intended to administer to Patient J.

81. Paragraph 23 in its entirety has been found proved.
The Panel's reasons for this are set out in the sections above entitled "Stem cell therapy…" and "The Patients".

82. Paragraph 24 in its entirety has been found not proved in respect of Patient B.
There is no evidence that Dr Trossel offered to treat Patient B by stem cell therapy.

83. Paragraph 24(i) has been found proved in respect of Patients A, C, D, F, H, I and J.
The Panel finds this proved in the light of its findings as set out in the section entitled “Stem cell therapy…”: Dr Trossel adhered unquestioningly to procedures which had no evidence base. Furthermore, he did so knowing that in 2003 the United States FBI were investigating V R and B of BioMark and that in 2004 they had been charged with fraud and related offences in respect of their supply of stem cells. He therefore failed to make the care of these patients his first concern.

84. Paragraph 24 (ii) has been found proved in respect of Patients A, C, D, F, H, I and J.
“Good Medical Practice” (May 2001) states that Doctors must: “give patients information in a way they can understand”. It goes on to state: “You must respect the right of patients to be fully involved in decisions about their care. Wherever possible, you must be satisfied, before you provide treatment, or investigate a patient’s condition, that the patient has understood what is proposed and why, any significant risks or side effects associated with it, and has given consent.”

85. The Panel finds that Professor L’s evidence about informed consent, as referred to earlier in the section “Stem cell therapy”, is of particular relevance to this provision.

86. The Panel is satisfied that there was neither sufficient scientific nor clinical medical evidence upon which to proceed with the stem cell therapy. Further, Dr Trossel did not have the necessary neurological or scientific expertise upon which to proceed with such therapy. Consequently, Dr Trossel was not in a position to supply adequate information to ensure that patients could give informed consent. In respect of the patients listed above, the Panel is satisfied that Dr Trossel failed to respect the rights of the patients to be fully involved in the decision about their care for the following reasons:-

- He exaggerated the benefits of the treatment.
- He did not describe accurately how the stem cells would work.
- He overstated his success rate in treating patients with MS.
- He failed to inform the patients fully of what was contained in the freeze medium in which the stem cells were delivered, namely that it contained bovine calf serum.

87. Paragraph 24(iii) has been found proved in respect of Patients A, C, D, F, H, I and J.
The Panel has found that Dr Trossel’s offer of and/or treatment by means of stem cell therapy of these patients was unjustifiable on the basis of the available scientific or clinical medical evidence, inappropriate, not in best interests of the patients and was exploitative of a vulnerable patient. It was therefore an abuse of his position as a doctor.

88. Paragraph 25 has been found proved.
The nursing notes for patients C, D, H and I indicate that each of them was injected with RNA material manufactured by Regeneresen. The ACT website stated that: “no animal products or by products are used in the processing, culture or freeze media of ACT PP-CBSC vials and therefore, contamination by animal agents is not an issue”. Dr Trossel accepted that his procedure was at variance with what was stated on the ACT website and that the source of the RNA should have been stated on the consent form; indeed, he later amended the consent form to include it. Dr Trossel agreed that he did not inform his UK patients that the RNA contained bovine brain and spinal cord material. Furthermore, that he would not have used the term “bovine” unless specifically asked by the patient. The Panel has concluded that in the absence of this information, informed consent could not have been given.

89. The Panel will resume consideration of Dr Trossel’s case on 6 September 2010 when it will invite further evidence and submissions from both parties as to whether, on the basis of the facts found proved, Dr Trossel’s fitness to practise is impaired.

DETERMINATION ON IMPAIRED FITNESS TO PRACTISE (ANNOUNCED ON 10 SEPTEMBER 2010)

Dr Trossel: This determination should be read in conjunction with the Panel’s determination on the facts, dated 11 April 2010. The Panel found proved that your actions in offering stem cell therapy and/or Aqua Tilis Therapy were unjustifiable on the basis of the available scientific or clinical medical evidence, inappropriate, not in the best interests of patients and were exploitative of vulnerable patients. Further, in offering to treat patients by stem cell therapy in this manner, you failed to make the care of these patients your first concern. You also failed to respect the rights of patients to be fully informed in the decision about their care and you abused your position as a doctor.

The Panel has considered, on the basis of the facts found proved, whether your fitness to practise is impaired by reason of misconduct, caution and conviction. In so doing, the Panel has taken into account all the evidence adduced in this case during the findings of fact stage between January and April 2010, including your own oral evidence given in February 2010. It has also had regard to the evidence adduced at this stage of proceedings, namely your oral evidence and that of Dr R and Dr S. The Panel has also considered carefully the submissions made by Mr Kark on behalf of the General Medical Council (GMC) and those made by Mr Jay on your behalf.

Mr Kark submitted that your fitness to practise is impaired by reason of your misconduct, caution and conviction. He referred to the Panel’s findings of fact on your treatment of the patients in this case. He told the Panel that you abused your position as a doctor; many of the patients came to you in the belief that your treatment would improve their condition. In summary, Mr Kark submitted that your conduct, repeatedly, fell seriously below the standards of the GMC’s guidance “Good Medical Practice” (GMP) and referred to the relevant sections of that guidance. Mr

Kark also referred to various legal authorities, set out below, during the course of his submissions.

Mr Jay referred to the Panel's findings of fact in relation to the misconduct element of the GMC's case, including its finding that your treatment and/or offers of stem cell therapy and/or Aqua Tilis Therapy lacked the necessary scientific and clinical medical justification. The Panel did not, however, find that you were dishonest because it accepted that you believed the claims you were making.

Mr Jay also referred to the evidence you gave before this Panel on 6 September 2010 in which you accepted that you had been "too enthusiastic" about the use of stem cell therapy and that you no longer intended to offer patients this form of therapy. He submitted that you had a desire, albeit misguided, to do the very best for the patients. In treating patients with stem cell therapy you had no ulterior financial motive. He further submitted that the findings against you should be put in the context of your overall practice in the Netherlands, where you have been practising as an otherwise safe doctor. In summary, he submitted that the matters concerning your misconduct are capable of being remedied and have now been addressed.

Mr Jay referred to the circumstances in which you were given, and accepted, a caution, namely that you were not aware of the legal implications of accepting a caution, or that you were required to notify the GMC. He submitted that there was no risk of repetition.

In respect of your convictions in Belgium, Mr Jay invited the Panel to find that your fitness to practise is not impaired on the basis that the two offences for which you were convicted in Belgium did not constitute a criminal offence in England, and were, in any event, subject to appeal.

The Panel has exercised its own independent judgment on the matter of impairment. It notes that there is no burden or standard of proof to be applied. It has also taken into account a number of authorities in respect of the principles in deciding impairment, including the case of Meadow v GMC 2006 EWCA , 1390 (Admin); Cohen v GMC 2008 EWHC, 581 (Admin); Zygmunt v GMC 2008 EWHC 2643 (Admin); Azam v GMC 2008 EWHC, 2711 (Admin), and Yeong v GMC [2009] EWHC 1923 (Admin).

It has taken into account your present skills and conduct, and any steps taken since the conduct criticised to remedy any failings. It has also considered whether you have demonstrated deep-seated attitudinal issues which are unlikely to be remediable.

Throughout its deliberations, the Panel has borne in mind the public interest, which includes, amongst other things, the protection of patients, the maintenance of public confidence in the profession and the declaring and upholding of proper standards of conduct and behaviour. It has considered separately the three elements of your case, namely, misconduct, caution and conviction, upon which the GMC is alleging that your fitness to practise is impaired.

Misconduct
In relation to Patient A, Patient C, Patient D, Patient H and Patient I, who were patients suffering from Multiple Sclerosis (MS) the Panel found that between August 2004 and August 2006 you injected into each of them a substance said to contain stem cells. The Panel found proved that your actions in this regard were unjustifiable on the basis of the available scientific or clinical medical evidence, inappropriate and were not in the best interests of the patients. It further found proved that your actions in this regard were exploitative of those vulnerable patients.

In respect of Patients C, D and Patient F, you advised/recommended them to undergo Aqua Tilis therapy. The Panel found that your actions in this regard were unjustifiable on the basis of the available scientific or clinical medical evidence, inappropriate, not in the best interests of the patients, and were exploitative of those vulnerable patients.

In relation to Patient F, the Panel heard that she attended a consultation with you at your consulting rooms at 57a Wimpole St, London in relation to her MS. During the consultation you recommended Aqua Tilis therapy followed by stem cell therapy to take place in Holland.

Following the consultation, you sent Patient F a letter dated 19 May 2006, together with other literature, in which the following claims were made: -

- That 600 patients had been treated with Stem Cell Therapy, of whom 75% had reported some degree of improvement,

- That the Preventief Medisch Centrum (PMC) clinic had treated 60 people with MS in 2005 and that, as a result of their treatment, 10% were out of their wheelchair and 80% had received a significant improvement to their health,

- That you personally had treated “approximately 120 patients over the last year and a half of which half had MS and 10% were now walking out of a wheelchair. Another 80% have had a ‘proven significant clinical benefit”,

- That “Ei” Aqua Tilis Therapy had caused the improvement or complete removal of the symptoms of ‘many patients’,

- That the following diseases (among others) were treatable effectively with Core Blood Stem Cell Therapy: heart disease, stroke, Alzheimers, and other neurological diseases like MS, ALS and spinal cord lesions as well as a number of other serious conditions and diseases,

- That you had achieved ‘spectacular results’ with core blood stem cell treatments.

The Panel found proved that the claims made in your letter and in the accompanying literature provided by you seriously exaggerated the benefits of the treatment proposed for Patient F and were unsupported by scientific or clinical evidence.

Further, the Panel found proved that the claims made in that material were misleading, exploited the patient's vulnerability and failed to warn of the potential risks of stem cell therapy.

On 8 August 2006 Patient H and Patient I attended the PMC clinic in Rotterdam. You arranged for Patient H to have an infusion of vitamin C in order, purportedly, to 'flush out' a bladder infection. You told her that it was necessary first to cure her bladder infection to avoid diversion of stem cells to the infection site. The Panel concluded that, even if vitamin C had been an appropriate treatment for a bladder infection, there was insufficient time for this to take effect before you injected the stem cells into Patient H immediately after the vitamin C infusion. The Panel found proved that your action in this regard was unjustifiable on the basis of the available scientific evidence, inappropriate, not in her best interests and was exploitative of a vulnerable patient.

Patient J suffered from Secondary Progressive MS. The Panel heard that an appointment had been arranged for stem cell treatment to be administered to her. Accompanied by Mr K (Patient J's husband) and their daughter, she attended the PMC clinic in Rotterdam on 4 September 2006 in relation to the stem cell treatment.

At that consultation, you informed Mr K and Patient J that, prior to the Newsnight exposė of ACT on 29 August 2006, you had been satisfied as to the safety and efficacy of the stem cells which ACT had supplied, and which you had intended to administer to Patient J. On request, you provided her with a Certificate of Analysis in respect of the stem cells you had intended to use in her treatment. The certificate of analysis stated that the cells were not intended for use in humans.

The Panel found proved that your offer of treatment by means of stem cell therapy was unjustifiable on the basis of the available scientific or clinical medical evidence, inappropriate, not in the best interests of the patient and exploitative of a vulnerable patient.

"Good Medical Practice" (May 2001 edition) states: 'Patients must be able to trust doctors with their lives and well-being. To justify that trust, we as a profession have a duty to maintain a good standard of practice and care and to show respect for human life. In particular, as a doctor, you must: make the care of your patient your first concern … respect the rights of patients to be fully involved in decisions about their care … avoid abusing your position as a doctor.' In relation to Patients A, C, D, F, H, I, and J, the Panel found proved that in offering to treat them by stem cell therapy, in the manner proposed, you breached that guidance. In particular, the Panel considered that you abused your position in relying on your status as a doctor to exploit vulnerable patients. These are grave breaches of "Good Medical Practice".

You accepted that you had no background in neurology or haematology and that you were not an expert in stem cell research. Nevertheless, you treated MS patients with stem cell therapy. This was clearly inappropriate and not in the best interests of these patients.

“Good Medical Practice” (May 2001) states: ‘You must keep your knowledge and skills up to date’ and ‘recognise the limits of your professional competence.’ The Panel considers that these matters are relevant, given that you embarked on an area of practice of which you had scant knowledge and for which the Panel found that stem cell therapy was unjustifiable on the basis of the scientific or clinical medical evidence.

“GMP” (May 2001) further states that Doctors must: ‘give patients information in a way they can understand.’ It goes on to state: ‘You must respect the rights of patients to be fully involved in decisions about their care. Wherever possible, you must be satisfied, before you provide treatment, or investigate a patient’s condition, that the patient has understood what is proposed and why, any significant risks or side effects associated with it, and has given consent.’ Informed consent is an essential part of the doctor-patient relationship.

In relation to Patients C, D, H and I, the Panel found that, without obtaining the patient’s consent prior to doing so, you had injected them with RNA material manufactured by Regeneresen, which you knew to contain Bovine Brain and Spinal Cord live cells. The Panel found your omission in this regard to be serious.

In respect of Patient B, who was a freelance journalist, posing as a patient, the Panel heard that he was undertaking an investigation into complementary and alternative therapies offered by doctors and others treating cancer. Patient B claimed to be a person suffering from Hodgkins’ Disease, who had undergone a course of chemotherapy and had been in remission. He described how a recent scan had shown that the disease had returned to his liver.

The Panel found proved that during the consultation you did not question Patient B appropriately about his medical history, perform a physical examination of him or undertake an adequate assessment of the case before giving him medical advice.

During the consultation you discussed Aqua Tilis therapy with Patient B. You described this as a treatment in a steam room involving a “therapeutic MRI machine”. You asserted that there was ‘a good chance’ that Aqua Tilis Therapy would be an effective remedy for the patient’s illness and that this therapy had cured people with cancer such as that suffered by the patient. You further asserted that the inventor of the MRI (Magnetic Resonance Imaging) machine had made a ‘therapeutic’ MRI machine.

The Panel found that these statements were false and misleading. However, it was satisfied that when you made the statements, you believed them to be true.

“Good Medical Practice” (May 2001) states that, in providing care, you must: ‘prescribe drugs or treatment, including repeat prescriptions, only where you have adequate knowledge of the patient’s health and medical needs.’ In its determination on the facts, this Panel found that before advising Patient B, you should have seen his MRI scan, his medical records, or a report from his treating consultant. In the absence of this information, the Panel found that you should not have recommended that he undergo Aqua Tilis Therapy.

Having regard to its findings on the facts, and the detailed reasons set out in relation to those findings in its determination of 11 April 2010, the Panel has concluded that you have persistently breached important principles of "Good Medical Practice" and that your conduct has brought the medical profession into disrepute.

The Panel is satisfied that the facts found proved amount to serious misconduct.

The Panel went on to consider whether your fitness to practise is impaired by reason of your misconduct. In so doing, it has had regard to all the relevant factors and information, including the question of insight and remediation. It has borne in mind the legal authorities, including the judgment of Cranston J, in *Cheatle v GMC*:

> *"There is clear authority that in determining impairment of fitness to practise at the time of the hearing regard must be had to the way the person has acted or failed to act in the past. As Sir Anthony Clarke MR put it in* Meadow v General Medical Council *[2006] EWCA Civ 1390;*
>
> > *'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 FPP 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 (para 32)' "*

The Panel has also had regard to the judgment of Silber J who stated in paragraph 35 of Cohen:

> *"It must be highly relevant in determining if a doctor's fitness to practise is impaired that first, his or her conduct which led to the charge is easily remediable, second that it has been remedied, and third, that it is highly unlikely to be repeated."*

Your evidence was that, having read this Panel's determination on the facts, the GMC's guidance, including "Good Medical Practice" and the expert evidence of Professor L (called on behalf of the GMC), you had a change of heart about your previous use of stem cell therapy. You told the Panel that you should have been more careful in the advice you gave to your patients about the efficacy of this treatment. You also told the Panel that the follow up consultations with your patients "should have been done with more scrutiny" and that you regret not having done so. You assured the Panel that you carry out follow up physical examinations of patients who attend your clinic in Rotterdam.

Your evidence was that you thought that it could be helpful to send your patients a letter of reassurance about the safety of the bovine source and RNA, and to include within this an apology for the distress this may have caused. However, you have not

done so, despite the fact that the Panel's judgment was known to you some five months ago. You apologised to the patients through this Panel.

You maintain that you still believe in the therapeutic value of Aqua Tilis Therapy and that you would recommend it to your patients at your clinic in Rotterdam. You accept it is a "totally unproven therapy" and will make this clear to patients in future.

In reaching its conclusions, the Panel is obliged to take into account the public interest. It notes that this is a case in which there is a consistent and potentially unsafe thread running throughout its course. The Panel has received no evidence of your having the necessary capacity to anticipate the consequences of your actions, whether these take place in a clinical or any other setting. You said you would in future rely, merely informally, on those closest to you to set the boundaries of your medical practice. Despite your assertions that you have reflected on your failings, the Panel is concerned that you have demonstrated little insight into the seriousness of your misconduct and the effects this may have had on your patients. It cannot conclude that the misconduct found proved will not be repeated.

The Panel has determined that the totality of the facts found proved constitute repeated and serious breaches of many of the essential tenets of "Good Medical Practice". Public confidence in the good name of the medical profession is likely to have been damaged by your behaviour. Accordingly, the Panel has determined that your fitness to practise is impaired by reason of your misconduct.

Police Caution
On 26 June 2007 at Stansted Airport in Essex you committed the offence of making off without payment for a service contrary to Section 3(1) and (4) of The Theft Act 1978. On 16 August 2007 you were formally cautioned by the police for the offence, admitted your guilt and agreed to repay £472.50 to NCP Car Parks.

The Panel has taken into account the circumstances of this caution. In your evidence, you told the Panel that your flight from Holland had been delayed; you could not find an attendant; you spent some time looking for your car and you could not find your ticket. You went on to explain that it was late, that you wanted to get home and you saw "no other option" than to tailgate another vehicle out of the car park. You accepted that the steps you took to pay later were neither sustained nor successful and that it was your obligation to have made more effort to do so.

You also accepted that you failed to notify the GMC of this caution out of ignorance of the fact that, as a GMC registrant, it was mandatory upon you to do so.

In considering whether your fitness to practise is impaired by reason of this caution, the Panel has borne in mind the public interest, which includes, amongst other things, the declaring and upholding of proper standards of conduct and behaviour and the maintenance of public confidence in the profession.

The Panel has considered the words of Sales, J in the case of Yeong v GMC that: "The public's confidence in engaging with him [the doctor] and with other medical

practitioners may be undermined if there is a sense that such misconduct may be engaged in with impunity."

The Panel takes a serious view of your caution, which was in connection with an offence of dishonesty. It considers that you should have been aware of the consequences of your actions of making off without payment, and that this conduct would be judged by the medical profession and the public to be a serious breach of the requirement that doctors behave honestly at all times.

The GMC's publication "Good Medical Practice" (November 2006), under the heading 'Being honest and trustworthy' states: 'You must inform the GMC without delay if, anywhere in the world, you have accepted a caution, been charged with or found guilty of a criminal offence'. The Panel considers that it is incumbent upon you, as a doctor registered in the United Kingdom, to make yourself aware of this guidance, and, at the very least, to have sought advice from a defence body, medical association, or from the GMC as to whether your caution affected your registration as a doctor.

Taking all these factors into account, the Panel has determined that your fitness to practise is impaired by reason of your caution.

Conviction
On 17 February 2009 you were convicted in the Court of First Instance of the Court District of Antwerp of the following offences taking place between 9 October 2006 and 26 January 2007:

i. Failing to comply with the statutory provision that every removal and transplant of tissues, cells and organs must be carried out by a physician at a hospital as laid down by the Belgian Hospital Act of 23 December 1963 by removing or transplanting stem cells at a place which was not a recognised Hospital.

ii. The illegal practice of medicine in Belgium by assisting Mr Q who failed appropriately to notify the Ministry of Public Health in Belgium of his intention to perform medical services namely the carrying out of stem cell treatments.

Upon your conviction, you were sentenced to five months imprisonment which was suspended for three years and a fine of four thousand Euros. The Panel notes that you have appealed against this conviction, and that a date for the appeal hearing has not yet been fixed.

Section 35C(2)(c) of the Medical Act 1983, as amended, states that a person's fitness to practise shall be regarded as impaired by the purposes of this Act by reason only *of '(c) a conviction or caution in the British Islands for a criminal offence, or a conviction elsewhere for an offence which, if committed in England and Wales, would constitute a criminal offence."*

Mr Kark invited the Panel to find that at the relevant time, there were provisions of English law which would have made your conduct in Belgium a criminal offence in England. He submitted that the Panel should find that your fitness to practise is impaired by reason of your conviction. In respect of the first offence for which you were convicted, he submitted that this requirement in Belgium is mirrored in the UK by the requirement that any such activity takes place under the authority of a licence issued by the Human Tissues Authority, the relevant legislation being Sections 16 and 25 of the Human Tissue Act 2004. Section 16 sets out what is required to deal with tissue in this country. Section 25 makes a breach of Section 16 an offence.

In respect of the second conviction, which relates to the practice of medicine without being registered, Mr Kark cited section 49 of the Medical Act 1983, as amended, which makes it an offence for any person to take or use the name physician or doctor of medicine or any description to imply that he is registered under any provision of the Act. He therefore submitted that your convictions in Belgium are properly charged as convictions under Section 35(C) of the Medical Act.

Mr Jay submitted on your behalf that the offences on which the GMC rely in English law do not correlate with the offences for which you were convicted in Belgium. He said that the Belgian offence related to the transplantation of tissue only in a hospital does not equate to the offence created by the Human Tissues Act as the former relates to where such activity takes place and the latter relates to the requirement that such activity be licensed.

Mr Jay further submitted that the Belgian offence of aiding and abetting someone to practice medicine without being registered is one of strict liability, whereas the offence under the Medical Act requires there to be a mental element of 'willfully and falsely' pretending to be a registered practitioner.

The Panel received advice from the Legal Assessor in relation to the convictions. His advice in relation to the first conviction was that the Belgian offence related to the site where tissue is dealt with, whereas the offence under the Human Tissues Act was concerned with licensing such activities. There is no requirement under the Act for the activity to take place in a hospital. He advised that the Panel had insufficient material to decide whether you would have been granted a licence or the terms of it had it been granted and it would not therefore, be proper to speculate on the subject.

The Panel has taken account of the advice of the Legal Assessor and has determined not to speculate about whether the circumstances of the offence as set out in paragraph 27(i) of the allegation, for which you were convicted in Belgium, could have resulted in a conviction in English law. The Belgian offence of transplanting tissue other than in a hospital is different in nature to the offence under the Human Tissues Act which is concerned with licensing of transplantation, not the place where that activity takes place.

In relation to the second conviction, the Legal Assessor advised that the offence under the Medical Act required there to be a mental element of acting 'willfully and falsely' whereas the Belgian offence did not appear to require any such element of dishonesty. There was no direct correlation between the two offences as the Belgian

offence could be committed without any dishonest intent, whereas in England dishonest intent was necessary.

The Panel has determined that the Belgian and English offence is not comparable as the former does not require an intent of dishonesty whilst the English offence does.

The Panel has concluded for the reasons set out above that your fitness to practice is not impaired by those convictions in Belgium.

The Panel will now invite submissions from both parties as to the appropriate sanction, if any, to be imposed on your registration.

DETERMINATION ON SANCTION (ANNOUNCED ON 29 SEPTEMBER 2010)

Dr Trossel: The Panel has taken into account all the evidence presented in this case, including the material submitted in mitigation. It has considered the submissions made by both Counsel as well as the advice of the Legal Assessor. The Panel has borne in mind the GMC's publications, *Good Medical Practice* and *Indicative Sanctions Guidance*. It has taken account of all the relevant case law referenced. It has had due regard to the principle of proportionality and the need to act in a manner which is no more severe than necessary. It is conscious that the purpose of a sanction is not to punish and it has given due weight to the mitigation advanced on your behalf. The Panel is conscious of its duty to protect patients and of the public interest and is mindful that it must impose the sanction it deems necessary, notwithstanding any inadvertent punitive effect.

The Panel has found your fitness to practise to be impaired and that your actions have been:

- unjustifiable and without scientific or other clinical/medical basis;
- inappropriate;
- not in the best interests of your patients;
- exploitative of vulnerable patients;
- inconsistent with good clinical practice;
- misleading;
- below the standard expected of a registered medical practitioner, particularly with regard to your failures to:
    - make the care of your patients your first concern;
    - respect the rights of your patients to be fully involved in decisions made about their care; and
    - obtain informed consent prior to undertaking medical treatment of your patients;
- an abuse of your position as a doctor; and
- (in relation to your police caution) dishonest.

You have been in breach of a number of duties and responsibilities prescribed in *Good Medical Practice* and your actions are damaging to the reputation of the

medical profession. The serious nature of the findings made against you means that this is not a case where ‘no action’ would be appropriate.

It was submitted, on your behalf, that conditions would be an appropriate and sufficient sanction. To impose conditions the Panel must be satisfied that any condition imposed is workable, proportionate, and sufficient.

You have told this Panel, repeatedly, that you believe in the efficacy of your treatments, although you accept that there is no scientific and/or clinical medical evidence to underpin some of your claims. Furthermore, notwithstanding your very recent admissions, the Panel has concluded that in reality you continue to believe that your actions were in the best interests of your patients. The Panel cannot, therefore, rely upon you to make the welfare of your patients your first concern; or be confident that the safety of patients you treat would be ensured.

You have also told the Panel that in future your wife and professional colleagues could ensure that you do not again become ‘over enthusiastic’ in your work. The Panel cannot accept that such an assurance is sufficient to protect patients and the wider public interest; in itself, your suggested informal reliance on others demonstrates a significant lack of insight.

In all the circumstances the Panel cannot be satisfied that conditions would be sufficient adequately to protect patients or the wider public interest. In reaching this decision the Panel has taken into account your wholesale departures from the essential duties of a doctor as set out in *Good Medical Practice*; your breach of the principles and tenets set out in that document; your reckless, if well intentioned, attitude; and your disregard for the safety of patients.

The Panel next considered whether suspension could be a sufficient and proportionate sanction, giving you time to provide evidence of insight or actions to put matters right. However, you have been suspended from the Medical Register for three years since 2007 and in that time have not produced any persuasive evidence to demonstrate that you have attempted to take such action or gain the necessary insight.

You have exploited vulnerable patients and their families. You have given false hope and made unsubstantiated and exaggerated claims to patients suffering from degenerative and devastating illnesses. Your conduct has unquestionably done lasting harm, if not physically, then mentally and financially, to these patients and also to their families and supporters. It is, therefore, undeniable that you have abused the position of trust afforded to you. You continue to advocate untested and unproved treatments, using your status as a registered doctor to reinforce your personal beliefs.

In addition to considering your extensive clinical misconduct, the Panel has also had to take into account issues relating to your honesty and integrity. The Panel has determined that the actions which led to your police caution were dishonest. Furthermore, your attempts to rectify the situation were wholly insufficient and as a consequence you have demonstrated a lack of integrity and accountability.

Your misconduct is fundamentally incompatible with being a doctor. You have repeatedly demonstrated deep-seated attitudinal problems and a propensity for misleading conduct which is unlikely to be remediable. The Panel is satisfied that, based upon the evidence relating to your clinical practice alone, the sanction of suspension is not sufficient.

Cumulatively, taking into account your dishonest conduct and your clinical deficiencies, the Panel is satisfied that it is necessary, appropriate and proportionate to direct that your name is erased from the Medical Register.
The effect of the direction for erasure is that, unless you exercise your right of appeal, your name will be erased from the register 28 days from today.

Having concluded that your name be erased from the Register, the Panel will now go on to determine whether it considers it necessary for the protection of members of the public, or otherwise, to be in the public interest or in your own interests, to order that your registration be suspended forthwith.

DETERMINATION ON IMMEDIATE SANCTION
(ANNOUNCED ON 29 SEPTEMBER 2010)

Dr Trossel: Having determined to erase your name from the register the Panel has then gone on to consider the necessity of immediate suspension.

It has taken account of the submission made on behalf of the GMC.

In all the circumstances the Panel is satisfied that it is necessary for the protection of members of the public, in the public interest and in your own interests to suspend your registration with immediate effect. For the avoidance of doubt the direction for immediate suspension will remain in effect should you appeal the Panel's decision today.

The Interim Orders Panel order for interim suspension is hereby revoked

The Panel notes that for all intents and purposes this order for immediate suspension will come into effect simultaneously with the revocation of the interim order.

That concludes your case.

Confirmed

Date 7 October 2010 Chairman