

Record of Determinations – Fitness to Practise Panel

Allegation and Findings of Fact

1. On 13 September 2012 in an email to Patient A, you stated in relation to your proposed treatment of him involving the use of Sono Photo Dynamic Therapy (“SPDT”), “there is a strong possibility that we would be able to increase your median survival time”;
Admitted and found proved
2. On 18 December 2012 at the Dove Clinic, Wimpole Street, London, you stated to Person X
 - a. SPDT is able to achieve tumour cell death in 80% of cases involving deep-seated tumours, or words to that effect,
Admitted and found proved
 - b. There is a slightly less than 10% complete response rate in cancer patients treated with SPDT, or words to that effect,
Admitted and found proved
 - c. Caution had to be taken with cancer patients treated with SPDT because it tended to produce too much tumour cell death, or words to that effect;
Admitted and found proved
3. On 20 December 2012 in a telephone call with Person X, you stated that
 - a. 80% of SPDT patients show clinical evidence of tumour ~~cell~~, cell death, or words to that effect,
Admitted and found proved
 - b. Cancer immunotherapies have a 10% complete response rate, or words to that effect,
Admitted and found proved
 - c. You had achieved a complete response equating to a cure using SPDT in patients with late stage cancers, or words to that effect;
Admitted and found proved
4. On 20 December 2012 in an email to Person X, you stated that
 - a. ~~You subsidise every patient that comes to see you, or words to that effect,~~
Withdrawn by the GMC

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- b. 80% of SPDT patients show clinical evidence of tumour cell death, or words to that effect;

Paragraph 4 was amended due to the withdrawal of 4a and now reads as follows:

4. On 20 December 2012 in an email to Person X, you stated that 80% of SPDT patients show clinical evidence of tumour cell death, or words to that effect; (paragraph 4b was renumbered to paragraph 4 by the Panel)

Admitted and found proved

Exclusion of press and public

All heard in public.

Determination on Facts

Dr Kenyon:

1. At the outset of these proceedings, the Panel acceded to an application made by Mr FitzGerald, Counsel, on behalf of the General Medical Council (GMC), to withdraw paragraph 4a, with paragraph 4b becoming paragraph 4. The Panel also amended a typographical error in paragraph 3a.

2. Mr Kennedy, Counsel, made a number of admissions on your behalf and the Panel announced the following paragraphs as admitted and found proved:

1. On 13 September 2012 in an email to Patient A, you stated in relation to your proposed treatment of him involving the use of Sono Photo Dynamic Therapy ("SPDT"), "there is a strong possibility that we would be able to increase your median survival time";

Admitted and found proved

5. On 18 December 2012 at the Dove Clinic, Wimpole Street, London, you stated to Person X

- d. SPDT is able to achieve tumour cell death in 80% of cases involving deep-seated tumours, or words to that effect,

Admitted and found proved

- e. There is a slightly less than 10% complete response rate in cancer patients treated with SPDT, or words to that effect,

Admitted and found proved

- f. Caution had to be taken with cancer patients treated with SPDT because it tended to produce too much tumour cell death, or words to that effect;

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Admitted and found proved

6. On 20 December 2012 in a telephone call with Person X, you stated that
- d. 80% of SPDT patients show clinical evidence of tumour ~~cell~~, cell death, or words to that effect,
Admitted and found proved
- e. Cancer immunotherapies have a 10% complete response rate, or words to that effect,
Admitted and found proved
- f. You had achieved a complete response equating to a cure using SPDT in patients with late stage cancers, or words to that effect;
Admitted and found proved
7. On 20 December 2012 in an email to Person X, you stated that
- ~~e. You subsidise every patient that comes to see you, or words to that effect,~~
Withdrawn by the GMC
- d. 80% of SPDT patients show clinical evidence of tumour cell death, or words to that effect;

Paragraph 4b was amended due to the withdrawal of 4a and now becomes paragraph 4 as follows:

4. On 20 December 2012 in an email to Person X, you stated that 80% of SPDT patients show clinical evidence of tumour cell death, or words to that effect;
Admitted and found proved

Background

Sono Photo Dynamic Therapy ("SPDT")

3. In 2011, in the journal Current Drug Therapies you described SPDT as 'a novel cancer treatment approach'. You explained that SPDT involves administering the patient with a photosensitive agent or 'sensitiser' (in this paper Sonnelux-1) and with ultrasound. The agent is said to be preferentially absorbed into tumour cells within the body. The patient is then exposed to a cycle of light and low-intensity ultrasound, using a light bed and a hand held ultrasound device. This process is said to activate the sensitiser within the tumour site, leading to 'activated tumour cell necrosis' as well as a subsequently enhanced anti-tumour immune response within the patient.

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4. In September 2012, Patient A consulted you at the Dove Clinic, Wimpole Street, London, in relation to your treatment of him involving the use of SPDT. Patient A's brother Mr A also attended the consultation. At the time, Patient A was suffering from mediastinal germ cell tumour with significant metastases for which he had received chemotherapy. Following the consultation, in an email to Patient A, dated 13 September 2012, you stated in relation to your proposed treatment of him involving the use of SPDT, 'I am not claiming we can cure you, but there is a strong possibility that we would be able to increase your median survival time with the relatively low-risk approaches described here.'

5. On 18 December 2012, Mr B, an undercover journalist from the Sunday Times newspaper, visited you at the Dove Clinic posing as the husband of a fictitious female patient who had been diagnosed with breast cancer with metastases in her hip. You were not aware that Mr B was a journalist. During that consultation you told Mr B that SPDT is able to achieve tumour cell death in 80% of cases involving deep-seated tumours and that there is a slightly less than 10% complete response rate in cancer patients treated with SPDT. You also told him that caution had to be taken with cancer patients treated with SPDT because it tended to produce too much tumour cell death, or words to that effect.

6. On 20 December 2012, Mr B contacted you by telephone and identified himself as a journalist. Half way through the conversation Mr B revealed that he had posed as the husband of a fictitious patient. During the conversation you stated that 80% of SPDT patients show clinical evidence of tumour cell death, cancer immunotherapies have a 10% complete response rate, and that you had achieved a complete response equating to a cure using SPDT in patients with late stage cancers, or words to that effect. In an email to Mr B on the same date, 20 December 2012, you stated that 80% of SPDT patients show clinical evidence of tumour cell death or words to that effect.

Witnesses

7. The Panel heard oral evidence from the following witnesses called by the GMC:

- Mr B, Sunday Times journalist
- Dr B, Consultant in Medical Oncology, called as an expert witness
- Mr A, Patient A's brother

Called on your behalf:

- Professor C, Professor of Surgery, called as an expert witness
- Professor D, Professor of Oncology
- Patient Y who has been treated by you
- Patient Z who has been treated by you

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You also gave oral evidence to the Panel.

The Legal Assessor's advice regarding misleading and dishonesty

8. In considering the definitions of 'misleading' and 'dishonest' the Panel accepted the advice of the Legal Assessor. He advised that the word 'misleading' should be given its ordinary English meaning. He referred the Panel to the judgement of Mr Justice Bean, in the case of Dr Negin SHAMSIAN v GMC [2011] EWHC 2885 (Admin), who affirmed the GMC's definition of a misleading statement as:

'... one which leads someone to believe something is true when it is not true. There is no implication of dishonesty or any intention to mislead...'

9. The Legal Assessor reminded the Panel that the GMC invited a finding of misleading on the basis that your statements were inaccurate or gave a misleading impression. He advised the Panel not to determine whether your statements were or were not true, but whether they gave an inaccurate and therefore misleading impression.

10. The Legal Assessor advised the Panel that in order to find dishonesty it should consider first whether your conduct was dishonest by the ordinary standards of reasonable and honest people and secondly whether you yourself realised that, by those standards, your conduct was dishonest.

11. In citing the case of *Twinsectra Ltd v Yardley and others* [2002] UKHL 12, 2 AC 164, he referred to the words of Lord Hutton that a doctor:

"should not escape a finding of dishonesty because he sets his own standards of honesty and does not regard as dishonest what he knows would offend the normally accepted standards of honest conduct."

The Panel's Approach

12. The Panel has borne in mind that the burden of proof rests on the GMC throughout and that the standard is the civil standard of proof ie on the balance of probabilities. The Panel has borne in mind that you do not have to prove anything nor do you have to demonstrate that SPDT is safe or that it is an effective form of treatment for cancer.

13. The Panel has considered all of the evidence adduced in this case. It has taken account of Mr FitzGerald's submissions on behalf of the GMC and Mr Kennedy's submissions on your behalf.

14. When considering whether or not a statement made by you was dishonest the Panel has borne in mind that the GMC has put its case that if the Panel finds the allegation is not misleading it cannot then find the allegation to be dishonest. The Panel accepted this approach.

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The Panel considered the remaining paragraph of the allegation:

- '5. Your conduct as set out above in paragraphs 1-4 was
 - a. misleading,
 - b. dishonest.'

The Panel has considered whether your conduct was misleading and if so whether it was also dishonest in relation to paragraphs 1-4 of the allegation and has made the following findings on the facts:

Paragraph 1

On 13 September 2012 in an email to Patient A, you stated in relation to your proposed treatment of him involving the use of Sono Photo Dynamic Therapy ("SPDT"), "there is a strong possibility that we would be able to increase your median survival time";

Found proved in relation to misleading

Found not proved in relation to dishonest

15. The Panel considered Dr B's opinion in his report dated 18 February 2014, in which he stated that the use of the wording 'strong possibility' and 'increasing median survival' are misleading in the context of Patient A. In his oral evidence he stated that

'a patient reading the email with advanced chemo resistant disease would interpret this as a strong possibility, as a substantial chance of improving life expectancy, which is likely to have been a door that has been more or less closed to them by previous medical staff...'

He stated his concern was

'that a patient reading these words put together within the same five or six lines is going to think here is something that will give them a much better chance of survival than they have been offered before'

and he thought that

'the impression they would come away with would be it is not a guarantee at all but there is a substantial chance probably less than 50 per cent, 35 per cent'. He stated that 'that is how they would interpret it that they have got a strong possibility, 30 to 40 per cent chance of improving their life expectancy.'

16. Professor C in his oral evidence stated that based on the patients you had reported on, he would assume that:

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'...there is a fair chance for a patient undergoing this treatment to have a significant better median survival, yes'.

17. When asked if he would use the term 'strong possibility' Professor C stated:

'No, I do not think I would word it directly like that, but I would tell my patient that, having received the treatments he already had, that there is a strong possibility that the prognosis is very poor and, as such, it is absolutely justified to go for this type of treatment which offers a chance in addition to what he had to prolong his life, that is how I would see it'.

18. The Panel accepted that both experts were broadly in agreement that they would not have said that there was a substantial chance of improving life expectancy in Patient A's case. The Panel determined that a patient with advanced chemo resistant disease would interpret what you stated a 'strong possibility' as equating to a substantial chance of improving life expectancy. Therefore, the Panel finds that your email to patient A was misleading. Accordingly, the Panel finds paragraph 1 proved in relation to misleading.

19. The Panel considered whether your conduct was dishonest in relation to the email that you sent to Patient A on 13 September 2013. The Panel has accepted your enthusiasm for SPDT and it considers that you believed that you were acting in the best interests of Patient A. The Panel also looked at the context of the words 'strong possibility' within the whole sentence of your email. The sentence states 'I am not claiming we can cure you, but there is a strong possibility that we would be able to increase your median survival time with the relatively low-risk approaches described here.' The Panel has also noted the Dove Clinic's 'Evidence Base' document on SPDT that was given to Patient A, which refers to SPDT as palliative and experimental treatment. Having considered your oral evidence the Panel accepted that by making this statement there was no intention to act dishonestly as the words used in totality gave an enthusiastic impression of the effects of SPDT but did not, in the Panel's judgment, deliberately intend to deceive. On that basis the Panel concluded that both objectively and subjectively the statement was not dishonest. Accordingly, the Panel finds paragraph 1 not proved in relation to dishonesty.

Paragraph 2a

On 18 December 2012 at the Dove Clinic, Wimpole Street, London, you stated to Person X, SPDT is able to achieve tumour cell death in 80% of cases involving deep-seated tumours, or words to that effect

Found proved in relation to misleading

Found not proved in relation to dishonest

20. Professor C in his oral evidence referred to the paper, 'Sonodynamic Therapy – a review of the synergistic effects of drugs and ultrasound', Ionel Rosenthal, Joe Z

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Sostaric and Peter Reisz, Ultrasonic Sonochemistry 11 (2004) 349-363 (The Rosenthal paper). The Panel noted that this was a paper reviewing preclinical studies. In his oral evidence Professor C told the Panel that his assumption that 80% of patients will achieve tumour cell death was based on these preclinical studies and the observed effects of Photo Dynamic Therapy (PDT), not SPDT.

21. In his report dated 10 March 2014 Dr B stated

‘There is no clinical evidence presented (ie in human subjects) that there is tumour cell death to an extent likely to be of benefit to patients in anything like 80% of patients’.

22. The Panel accepted the clear evidence from Dr B that a claim of 80% cell death in deep seated tumours was unwarranted because this information had been extrapolated from preclinical studies. The Panel finds your statement to have been misleading. Accordingly, the Panel finds proved that your conduct, as set out in paragraph 2a, was misleading.

23. At the consultation on 18 December 2012 Mr B was posing as the husband of a fictitious female cancer patient, although he was actually an undercover journalist. Mr B confirmed in his oral evidence that SPDT was described as an ‘experimental treatment’. When further asked whether this information had to be dragged out of you, he stated: ‘No, he volunteered’.

24. The Panel considers that Mr B represented a reasonably informed member of the public and that, whilst ultimately a matter for the Panel, it placed weight on his opinion that you are not dishonest and that you believed in your statement. The Panel has also noted that you informed Mr B that SPDT is an experimental treatment, and in your oral evidence you confirmed that this is what you tell your patients. The Panel considers that you were not dishonest when you made the statement. Accordingly, the Panel finds Paragraph 2a not proved in relation to dishonesty.

Paragraph 2b

On 18 December 2012 at the Dove Clinic, Wimpole Street, London, you stated to Person X, there is a slightly less than 10% complete response rate in cancer patients treated with SPDT, or words to that effect,

Found proved in relation to misleading

Found not proved in relation to dishonest

25. The Panel notes that Mr B was posing as the husband of a fictitious patient with end stage cancer. In your oral evidence you stated that you rely on your own studies of SPDT and usually provided your ‘Evidence Base’ document to explain SPDT to patients. You told the Panel that you did not give Mr B the Evidence Base document on the day of the consultation.

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26. The Panel has taken account of Dr B's conclusion in his report, which stated

'In conclusion , my view is that no reliable conclusions on benefit can be drawn from these incompletely described patients in the papers, irrespective of the fact that they may have been peer reviewed and have been published in a journal. The claim of 'slightly less than 10% complete response rate' cannot be substantiated by the evidence and is misleading.'

27. The Panel took account of the transcript of the consultation between you and Mr B which stated

'DR KENYON: Chemotherapy is nothing like as effective at killing tumour mass off, so in other words 80 per cent of the patients are walking through the door with late stage cancer and in 80 per cent you are going to kill significant tumour mass off. Are you going to cure them? The answer is one does not know. We do get some long term survivors and we call those complete responses.

Mr B: What, in remission.

DR KENYON: Oh completely, yes. Look, I have got patients who are still alive and completely well today and we have done this nearly eight years ago – and they had metastatic cancer, yes.

Mr B: Mmm.

DR KENYON: Now what's the percentage of complete responses? It's probably slightly less than 10 per cent.'

28. The Panel observed that Professor C gave evidence about cancer immunotherapies in general rather than specifically SPDT.

29. The Panel has accepted Dr B's evidence that no reliable conclusions on benefit can be drawn from the incompletely described patients in your papers. The Panel considers the conversation you had with Mr B in relation to complete responses was misleading. Accordingly, the Panel finds paragraph 2b proved in relation to misleading.

30. In relation to dishonesty the Panel noted Mr B's oral evidence during questioning as follows:

'Q We looked at it - and if I am wrong no doubt somebody will correct me - and that, as you say, he said that in 10 per cent of cases he produces a complete response - was the expression?

A Yes.

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Q What he also did, as you say, was he explained to you that this was experimental treatment?

A Correct.

Q You did not have to drag that out of him, did you?

A No, he volunteered. I cannot recollect but I think that it is on the website and also it is not curative, as we made clear in the article.'

The Panel has also taken account of the transcript of your conversation with Mr B where you inform him that SPDT is 'experimental essentially'. The Panel also noted that you qualified the claim saying that it was 'probably' slightly less than 10%. The Panel accepted Mr B's opinion that you were misguided but not dishonest. Accordingly, the Panel has found paragraph 2b not proved in relation to dishonesty.

Paragraph 2c

On 18 December 2012 at the Dove Clinic, Wimpole Street, London, you stated to Person X, caution had to be taken with cancer patients treated with SPDT because it tended to produce too much tumour cell death, or words to that effect;

Found proved in relation to misleading

Found not proved in relation to dishonest

31. The Panel has noted that during this consultation Mr B was posing as a fictitious patient's husband.

32. The Panel has taken account of Dr B's supplementary report dated 14 March 2014 in which he states:

'Dr Kenyon describes with SPDT there is too much tumour cell death and the therapy has to be fractionated – he relates this to inflammatory response to tumour cell death.... The implication, if that message were given to a vulnerable patient, is that the treatment is so effective that it has to be fractionated or controlled by anti-inflammatory drugs such as steroids. It is a common lay perception that the more the side effects, the greater the anti-tumour effects, whereas in clinical practice this may, or may not be the case and in my view Dr Kenyon is exploiting that perception with this statement.'

33. The Panel also took account of Professor C's report dated 21 March 2014 in which he states:

'Dr Kenyon's comments which warn about the risk of too much tumour cell death following SPDT application are absolutely true. I have personally faced this problem in patients where the immune response following DC- [Dendritic Cell] vaccination where the immune response following DC vaccination was so intense that the amount of tumour destruction caused considerable pain and - in the worst case scenario - induced a crush kidney failure. This was due to overload of degraded tumour proteins which occluded the renal

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tubular system. Since SPDT can elicit strong tumour cell destruction and elicit subsequent inflammation and DC activation as outlined above, there is no doubt that such a scenario in very rare cases might happen following intensive SPDT in patients with abundant tumour masses.'

34. The Panel preferred the evidence of Dr B. It considers that it was inappropriate for Professor C to extrapolate from his experience of DC vaccination to SPDT.

35. The Panel also finds that the wording 'too much tumour cell death' gives the patient a high expectation of the effectiveness of SPDT.

36. The Panel has not been presented with any evidence to support the contention that SPDT can cause too much tumour cell death. The Panel considers this statement would have been misleading to a patient. Accordingly, the Panel finds paragraph 2c proved in relation to misleading.

37. The Panel has noted previously the oral evidence of Mr B that he found that you very much believed in SPDT. He stated that you were very open and honest, but concluded that you were misguided and that the information you were giving was misleading. The Panel has noted that in your oral evidence, you stated that you were relying on your own research and conclusions and on anecdotal information from Dr D in Australia and Dr E in China. The Panel considers that you believe in SPDT and that your view is shared by others and in that belief you were not acting dishonestly. Accordingly, the Panel finds paragraph 2c not proved in relation to dishonesty.

Paragraph 3a

On 20 December 2012 in a telephone call with Person X, you stated that 80% of SPDT patients show clinical evidence of tumour ~~cell~~, cell death, or words to that effect,

Found not proved in relation to misleading

Found not proved in relation to dishonest

38. The Panel has noted that at the outset of the telephone conversation with you Mr B identified himself as a journalist from the Sunday Times newspaper. The Panel has taken account of the transcript of the telephone conversation from where the allegation has been extracted and it considered this statement in relation to the whole of the conversation. It notes that later in the conversation you explain fully your own findings and the reasons why and how you equate your 80% figure to tumour cell death. Overall the statement was qualified by your further comments.

39. Accordingly, the Panel finds paragraph 3a not proved in relation to misleading.

As the Panel found paragraph 3a not proved in relation to misleading, it therefore finds paragraph 3a in relation to dishonesty not proved.

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Paragraph 3b

On 20 December 2012 in a telephone call with Person X, you stated that cancer immunotherapies have a 10% complete response rate, or words to that effect,

Found not proved in relation to misleading

Found not proved in relation to dishonest

40. The Panel took account of the conclusion in the 'Complete clinical responses to cancer therapy caused by multiple divergent approaches: A repeating theme lost in translation', Brendon J Coventry Martin L Ashdown – Cancer Management and Research 2012:4, 137-149 (The Coventry and Ashdown paper) which states

'The observed rates of CR (Complete Response) across almost all of these approaches of anticancer therapy for advanced human cancers (excepting testicular cancer, acute childhood leukaemia, choriocarcinoma, and perhaps some lymphomas) are of the order of 0% - 20% by most methods averaging at around 5%-10% overall. Moreover, many approaches regarded as current 'standard-of-care' therapy have CR rates of well less than 10% (eg, lung, melanoma, mesothelioma, pancreatic cancers) and very low five year survival rates.

Two perhaps surprising points are evident from this broad clinical observation. (1) That the similarly uniformly low rates of CR are obtained despite a wide and diverse range of modalities being used for cancer therapy, and (2) that purely immunological therapies can produce CRs at approximately the same rates as ablative therapies.'

41. As the Coventry and Ashdown paper states that the observed rates are in the order of 0% to 20%, it might have been more appropriate to have quoted 0% - 20%. Nevertheless, the Panel finds it reasonable that you quoted a 'slightly less than 10% rate'. Accordingly, the Panel finds paragraph 3b not proved in relation to misleading.

42. The Panel concluded that paragraph 3b is not proved in relation to misleading, it therefore finds paragraph 3b in relation to dishonesty not proved.

Paragraph 3c

On 20 December 2012 in a telephone call with Person X, you stated that you had achieved a complete response equating to a cure using SPDT in patients with late stage cancers, or words to that effect;

Found not proved in relation to misleading

Found not proved in relation to dishonest

43. The Panel has noted the contents of the transcript of the telephone conversation with Mr B from where the allegation has been extracted. It notes that whilst at one point in the conversation you stated that a complete response equated to a cure, later in the conversation you explained further and clarified to Mr B stating

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'We never claim we can cure a tumour. We never claim that'. In his oral evidence Mr B confirmed that he was not having to drag information from you and that you were volunteering the experimental nature of the treatment and the need for greater research. As a standalone statement the Panel considers that it may be misleading. However, taken within the context of the whole conversation and your further explanation, the Panel considers that it is not misleading. Accordingly, the Panel finds paragraph 3c not proved in relation to misleading.

44. As the Panel finds paragraph 3c not proved in relation to misleading, it therefore finds paragraph 3c in relation to dishonesty not proved.

Paragraph 4

On 20 December 2012 in an email to Person X, you stated that 80% of SPDT patients show clinical evidence of tumour cell death, or words to that effect;

Found not proved in relation to misleading

Found not proved in relation to dishonest

45. The Panel has noted that the email was sent to Mr B, who you knew was a journalist from the Sunday Times newspaper as you had spoken to him at length on the telephone earlier that day. The Panel has noted the transcript of the telephone conversation in which you gave a full explanation of your own findings on tumour cell death. The Panel considers that your email was a clarification of the telephone conversation. The Panel noted that in the email you stated that '80% of our SPDT patients show clinical evidence of some tumour cell death...'. The Panel has noted that you were referring to your own studies when you used the term 'our' and that you also used the term 'some'. The Panel considers that Mr B was a reasonably informed journalist and that you had fully explained your reasoning to him earlier in the day. The Panel does not consider your email to be misleading. Accordingly, the Panel finds paragraph 4 not proved in relation to misleading.

46. As the Panel found paragraph 4 not proved in relation to misleading, it therefore finds paragraph 4 in relation to dishonesty not proved.

Determination on Impairment

Dr Kenyon:

1. The Panel has considered under Rule 17(2)(j) of the General Medical Council (GMC) (Fitness to Practise) Rules Order of Council 2004 whether, on the basis of the facts found proved, your fitness to practise is impaired. It has taken account of all of the evidence adduced. It has also taken account of Mr FitzGerald's submissions on behalf of the GMC and Mr Kennedy's submissions on your behalf.

Counsel's submissions

2. Mr FitzGerald submitted that your actions constituted misconduct and that your fitness to practise is impaired as a result. He submitted that your behaviour in

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making misleading statements about the effectiveness of Sono Photo Dynamic Therapy (SPDT) to a terminally ill patient and to someone who you believed to be the husband of a terminally ill patient, constituted serious departures from the GMC's guidance *Good Medical Practice (2006)*, specifically paragraphs 1, 20, 57 and 61. He reminded the Panel that you denied that the statements you made were misleading and that you have not demonstrated any insight or remediation.

3. Mr Kennedy told the Panel that your position on impairment is neutral. He stated that in this case the Panel has no evidence of remediation. However, he reminded the Panel that there is no evidence of patient harm or patient disadvantage. He told the Panel that you acknowledge the importance of presenting a balanced picture, particularly in circumstances such as these where the treatment is experimental and the patients are vulnerable. He stated that in a number of respects you failed in your duty to be balanced. He also stated that the views you hold about SPDT are genuine and shared with others.

The Panel's Approach

4. In relation to impairment, the Panel accepted the advice of the Legal Assessor and undertook a two stage process. It considered whether the facts found proved amounted to misconduct which was serious and secondly, whether as a result, your fitness to practise is currently impaired.

5. The Panel has borne in mind that its findings are a matter for itself alone exercising its judgment. The Panel took into account the public interest which includes, amongst other things, the protection of patients, maintenance of public confidence in the profession and the declaring and upholding of proper standards of conduct and behaviour.

Misconduct

6. The Panel found that you made highly significant misleading statements to a vulnerable and terminally ill patient and also to someone who you believed at the time to be the husband of another vulnerable patient. You did so on two separate occasions.

7. The Panel found that at the time of the consultations you knew that SPDT was experimental and you should have given a more balanced view. You were dealing with a gravely ill patient and a relative of such a patient and it was your duty to state the effectiveness of proposed treatment and resultant prognosis with great caution and to be realistic about outcomes. It was your responsibility to provide information that the majority of mainstream medical practitioners did not necessarily share your views regarding SPDT and that your practice was at one end of the spectrum of medical opinion. You presented yourself as a 'leader in the science' of SPDT, which would have increased the impact your misleading statements had on vulnerable patients.

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8. The Panel has seen the “Evidence Base Document” which you give to patients. In your oral evidence you told the Panel that you had been advised by four oncologist colleagues that the most you could state in this document was that SPDT was palliative and that it ‘may be’ effective. However, this was not the impression that you gave during the consultations.

9. The Panel considers that your conduct in making misleading statements regarding SPDT to vulnerable patients or relatives of vulnerable patients, on two separate occasions, amounted to misconduct which was serious.

Impairment in relation to misconduct

10. Paragraphs 22 and 61 of *Good Medical Practice (2006)* state:

'22. To communicate effectively you must...

b. share with patients, in a way they can understand, the information they want or need to know about their condition, its likely progression, and the treatment options available to them, including associated risks and uncertainties

'61. You must not make unjustifiable claims about the quality or outcomes of your services in any information you provide to patients. It must not offer guarantees of cures, nor exploit patients' vulnerability or lack of medical knowledge.'

11. In making the misleading statements on two occasions you failed to give a balanced view of SPDT, you made unjustifiable claims about SPDT and failed to explain the associated uncertainties. The Panel also considers that you exploited patients' vulnerability and lack of medical knowledge. The Panel considers that you have demonstrated a departure from the principles set out in *Good Medical Practice* on two separate occasions.

12. The Panel considers that your misconduct may be remediable were you to adopt the right attitude. However, the Panel has not been provided with any evidence of your remediation, despite your misconduct occurring in 2012. The Panel considers that you have shown some limited insight, but at this time it cannot be satisfied that your misconduct might not be repeated in the future.

13. The Panel finds that your misconduct has brought the profession into disrepute. In making misleading statements on two separate occasions to two persons, one of them being a patient with terminal cancer and the other being the spouse of a fictitious patient suffering with advanced cancer, you failed to uphold proper professional standards. The Panel is of the view that public confidence in the profession would be undermined if a finding of impairment were not made in the circumstances of this case.

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14. Therefore, the Panel has determined that your fitness to practise is currently impaired by reason of your misconduct pursuant to Section 35C(2)(a) of the Medical Act 1983, as amended.

Determination on Sanction

Dr Kenyon:

1. Having determined that your fitness to practise is impaired by reason of misconduct, the Panel has now considered what action, if any, it should take with regard to your registration.
2. In so doing, the Panel has given careful consideration to all the evidence adduced, together with Mr FitzGerald's submissions on behalf of the General Medical Council (GMC) and those of Mr Kennedy on your behalf.

Submissions

3. Mr FitzGerald submitted that the appropriate sanction in your case is at least suspension. He submitted that there are three factors for the Panel to consider: the seriousness of your breach of Good Medical Practice in making highly misleading statements to two individuals, the likelihood of repetition of your misconduct in light of your lack of insight and of remediation and the need to uphold proper standards of conduct and behaviour to maintain confidence in the profession.
4. Mr Kennedy reminded the Panel that you have been subject to an interim order of conditions, which include six general conditions and one condition specific to Sono Photo Dynamic Therapy (SPDT). You previously told the Panel that the interim conditions on your registration have worked well. Mr Kennedy told the Panel that SPDT represents approximately 10% of your practice and submitted that conditions are the appropriate and proportionate sanction, given the circumstances of your case. On your behalf Mr Kennedy produced a bundle of testimonials from patients and fellow professionals.
5. At this stage of the proceedings, the Panel has been provided with further evidence relating to your previous history with the GMC. The Panel noted that following a fitness to practise hearing in 2013, your fitness to practise was found not impaired, even though that Panel made a finding of misconduct and issued you with a formal warning. This Panel noted that the facts found proved in that case were dissimilar to those in the present case.

The Panel's Approach

6. The decision as to the appropriate sanction to impose, if any, in this case is a matter for this Panel exercising its own independent judgement.

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7. In reaching its decision, the Panel has taken account of the GMC's Indicative Sanctions Guidance (revised April 2014). It has borne in mind that the purpose of the sanctions is not to be punitive, but to protect patients and the wider public interest, although they may have a punitive effect.
8. Throughout its deliberations, the Panel has applied the principle of proportionality, balancing your interests with the public interest. The public interest 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.
9. The Panel has already given a detailed determination on facts and impairment and it has taken those matters into account during its deliberations on sanction.
10. In coming to its decision as to the appropriate sanction, if any, to impose in your case, the Panel first considered whether to conclude the case by taking no action. The Panel determined that in view of its findings on impairment, that you made highly significant misleading statements regarding SPDT to a vulnerable and terminally ill patient and to a relative of a fictitious vulnerable patient, which amounted to misconduct that was serious, it would be neither sufficient, proportionate nor in the public interest, to conclude this case by taking no action.
11. The Panel next considered whether it would be sufficient to impose conditions on your registration. It has borne in mind that any conditions imposed would need to be appropriate, proportionate, workable and measurable.
12. The Panel found that you demonstrated a departure from the principles set out in Good Medical Practice in making the misleading statements about SPDT on two separate occasions to two persons, one of them being a patient with terminal cancer and the other being the spouse of a fictitious patient suffering with advanced cancer.
13. Although you departed from the principles in Good Medical Practice the Panel considers this was due to your enthusiasm for SPDT and it was not done with the deliberate intention to deceive. The Panel considers that your practice in relation to SPDT consultations is remediable.
14. The Panel considers that you have shown some limited insight. It has noted that you have begun, albeit late in the day, to attempt remediation by reviewing the appropriateness of your responses to patients and others when you receive enquiries or referrals.
15. It has also noted that you have rewritten the Dove Clinic's document on SPDT in order to make it clearer that SPDT is an experimental treatment. The Panel was however disappointed that you have not made reference to any mainstream medical

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criticisms of SPDT on this patient information document, in order to properly communicate the uncertainty associated with this treatment option.

16. The Panel did not find any evidence of harmful deep-seated personality or attitudinal problems. It has also noted the testimonials from patients and colleagues which attested to their perception of your openness and honesty. It has further noted that there has been no criticism that patients were either directly or indirectly at risk.

The Panel's Decision

17. The Panel considers that it is possible to formulate appropriate and practical conditions to impose on your registration. In order to provide you with an opportunity to adhere to the principles set out in Good Medical Practice, to reflect on your practice and improve your communication skills, in particular in relation to SPDT consultations, the Panel has concluded that it is appropriate, necessary and proportionate to impose conditions on your registration for a period of twelve months. The following conditions relate to your professional practice and will be published:

1. You must notify the GMC promptly of any post you accept for which registration with the GMC is required and provide the GMC with the contact details of your employer.
2. At any time that you are providing medical services, which require you to be registered with the GMC, you must agree to the appointment of a workplace reporter who you will nominate, and whose suitability for the role will be approved by the GMC.
3. You must allow the GMC to exchange information with your employer or any contracting body for which you provide medical services.
4. You must inform the GMC of any formal disciplinary proceedings taken against you, from the date of this determination.
5. You must inform the GMC if you apply for medical employment outside the UK.
6. You must obtain the approval of the GMC before accepting any post for which registration with the GMC is required.
7.
 - a. You must not carry out Sono Photo-Dynamic Therapy unless the patient seeking this therapy has been directly referred to you in writing by their registered GP or their treating medical Consultant.
 - b. You must maintain a log detailing every case where you have undertaken Sono Photo-Dynamic Therapy, which must include the

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name of the referring registered medical practitioner and the date of the referral.

- c. You must provide a copy of this log to the GMC on a quarterly basis or, alternatively, confirm that there have been no such cases during that period.
8. You must attend a relevant communication skills course for medical practitioners, as agreed with your workplace reporter, within six months of the date from which these conditions become effective and provide evidence of attendance to the GMC.
 9. You must inform the following parties that your registration is subject to the conditions, listed at 1 to 8 above:
 - a. Any organisation or person employing or contracting with you to undertake medical work
 - b. Any locum agency or out-of-hours service you are registered with or apply to be registered with (at the time of application)
 - c. In the case of locum appointments, your immediate line manager at your place of work (at least 24 hours before starting work)
 - d. Any prospective employer or contracting body (at the time of application).
18. In the light of the GMC's submissions the Panel did consider imposing a period of suspension on your registration. Whilst the Panel found that your misconduct was serious it found that it was not serious enough to require temporary removal from the Register. The Panel considers that suspension would be disproportionate.
19. Shortly before the end of the period of conditional registration, your case will be reviewed by a fitness to practise Panel. A letter will be sent to you about the arrangements for the review hearing. At the next hearing, the Panel reviewing your case will wish to be assured that you have addressed your shortcomings. The review Panel may be assisted in seeing:
- A reflective statement detailing your understanding of this Panel's findings and how you have applied that understanding to your practice, with specific reference to consultations with potential SPDT patients, if any
 - Testimonials from medical practitioners who have referred patients for SPDT, if any.

Determination on Immediate Order

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Dr Kenyon:

1. Having determined that your registration will be subject to conditions for a period of 12 months, the Panel has considered, in accordance with Section 38 of the Medical Act 1983, as amended, whether your registration should be subject to an immediate order.
2. On behalf of the General Medical Council, Mr FitzGerald submitted that in view of the serious nature of misconduct found and in view of your lack of insight, an immediate order is necessary for the protection of members of the public and in the public interest. He also submitted that the Panel revoke your interim order of conditions.
3. On your behalf, Mr Kennedy submitted that you are content for the Panel to impose an immediate order and to revoke the interim order with immediate effect.
4. The Panel considered paragraph 122 of the Indicative Sanctions Guidance which states that,

“The Panel may impose an immediate order where it is satisfied that it is necessary for the protection of members of the public, or is in the public interest, or is in the best interests of the practitioner...”
5. Having considered the submissions, and in the light of all the circumstances of the case, in particular, the identified misconduct in your practice, the Panel is satisfied that it is necessary for the protection of the public and in the public interest for your registration to be made conditional forthwith.
6. Your interim order of conditions is hereby revoked.
7. The substantive direction for conditions as already announced, will take effect 28 days from when notice is deemed to have been served upon you, unless you lodge an appeal in the interim. If you do lodge an appeal, the immediate order for conditions will remain in force until the appeal is determined.
8. That concludes this case.

Confirmed

Date 09 December 2014

Dr Surendra Kumar, Chair