GENERAL MEDICAL COUNCIL

FITNESS TO PRACTISE PANEL (MISCONDUCT/PERFORMANCE)

On:
Tuesday, 15 November 2011

Held at:
St James's Buildings
79 Oxford Street
Manchester M1 6FQ

Case of:

GORDON ROBERT BRUCE SKINNER
MB ChB 1965 University of Glasgow
Reference No: 0726922
(Day Two)

Panel Members:
Dr N Hester (Chairman)
Dr M Jeffries
Mrs S Pond
Mr R Ince (Legal Assessor)

MR C FOSTER, Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of the doctor, who was present.

MR P ATHERTON, Counsel, instructed by GMC Legal, appeared on behalf of the General Medical Council.

Transcript of the shorthand notes of
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THE CHAIRMAN: Good morning, everyone. Before we start, can I just say that the documents that were handed to us last evening we have labelled Addenda 1, which contains 60 and 62, the medico-legal report and testimonials, they are marked as C2; Addenda 2, which is number 63, testimonials, C3; and Addenda 3, which is 64, testimonials, 65, letter from Dr Skinner dated 29 August, C4.

MR ATHERTON: Thank you, sir. In light of my explanation of the case to you yesterday introducing the preliminary issue, I do not propose to say anything more by way of opening of a background to the case. I am aware that the Panel has now had an opportunity to read the main Panel bundle and the addenda items. I propose, therefore, to call Dr Akintewe straight away but, before doing that, there are two further documents that I would invite you to receive. The first is a full CV for Dr Akintewe. *(Same handed to the Panel)*

THE CHAIRMAN: We will label the CV, C5.

MR ATHERTON: The second, I am grateful my learned friend for preparing a bundle of specific documents to which Dr Akintewe has referred in the addendum to his report. In light of your determination yesterday and, on reflection, it has been felt on both sides of the room that it would in fact be helpful for you to have what we were speaking of yesterday as the addendum to Dr Akintewe's report which you will see merely identifies from Dr Skinner's own documents the patients to which Dr Akintewe has referred where he has been able to say that thyroxine has been prescribed notwithstanding a normal thyroid chemistry and those patients who he has identified from those documents as having been treated with Armour Thyroid. I understand that my learned friend has bundles of these documents available.

MR FOSTER: Sir, yes, indeed. *(Same handed to the Panel)*

THE CHAIRMAN: We will call this C6.

MR ATHERTON: With your permission, sir, I call Dr Akintewe.

THOMAS AKINTEWE, sworn

THE CHAIRMAN: Good morning, Dr Akintewe. Please sit down and make yourself comfortable. Draw yourself more or less towards the microphone so that we will be able to hear you clearly. My name is Dr Hester, I am the Chairman of the Panel, the other panellists on my left are Dr Jeffries, medical Panellist, and on my right Mrs Pond, a lay Panellist. The gentleman on my right is the Legal Assessor, Mr Ince, who is here to guide us through points of legal nicety and on my left is the Panel Secretary, Ms Kramer. Part way down the room you will see Dr Skinner and his legal team, in particular Mr Foster. Opposite Mr Foster is Mr Atherton, the barrister for the GMC. The lady on your immediate right is taking copious shorthand notes of the occasion so it is very important that you speak clearly and distinctly so that in particular she can get a good record of everything that takes place.

First of all Mr Atherton will ask you some questions.

Examined by MR ATHERTON

Q Dr Akintewe, the Panel has just received a copy of your *curriculum vitae*. Can I ask you just to look at it, please? We can see that you are Dr Thomas Akintewe.
A Yes.

Q You are currently consultant physician endocrinologist and diabetologist at the BMI Highfield Hospital in Rochdale?
A That is correct.

Q You have held that position since 1996?
A Correct.

Q You graduated MB ChB in July 1971 from the University of Aberdeen?
A Correct.

Q MRCP November 1977?
A Yes.

Q A Fellow of the Royal College of Physicians of Edinburgh, November 1988?
A Yes.

Q You have set out in your CV your various previous appointments since your first position as a House Officer in Aberdeen in August 1971?
A *(The witness nodded)*

Q You have summarised your general medical experience: 35 years of internal medicine both in the United Kingdom and in Nigeria?
A That is right.

Q As a consultant since 1984 with specialty experience in medicine and a sub-specialty experience in diabetes and endocrinology?
A That is right.

Q You have been the lead author of the publications listed on page 6. Is that correct?
A Correct, yes.

Q On pages 7 and 8 you have set out your research activities. On page 8 you give some detail as to the international conferences that you have attended in the course of the last six years or so.
A Correct.

Q On page 9 you set out your teaching experience, administrative experience and Societies of which you are a Member?
A *(The witness nodded)*

Q Dr Akintewe in, I think, September of this year you were asked by the General Medical Council to review documentation that had been compiled by Dr Skinner pursuant

to conditions that were imposed upon his registration with the General Medical Council in 2007. Is that right?
A Correct.

Q You have prepared a report which is dated October 2011 which sets out the results of your work in that respect. Is that correct?
A That is correct.

Q The Panel has received a copy of your report and we can see that, very properly, you have set out the background in a short paragraph followed by the instructions that you received. In paragraph 5 of your report you record the conditions upon Dr Skinner's registration; similarly in paragraph 6 and 7. Under the heading of "Issues to Address" you say:

> "I should report as to whether in my opinion Dr Skinner has complied with conditions 5, 6 and 7…previously imposed by the [Fitness to Practise] Panel."

We can see that you reviewed the cases of 662 new patients and then you set out the questions that were put to you by the General Medical Council for your opinion. Those questions were these:

> "Is there evidence of the referral of a new patient by a fully registered medical practitioner?
>
> [Second]: Is there evidence that Dr Skinner has communicated his diagnosis and suggested care plan to the patient, to his or her GP and any other referring medical practitioner, and that this was done prior to initiating or varying any treatment regime?
>
> [Third]: Is there evidence in the logbooks of the reasons for the consultations with new patients?
>
> [Fourth]: Is there evidence in the logbooks of the reasons for any prescribing outside UK recommended guidelines in respect of all patients?"

You then record the documentation that was made available to you, that being several Lever Arch files labelled A to H and log books, also labelled A to H.

Then you set out your opinion. With regard to the first of those questions you say:

> "Yes. All the new patients seen by Dr Skinner were referred to him by registered medical practitioners."

In answer to the second you say:

> "Dr Skinner wrote and communicated his diagnoses to the GPs, and he suggested care plans to the GPs. There is no evidence that he

> wrote separately to the patients. He must have communicated his impressions to the patients during consultations. This was done prior to initiating or varying treatment regimes. When a prescription was given to the occasional patient before writing, he did say that those patients should not start treatment until they had seen their GPs."

In answer to the third question you state:

> "The reasons for the consultations were given in the Lever Arch Files, but not in the logbooks. I note the reasons given, but may not necessarily agree with the concept of these reasons."

In answer to the fourth question you say:

> "Dr Skinner's reasons were given in the Lever Arch Files. He believed that clinical features should transcend the conventional thyroid chemistry. He often quoted that the conventional thyroid chemistry is 'a good servant but a bad master'. These opinions influenced the way he treated his thyroid patients."

Then you make an observation about some of the Glasgow patients.

You were then asked whether you had any concerns arising out of the documentation. You inserted a paragraph in your report setting out the concerns that you had. Is that correct?

A That is correct.

Q In your conclusion you state that Dr Skinner has complied with conditions 5, 6 and 7 imposed by the Fitness to Practise Panel in 2007:

> "One may not agree with his views on treatment of hypothyroid patients with normal thyroid chemistry, nor with his use of Armour Thyroid.
>
> I note that the letter from the GMC said that my conclusion should answer the key question as to whether the standard of care provided by Dr Skinner fell below that expected of a reasonably competent doctor of the same discipline and grade.
>
> I may not always agree with the types of treatment provided by Dr Skinner, but believe that the question of his competence is up to the Panel to decide."

Your report was signed and dated with a Statement of Truth on the 6 October of this year.

I think subsequently you were just asked to identify from the documentation those patients in respect of whom you had been able to see that thyroxine had been prescribed notwithstanding a normal chemistry and also those patients to whom Armour Thyroid

was prescribed and you have provided a list of references. Is that correct?
A That is correct.

Q Is there anything else that you would want to add to your report or can you confirm that it represents your opinion for the purposes of this hearing?
A I can confirm that it represents my opinion.

MR ATHERTON: Thank you very much.

Cross-examined by MR FOSTER

Q Just a very few points, Dr Akintewe. In relation to the patients who were prescribed thyroxine you say in spite of having normal thyroid chemistry you have identified them and they are detailed in the Addendum 20 of those. I hope that a small bundle which contains all the relevant patient records has arrived, it is C6. If it has not a copy will be handed to you in a moment.
A Yes.

Q Have you got that?
A Yes.

Q Patient 1. Can you go to that patient, please, it is page 1.
A Sorry, what did you want me to do?

Q If you go to that patient, please. The records begin at page 1. Have you got that?
A Yes.

THE CHAIRMAN: My records begin at page 2. It is the back of the second…

THE LEGAL ASSESSOR: There are two numbers. There is the old Addendum numbering typed and there is this bundle numbering which is handwritten on the left hand side, so it is page 5 I think is the one you are referring to.

MR FOSTER: Can I jut check that we are singing from the same hymn sheet. *(Pause)* This patient's records begin, the numbering to which I am referring begins on the far right hand bottom corner page 1 and on the left hand you will see page 5.

THE CHAIRMAN: That is right, in a circle.

MR FOSTER: That is right, sir, yes.
A Okay, yes.

Q I have taken you to that page just so you can refresh your memory about this patient. What you have suggested here, this is in the Addendum, is that the TSH in this patient was 0.8. Yes?
A Yes.

THE LEGAL ASSESSOR: Mr Foster, for the benefit of the lay Panel member perhaps you could ask what TSH means.

MR FOSTER: Yes. Would you like to help about that?
A TSH is the hormone produced by the pituitary, thyroid stimulating hormone.

Q Thank you. If you go to page 3 in the bottom right hand corner. I think this is where you might have got that comment from. Third paragraph down, you will see in this letter from Dr Skinner back to the referring GP, at the end of that paragraph:

> "…indeed the TSH is more than three times the average for healthy patients which runs at 0.8 on account of the skewed distribution of TSH values."

Right? Can you see that?
A Right, yes.

Q I think you have concluded from that that this patient's TSH was actually 0.8. You can see that the letter says that the TSH is three times that.
A Okay. *(Pause)* Right.

Q I think that the doctor is trying to satisfy himself that there is no other reference to a TSH of 0.8 anywhere else in the records.
A That is probably true; yes.

Q I think you accept that your comment on the Addendum stems from a misreading of this letter, does it not?
A Where I said TSH 0.8?

Q Yes.
A With what you have just said it looks as if it is three times the 0.8.

Q Right.
A That was termed the normal.

Q The suggestion that there is normal TSH here is not right, is it? We can see what the TSH was by reference to page 3.
A Yes, 0.8. That is an error that you have just pointed out.

Q That is an error on your part?
A Three times of 0.8 will still be a normal TSH.

Q We can argue about that. What you are referring to there is the US as opposed to the UK value, is it not? There is a difference between these two things.
A No, we are all using the same value all over the world.

Q I will come back to that point because it may be that that misunderstanding lies beneath a number of your comments. Just on this short point, in fact the TSH here was over three times what you thought it was. Yes?
A True, but am I allowed to add that the standards we use, three times 0.8 will be 2.4; it is normal up to 5.

Q We will come back to that point. Patient 2, please. The records for this patient begin at page 4, bottom right hand corner. If you could go to page 6 you will see ---
A Of the handwritten documents?

Q No. Whenever I refer to page numbers I am going to be referring to the bottom right hand corner. Okay?
A Page 6, okay.

Q That is page 10 of the originally paginated notes.
A Right.

Q Your comment here was normal thyroid chemistry. Yes?

THE CHAIRMAN: The comment on the very first page of the bundle under Patient 2 is what Mr Foster is referring to, normal thyroid chemistry.
A Yes.

MR FOSTER: I do not want to take you by surprise, look anywhere in that patient's records that you want but can you see now any justification for that comment?
A That I made or I just made ---

Q What is your justification for saying normal thyroid chemistry?
A I shall read this paragraph:

> "The diagnosis which should of course be made on clinical grounds is nevertheless consonant with her thyroid biochemistry where the TSH is nearly three fold the average for healthy patients TSH values which runs around 0.8 on account of the left sided skewed distribution of TSH values and the free thyroxine level is lowish albeit within reference intervals."

Q Right. Is your point here the same as in the previous patient, namely that you think that three times 0.8 is still normal?
A Yes.

Q Is that the point you are making?
A Also the author of this letter himself says "albeit within reference intervals".

Q Right. Again, the difference between us is what the right reference interval is. Yes?
A Well, I work on this is of internationally accepted reference intervals.

Q Yes, you have said that and I have said that we will return to that. Patient 4. That patient's records begin at page 12 bottom right hand corner. On page 13 bottom right hand corner we see the letter from the GP which refers to normal T4 and TSH. I would just like to be clear: is that your justification for saying there was a normal thyroid test in this case?
A The values quoted here for 29 July 2010 are normal.

Q Can you give us a page number?
A Page 14. Page 14, Dr Amy Leckie.

Q Yes.
A First paragraph.

Q Yes.
A

> "Her TSH was done on 29 July 2010 and was 2.53."

2.53 was normal.

Q I think you are talking about the wrong patient, doctor. I have moved on to Patient 4.
A Is that 14 and 10 on the right hand side?

Q No. If you go to page 14 on the bottom right hand corner.
A Yes. Yes.

Q That has got 55 handwritten in the middle.
A Okay.

Q Have you got that? I will give you a chance to read the letter.
A *(Pause)* Page 13 on the right hand side and page 14, are those the letters?

Q No, page 14 bottom right hand side of the page.
A Right.

Q Yes?
A Yes.

Q You will see a letter there from Dr Skinner to the GP.
A Yes.

Q It comments there about thyroid chemistry. So far as you can work out, is that the thyroid chemistry which emerged from tests commissioned by the GP at the time of the referral?
A I will have seen the comments by the GP on page 13.

Q Yes.
A Which says:

> "I enclose her most recent blood tests which does include a normal T4 and TSH."

Q Yes. Your comment about the normal thyroid biochemistry comes from what the GP said?
A Yes.

Q That is all I am trying to establish.
A Yes.

Q Good.
A I am not sure we have a figure for this.

Q I could not find one but perhaps it does not matter in the light of that comment.
A Okay.

Q Let us move on to Patient 5 whose notes begin at page 15 of that bundle, bottom right hand corner. Your comment here was simply ---
A Sorry. I have got 14 and 16, I do not have 15.

Q Are your pages not double sided?
A Oh, okay.

Q These notes begin at page 15 for this patient.
A Okay.

Q Your comment here was the TSH is 2.9. If you go, please, to page 16, just over the page…
A Yes.

Q …you will see that the TSH on the 13 August was 2.9, was it not?
A Yes, yes.

Q Earlier it had been higher in June and higher in December 2007. Yes?
A Yes, and I would like to point out that in the United Kingdom and elsewhere those values are normal.

Q Right.
A They are normal up to 5.

Q Patient 7, please.
A I am sorry, before we actually leave that page, the actual thyroid hormones, not the TSH, the figures 14.9, 13.4 are also normal.

Q Yes. Patient 7, please. The records begin on page 23.
A Yes.

Q Your comment here was normal thyroid tests. If you go to page 25 you will see the letter back to the GP from Dr Skinner.
A 25, okay.

Q Third paragraph of that letter, second sentence:

> "There is a paucity of FT4 readings but she has a TSH reading well above the average for healthy patients which runs around 0.8…"

Okay?
A Yes.

Q In the light of that comment what is your justification for saying normal thyroid tests?
A I think we are probably agreed that we are using two different reference ranges.

Q That is a slightly different point, is it not? I am asking you at the moment what your justification is for saying that there are normal thyroid tests in this patient. Is the TSH level or any other index of thyroid biochemistry detailed in the notes that you have seen here?
A I could see no abnormal figure here, there was no figure given.

Q Right. Patient 11, please. That patient's records being on page 37.
A Sorry, 37?

Q 37.

MR ATHERTON: I am sorry to interrupt my learned friend. If it is being suggested that there is an abnormal figure there, I wonder if that might be put to Dr Akintewe.

MR FOSTER: I am asking him his justification for saying that there was a normal figure there. Patient 11, please. Records being on page 37.
A 37, yes.

Q Your comment here was normal TFT.
A Well, the GP also says here these have all been normal.

Q Go on.
A With the exception of a slightly elevated TSH of 6.4.

Q The GP is saying it is elevated at 6.4?
A Yes, but all the others have been normal.

Q Patient 12, please. Records begin at page 41.
A 41, yes.

Q Your comment here was again normal TSH.
A Well, it says here he has had five checks of his TSH ---

Q You are looking at page 42, I think, now are you not?
A Yes. The range of TSH 0.9 to 1.26 were quoted.

Q What is the FT4?
A It seems to be low.

Q What about the thyroxine?
A T4 came back with a reading of 8 which is normal, says the GP.

Q Do you agree with that?
A Well, different laboratories have different ranges for free thyroxine.

Q It is low, is it not?
A It depends on the laboratory. It can be marginally low in some laboratories and not low in others. The reference range given by different laboratories for free thyroxine and free T3 vary in the laboratory.

Q Right.
A What is useful here, since we did not have reference range is the TSH over five year periods which were normal, according to the GP. In fact, the opening paragraph says he has had consistently normal TSH.

Q Normal TSH.
A And normal free T4. Those were the words of the GP.

Q The evidence here is that there was a low or arguably low free thyroxine, was there not?
A With the permission of the Panel I would like to say figure 8 is meaningless. It depends on the reference intervals given which was missing here, so all I had to go by was the GP's comments about TSH over a five year period and one single free T4 which was – usually where you have got free thyroxine the TSH is raised. That is an established observation in most cases. With a finding that this patient's TSH is normal for five years one will presume his free thyroxine was not low. There are some rare exceptions where may not get normal or low TSH with normal thyroxine. I do not think we need to worry about that here because over a five year period he has been deemed normal by his GP.

Q The GP has referred to Dr Skinner presumably for some purpose?
A Yes and I have seen some of the comments over the whole records. I am not sure what interpretation you wish to put on that.

Q One interpretation that might be put is that this is a patient in respect of whom the GP has said on conventional analysis of thyroid function and other thyroid biochemistry I cannot see anything dramatically abnormal but there is something the root of which is in the thyroid which needs to be sorted out and Dr Skinner is the man to do it. Yes?
A Do I need to comment on that?

Q Let us move on to another patient. This returns to the point which was made earlier about reference ranges. It is patient 14 and the records begin at page 48.
A Right, yes.

Q Your comment again is normal TFT. If we go to page 51 ---
A Excuse me, let me just check. *(Pause)* Right. I hope we see the comments of the GP. Fortunately, yes, we have performed a number of TFTs over the years and never biochemically and clinically did we see evidence of a thyroid gland disease, ie normal.

Q The passage I was going to take you to was on page 51. This is the letter back from Dr Skinner to the GP. If you go three paragraphs up from the bottom we can see a

paragraph which perhaps crystallises a large part of the debate between us.
A Yes.

Q

> "The findings are consonant with his thyroid chemistry where the TSH indeed has been notably above the new upper value of the TSH 95% reference interval which has been set at 2.5 by our colleagues in the USA and I think there is a very good case for thyroid replacement."

You disagree that there is a good case for thyroid replacement here within the established orthodoxy. Fair?
A I must say here that we have guidelines, guidelines for the practice of thyroid medicine which all the doctors in the NHS work with. The normal value of TSH that we are given is 0.4 to 5. Even if it is more than 5 many leading review articles say that if TSH remains in single figures, ie even more than the upper limit, that you do not necessarily give thyroxine replacement. The only situation where you might give thyroid replacement will be if the TSH is in double figure plus or minus very high anti-thyroid thyroxine based antibody treatments, so even when the TSH is 6, 7, 8 many review articles say that there is no benefit whatsoever in giving thyroxine replacement.

Q NICE has repeatedly refused, have they not, to promulgate guidelines on this matter? There are none.
A There are review articles from several other sources.

Q The guidelines you are referring to are not from any authoritative body, are they?
A Oh, yes, *The Lancet*.

Q As you have just indicated, they are suggestions in papers. The bodies charged with the responsibility for promulgating guidelines have refused to lay these down in stone, have they not?
A Well, I do not accept that.

Q Where is it?
A I have not brought it with me but it is established there have been some major reviews in connection with some clinical hypothyroidism, ie raised TSH and normal thyroid hormone. The consensus of opinion is that if TSH is raised beyond 5, provided it is still in single figures, you do not necessarily prescribe thyroxine but you will prescribe thyroxine when TSH goes into double figures and the thyroid antibody level is high, ie autoimmune thyroiditis. These are clear working guidelines throughout the United Kingdom.

Q We will return to that issue because it is important. I would just like to look at the remainder of the patients that we have to examine and we will return to the general questions of guidelines and where you are getting your assertions from. We had got to Patient 14.
A Patient 14. What is the number on the right hand side?

Q We have dealt with Patient 14 and we are going to move on now to Patient 15.

That patient's records begin at page 53 in the bundle.
A Right.

Q Your comment here was normal TFT again.
A Yes.

Q Page 55, so that is 389 in the middle of the page ---
A Before we leave that, page 54…

Q Yes?
A "…despite being biochemically euthyroid" means the thyroid chemistry is normal, says the GP.

Q If you go to page 55…
A Right, 55.

Q Third paragraph.
A Yes.

Q You see this:

> "Thyroid chemistry is consonant with this diagnosis particularly with respect to the new upper value as suggested by our colleagues in the US of the TSH following a re-sampling of the population."

Do you know what is being spoken about there?
A Do I know what?

Q Do you know what is being spoken about in relation to the new upper value?
A The values that I am aware of internationally are as I have specified. There is no new values saying 2.6 is abnormal by general consensus of views by thyroid physicians. 5 is what UK physicians work with and even if the Americans think it is 2.6 we are working in the United Kingdom and bound by the United Kingdom authorities' views and the values laboratories all over the United Kingdom give as their normal reference values.

Q The question I asked you was are you aware that there has been a revision of the upper reference interval in the US?
A I do not think so.

MR ATHERTON: I am sorry, that really is not a very fair question, it should be more specific. If he is being asked about a particular publication it should be identified, in my submission.

MR FOSTER: Are you aware of a debate in the US about this at all?
A I do not think the majority of views in America is any different from United Kingdom or Australia or Germany. The values given are practically the same in all these countries. There is no new reference interval in thyroid medicine that says 2.6 is abnormal.

Q Let us jump to Patient 19.
A I would like to say that, please, with all the emphasis that I can muster.

Q Patient 19, please. Records begin at page 70.
A 70.

Q You have commented that the TSH was 2. In fact, if we go to page 71 and go a couple of inches down from the top of the page…
A 71. Okay, yes. TSH 2.22.

Q We can see "Serum TSH 2.00".
A Absolutely normal and free thyroxine of 9.4. Absolutely normal. All the laboratories in the United Kingdom will give those value as normal, I like to submit.

Q Can we turn to ---
A Before we leave that subject, is that accepted in this room? That all the laboratories in the United Kingdom will accept those values 2.22 TSH and free T4 of 9.4 as normal? We are working in the United Kingdom and bound by the United Kingdom figures.

Q Just look at the bottom of page 71 before we move on.
A Right.

Q We have got there right at the bottom above the "Yours sincerely" two references for the serum TSH and the serum free T4 and then what appear to be reference intervals.
A Yes.

Q Do those reference intervals seem to you to be right or do you have other figures in mind?
A 0.30 to 5.6 seem consistent with some of the ranges given by several laboratories and here we are with a free thyroxine of 7.5 to 21 and earlier on you were telling me 8 was low. This reference interval here says 7.5 to 21. I did submit at that point that reference values varies with different laboratories and this is a good case to illustrate my statement.

Q The patients on Armour Thyroid you have identified twelve of them.
A Okay.

Q It is agreed, I think, that there is a place for Armour Thyroid and the treatment of some thyroid complaints. Yes?
A No. It is not in BNF and where that is my Trust would not allow me to prescribe it. The PCTs in the place of practice will not allow me to prescribe it. It is not licensed and there have been comments, there is a comment by one of the of the eminent thyroid physicians that I put my reference that it is not appropriate in the UK.

Q That is a rather different matter for it not having a place. At the November 2007 hearing both Professor Weetman and Dr Wyn said that they themselves used desiccated thyroid preparations. You have just not used it yourself?
A The instructions in most hospitals, in fact all hospital in the UK, is that the

constituent of Armour Thyroid, which contains both T3 and T4 and some other such that is unknown, make it a not so good idea to use it. We do not know the compositions of thyroid or Armour Thyroid. *(Disturbance from the public gallery)* Excuse me, I am constantly being disturbed by comments from behind me.

MR ATHERTON: Sir, may I say that it really is quite inappropriate for members of the public to be passing comment in the course of this witness's or any witness's evidence or to be pulling faces or otherwise demonstrating their feelings. It is wholly unacceptable, in my submission.

MR FOSTER: I, of course, agree, sir.

THE CHAIRMAN: I was studiously avoiding looking at the members of the public but please do endeavour one hundred per cent to keep your feelings hidden within yourselves. We know that you have strong feelings about this case but it is not going to help Dr Skinner's cause and it certainly will not help the Panel to arrive at the appropriate conclusions, whatever they are, if they start to be sidetracked by untoward noises or face pullings or contortions or whatever within the members of the public, so please do be very careful.

MR FOSTER: Thank you, sir.

THE WITNESS: May I just make a statement? I have said that the practice in Britain is practically the same in everywhere you go and I am aware that there is no Trust in the UK and no PCT in the UK will allow the GP or a hospital doctor to prescribe Armour Thyroid. That is a statement of fact and the Bible we all use, the *British National Formulary*, does not have Armour Thyroid in it.

Q It may be that you are trying to assert to the Panel that the use of drugs which do not appear in the BNF is, for that reason, an inappropriate thing to do. If you are saying that I think you would probably agree that is too wide a generalisation. Yes?
A I am not sure what you intend to say by that statement.

Q By definition something which is unlicensed does not appear in the BNF. The BNF is a list of licensed preparations, is it not?
A Yes.

Q Physicians in all specialties very regularly use unlicensed preparations? For example, if we go to paediatric medicine there are very many drugs routinely used in paediatrics which are not specifically licensed for the treatment of children.
A Routinely is a very dangerous word. That statement is not correct.

Q It is the case, is it not, that many of the drugs in the paediatrician's armoury are not specifically licensed for use in children?
A I would not comment on that because I am not a paediatrician and we are not dealing with paediatric cases here.

Q Let us get more general, then, before going back to the specific cases that we have addressed. In your report you have specifically said that Dr Skinner's approach in

relation to the prescription of thyroxine in euthyroid patients and the prescription of Armour Thyroid is unorthodox. Yes? That is what it comes to.
A I did not use the word unorthodox.

Q You did not use that word but that is what it comes to.
A I would like to say that I am a physician who knows that I would not be allowed by my Trust or my PCT to prescribe Armour Thyroid.

Q That is a matter for your own Trust ---
A I will also not be allowed to prescribe thyroxine replacement for patients with accepted normal thyroid.

Q That is a matter for your Trust.
A No, many Trusts in the UK.

Q If you have such guidelines we would love to see them because we are not aware of any. You yourself do not hold yourself out as an expert in thyroid medicine, do you?
A In as far as endocrinologist I am a kind of expert but I have not spent the whole of my life only on thyroid medicine and other endocrine subjects.

Q Your CV does not have any publications in the area of thyroid medicine and your state of research does not have any thyroid medicine on it?
A Correct.

Q Do you agree that the clinical presentation of a patient is really rather an important measure of what a doctor should do?
A Clinical presentation is according to what you just said, but we are in an area of evidence-based medicine that you should have evidence for whatever clinical decision you make and we are all bound by that. As a medico-legal expert we also work within that conditions and limitations. If I prescribe thyroid medicine to somebody with normal thyroid figures and there is an issue of reactions that may be ascribed to unnecessary thyroid, the lawyers will get me.

Q That is the concern, is it?
A I am talking about the importance of evidence-based medicine. You are meant to limit yourself to what laboratory figures you have to back up your clinical impression, otherwise there is no point in doing laboratory tests.

Q Have you annexed to your report the evidence base which you consider is relevant?
A I do not annex. In fact, my report concentrates on the conditions that I was given and instructions that I was given and those are the conditions 5, 6 and 7 with a little question added to that which I also answered. Now, I think it is a bit surprising that you should spend the length of time you have on not the conditions, the main conditions of the instructions, but on what is considered as an accessory instruction, as it were. In fact, I looked at the instruction and said should I answer this or not? I did up to a point but refuse to give an opinion on competence as a result of that. You could see that I did say that.

Q That is a very helpful comment and perhaps it can shorten matters now.
A We seem to have spent a lot of time on not the main requirements of my instructions.

Q That is a very helpful comment. Perhaps we can shut this down very quickly, then. The concerns which you expressed…
A Yes.

Q …were essentially of what I have described as unorthodoxy. Yes?
A Well, it is not even my concerns. I backed it up by what some eminent physicians in the United Kingdom said.

Q All right. We will have to go back ---
A Professor Tofts and Professor Williams.

Q We will have to go back, then. Have you annexed to your report the material evidence base which you say ---

MR ATHERTON: I am sorry but my learned friend knows perfectly well that that is not annexed to the report. This is a teasing cross-examination and an unfair one for the reasons that Dr Akintewe has just explained. It is my learned friend who has cross-examined all this material into evidence before you, the GMC has not led it, and if he is asserting that there are documents of this type then, to be fair to the witness, they should be put to him. This sort of fishing expedition in cross-examination on the report is simply unfair.

MR FOSTER: It is not a fishing expedition at all. The doctor has said that he relies on the evidence of these eminent clinicians and I was just checking with him that the eminent clinicians to whom he refers are the ones whose papers are annexed to the report.

THE CHAIRMAN: With respect, your question was not entirely clear on that point but thank you for clarifying it. It is better just to concentrate on what relevance his actual annexes have to this question.

MR FOSTER: *(To the witness)* Are the concerns which are expressed in the report concerns which, to your mind, are justified by the literature which you have annexed to your report?
A The answer to your question is straightforward. The practice of medicine in the United Kingdom is based on evidence and to be able to work on evidence you work with figures, reference figures, it is as simple as that. If you ask any doctor in the NHS in the United Kingdom what are the normal reference values they will tell you between 0.3 to 0.4 to between 5 to 5.6. Now, that is what they are supposed to work with and even if it is 8 we still do not give thyroxine replacement. We know that TSH can be clinically raised but they have also done very many studies to find out whether there is any benefit in giving thyroxine replacement for a TSH of 7 or 8 and the answer is no. I happen to have seen very many review articles on that. The agreed consensus says but if it goes into double figure, ie 11, 12, 13, 14 and particularly if the thyroid antibody level is raised, ie suggesting thyroiditis, you now have good indications for treatment. This is an accepted practice. This GP has referred this patient to Dr Skinner, who is allowed to

prescribe thyroxine themselves but they would not do so because they feel that their PCT would jump on them if they do. This is why some of these GPs refer patients to the person who they believe would prescribe it. This is why I did not want to answer your question when it was asked earlier, why did they refer to Dr Skinner.

Q I will have another go at asking the question.
A Because the GPs know they can easily write a prescription for thyroxine, they do so every day of the week. The only reason they refer somebody they thought was hypothyroidic to Dr Skinner is because they know they are not allowed to prescribe outside those reference intervals. That is the fact.

Q I will have another go at asking the question. Annexed to your report are several papers. Will we find in those papers, in your view, the justification for the views about the legitimacy of prescription that you have just outlined to the Panel?
A What you will find in the papers I attached were merely statements from respected colleagues, professors, who feel that there is no logical reason for prescribing thyroxine replacement to somebody who has normal thyroid chemistry.

Q Normal thyroid chemistry. The reference intervals that you have given are the reference intervals which are applicable to asymptomatic patients, are they not?
A The laboratory figures for normality, it does not say whether symptomatic or not symptomatic. We send a sample to a laboratory and the laboratories now have co-ordinated their reference ranges to tie in with what is the guide consensus. The figures I have quoted are figures that the laboratories will give you as normal values, just as haemoglobin and serum iron and other things have normal values. I mean, we are working on the business of these figures that the laboratories produce.

Q We have, in the records that we have looked at this morning and in a large number of others, indications of GPs who have referred patients to Dr Skinner because they think that there is some clinical justification for the prescription of thyroxine or Armour Thyroid in circumstances where it might not usually have been prescribed. Yes?
A Sorry, I cannot comment on that.

Q You cannot comment?
A I have said enough to make that question totally unnecessary.

Q In relation to the concerns which you have expressed you were not prepared to go on and say that those concerns were so concerning that they should reflect on Dr Skinner's fitness to practise?
A It is…

Q It is not your business, you say?
A Not a question of business. In terms of competence of a doctor I was not asked to do that, especially when the case is coming up to the GMC review and the GMC Panel. My duties for that report writing were quite specific and I stuck to those duties.

Q You looked at a cohort of 662 patients?
A Yes.

Q You have identified, out of that 662, 32 patients in respect of whom you have concerns that they were not being treated in a way which you would regard as conventional. Yes?
A *(The witness nodded)*

Q You have not had the benefit of seeing any documents which indicate what happened to these patients subsequently, no follow-up reports?
A True.

Q There is no indication anywhere in the 662 that you looked at of any patients having come to harm. True?
A There is no comment whether they come to harm or not. The follow-up of these patients' conditions were not documented in the papers, in the records, I saw. They prescribed these medicines and they are told to go away and come back in two months or three months. I have no sight of any comments on what they were like after the prescription.

Q You would have got an idea of what they were like as a result of Dr Skinner's treatment had you had an opportunity to read the various patient testimonials which have been produced. Lots of those have been seen by the GMC. Have you been given an opportunity to read those?
A No.

MR FOSTER: No. Thank you very much.

THE CHAIRMAN: I wonder, I am going to come back to you but I wonder if it would be reasonable to have a mid-morning break now because Dr Akintewe has been there for over an hour and I think it would be fair to him as well as everyone else to have a comfort break and mid-morning break. Shall we resume at 25-past?

THE WITNESS: That is fine.

THE CHAIRMAN: During that time, of course, Dr Akintewe, you cannot speak to anyone about the issues that are currently before us. We will look after you.

THE WITNESS: Thank you.

(The Panel adjourned for a short time)

(In the absence of Dr Skinner)

THE CHAIRMAN: Before we start, while it is in my mind, can I ask the members of the public to make certain when you leave the room you take all your belongings with you, we do not want to be responsible for anything that is lost. Thank you.

MR FOSTER: Sir, I apologise for Dr Skinner's absence. He was here a moment ago and I presume that he will be on his way very shortly.

THE CHAIRMAN: I passed him the corridor.

(Dr Skinner entered the room)

THE CHAIRMAN: Yes, Mr Atherton.

Re-examined by MR ATHERTON

Q Dr Akintewe, you were asked about the importance of the patient's presentation for the purposes of assessing the patient and the diagnosis and prescription of thyroxine. Can I take you to page 6 of your report, you have it there. It is our page 574. Under the heading of concerns arising, you refer there to having identified in the documentation some patients having irritable bowel syndrome, depression, myalgic encephalopathy, chronic fatigue syndrome and obesity being given thyroxine in spite of a normal thyroid chemistry. Are those conditions such that they would generally be treated with thyroxine?

MR FOSTER: I am not sure how this arises out of cross-examination.

MR ATHERTON: I explained how it did. My learned friend cross-examined about the importance of clinical presentation and the importance of assessment, that is the very basis of Dr Skinner's case, that it does not matter what the blood chemistry says, it is the assessment clinically of matters and this question arises from that.

THE LEGAL ASSESSOR: Perhaps the question ought to be asked.

MR ATHERTON: Can you help us with that, Dr Akintewe?
A Yes. Those conditions you mention, even simple tiredness, simple depression, simple obesity, so many things given general symptomatology that can actually mimic under active thyroid. This is a situation where clinicians usually say Let us see whether blood tests will help one way or the other. ME, for instance, there is no diagnostic test for it, there is nothing, blood test or whatever to say this is serious depression. There are so many conditions and some of those you mention that gives almost similar pattern of presentation in a clinical way. Obesity is one area where the patient often looks hypothyroidic and you need to be able to separate that from genuine under active thyroid that is associated with obesity because under active thyroid gives you weight gain but then many people are weight gain without thyroid dysfunction. I do not know if that has answered your question.

Q Yes, thank you. You stated during your evidence that if you were to prescribe outside accepted practice in the NHS and there were to be complications then the lawyers would be after you. What sort of complications could arise in cases of prescribing thyroxine inappropriately?
A Well, there are issues of bone, for instance, that if one… This medicine it is quite powerful medicine, it works on your metabolism. Thyroxine can speed up all your metabolism, therefore if you are given thyroxine unnecessarily there is an inherent fear of the heart, for instance, being affected because it is being over stimulated, you might get irregular heartbeats. Even the patients who definitely have under active thyroid sometimes when you give thyroxine they complain of palpitation merely because you are altering the metabolism faster than it has been. Those two areas, bone resorption and

cardiac irregularities, are some of the things that can be affected by inappropriate thyroxine replacement.

Q What is the usual practice in terms of assessing whether those complications are arising?
A Most thyroid patients, particularly the ones that got under active thyroid, the replacement therapy is for life; you are on thyroxine replacement for life. On this basis patients should be followed up maybe once a year or twice a year and this is where you check that the patient is okay. Also you check that the level is not too much because sometimes it comes back too much and you have to reduce the dose. Sometimes it is not enough, you have to increase the dose.

Q Thank you. In terms of guidelines and practice you spoke of the importance of following UK practice and guidelines and it was put to you that there may be publications in the United States that give different advice about these matters. What is your practice in terms of looking at international papers or research or guidance?
A To be honest, these levels do not vary that much between countries and this is a fact. After all, Americans go to the UK and the UK residents go to America. I am not convinced that the laboratories there have completely different values from the UK. The biochemistry award does not just stop at thyroid, many of the other conditions are using the same levels, may have the same reference levels. When we diagnose haemochromatosis here the diagnosis will be on the same levels and the same is true of thyroid medicine, Addison's disease, mainly we are practising practically the same medicine: America, Australia, Germany, anywhere.

Q You were asked some questions about patient number 11 on page 37.
A Page 37. Is that at 61?

Q Yes.
A Yes, okay.

Q I think that it was being put to you that the levels were raised and it may be that I have just mis-noted the page number, I think it was relating to patient number 11.
A Yes, page 61 or 37.

Q I am referring to the bottom right hand corner pagination, page 61/page 37.
A Yes.

Q This was the patient you had made a short note it was a normal TFT.
A Yes.

Q I think it was being suggested to you that it was slightly raised. Is that to your recollection?
A Yes, I have got it in front of me and the statement that guides me on that is the statement that these have been normal, with the exception of a slightly elevated TSH of 6.4. I would like to submit that if the patient has a TSH of 6.4 and every free thyroxine and the free T3 are normal, I will not dream of giving that patient thyroxine.

Q I have no other questions for you but Panellists may wish to ask you questions.

A Thank you.

THE CHAIRMAN: I will introduce the Panel members more fully to you if they do have any questions for you. I will turn, first of all, to Dr Jeffries. Dr Jeffries is a medical member of the Panel.

Questioned by THE PANEL

DR JEFFRIES: Hello, Dr Akintewe. Can I just clarify a simple thing with you over your CV on page 2? We have got the latest one 1996 to the present. Well, it cannot be because you have had all sorts of other appointments between 1996, so would you like to just, for the record ---

A Perhaps I shall explain that.

Q Yes.

A I hope it is clarified there that I was employed by the Pennine Acute Trust for 16 years. When I reached the age of 65 I retired from the NHS. Instead of putting my feet up I decided that I was going to continue with the practice of medicine just because I enjoy medicine and it tops up my pension, so I am registered with a few local agencies over the country. When the Trust needs, as they often do, a pair of hands in the endocrinology laboratory I get asked if I would like to work there. Up until the end of last month I was in Durham and Darlington Hospital doing locum. I do not think that will be on my CV. Before then I was nine months in Bassetlaw Hospital, Bassetlaw and Doncaster Hospital, that was the longest locum I ever did. I did all these locums when the opportunity arises and they are also the NHS hospital practising the consultant medicine in endocrinology and diabetes and ---

Q Yes, that is fine, I sort of get the picture.

A Sorry. I should specify that the Highfield Hospital is a private hospital. I do that in addition to any other thing.

Q Thank you, that is all I needed to know. Medical norms change, do they not? I used to have a normal cholesterol level and then, you know, NICE guidelines came out and suddenly it was abnormal. When I was first in practice 150mg diastolic of mercury was okay, it was borderline, now there would be no question that you would treat it. Is that is what is happening in the area of thyroid disease? Are opinions just slowly changing?

A Thanks for that question. As a physician you will be aware of these changing guidelines. The first thing you said about cholesterol, up to today we have not reached the end of the story there. It used to be a 5, now in the European consensus it is now 4 or less and the feeling is that nobody knows the limits.

Q Is that the same situation with thyroid?

A Well, as I mentioned, as physicians you are aware of the changing, this is why we go through journals and report and internet sources, to be well informed. Some things are changing and some things still do not change often enough. As far as thyroid is concerned, from our laboratories and elsewhere we are still getting the same normal reference range, it has not changed. However, cholesterol has changed.

Q Cholesterol has changed as a result of opinion, expert opinion, research work, trials of life expectancy and cohort studies and so on. That must be happening in thyroid disease and my question is do you detect the potential for a change in opinion?
A I will be the first to react where the laboratories who must be current, the journals, the various medical things on the internet, where they make consistent advice for change where it is pertinent. As for thyroid I can stand up and say there has been no revision of the reference; if there is, the laboratories will soon tell us. They are the ones who test the bloods and issue out report sheets and put their normal range on ---

Q Okay. I am sure you appreciate that what the Panel is trying to do is to not merely determine whether Dr Skinner has complied with the letter of the conditions but whether his practice has been guided by the spirit and intention behind the conditions and what that comes to is patient safety. Can you, from your reading of these records, give us any instance where in your opinion a patient would potentially have been harmed by Dr Skinner's treatment?
A It is difficult for me to comment on the potential harm because the documentation – the format is quite clear, you have got consultation, you have got letter from GP and you get letter to the GP. There is no way. I do not have hospital notes, for instance. I do not have hospital case notes on these patients to be able to form an opinion on their state of health.

Q I am sorry to press you on this.
A Yes.

Q I appreciate you are trying to be fair and to not express an opinion.
A Yes.

Q You have repeatedly stated and given the impression that you would never treat a patient for whom all the laboratory indices fell within the reference range. You have repeatedly said that.
A Yes.

Q You have said in answer to counsel for the GMC that there were potential hazards of over treating with thyroid replacement therapy. I would like to press you and say given that and given the 600 odd patients that you looked at…
A Yes.

Q …you know what their thyroid tests were…
A Yes.

Q …and you know what they have been prescribed?
A Yes.

Q Can you actually tell us how many or any of these patients that would have been harmed by Dr Skinner's treatment? For me, that is what seems to be behind the spirit of the conditions.
A I can support anything I say with one or two people's views. This is Professor Gareth Williams, the Professor of Medicine, it says here at Edinburgh ---

Q Can you just point us to the page?
A I do not know if you have a copy of the reference in the report.

THE CHAIRMAN: It is in the back of your report so what page?
A This is page 814.

Q It is 814 and it is a letter to the BMJ?
A Yes, by Professor Gareth. It says ---

Q One moment.
A Sorry.

Q It is 814 in the bottom left hand corner, it is also 587 in the bottom right hand corner. It starts at he very bottom of the page.
A Yes.

Q In my copy there is a bit of a highlight mark.
A The title is "Distinguishing hypothyroid symptoms from common non-specific complaints is difficult". The conclusion is:

> "In the meantime, giving thyroid hormones to patients who are biochemically euthyroid [ie biochemistry is normal] must remain dubious and potentially dangerous on both scientific and medicolegal criteria."

DR JEFFRIES: We are still no closer to knowing what the dangers are that these patients of Dr Skinner's would have faced, are we?
A Well, as I mentioned, that if you are driving the metabolism of the patient with a chemical like thyroxine on a long term basis there is the possibility that you might suffer from osteoporosis. The other complication is like if you are treating an under active thyroid patient you do not just give the amount of thyroxine that you think they need, you start low dose and gradually work up because it can speed up the work of the heart and cause irregular heart beats. This is another complication that people fear. Unnecessary thyroxine replacement may cause irregular heart beats. Extrapolation is one I am talking about which actually can bleed to death. I think that is what Professor Gareth… He did not say what the dangers are but we, as clinicians, know that those are two areas ---

Q Thank you. In answer again to Mr Atherton, you mentioned conditions that mimic hypothyroidism.
A Yes.

Q You mentioned ME, you mentioned depression and so on. In patients where all their laboratory tests have come back normal with all their investigations and they are still suffering despite normal thyroid function tests, are there no conditions where you would allow a therapeutic trial of thyroxine?
A Thank you, sir, for that very important question. Yes, if your thyroid tests are done and repeated more than once and they are normal I will not give thyroxine replacement. On the basis that this patient looks under active thyroid I would not because (a) if I disclose that this patient has normal thyroid function tests they would not even be

allowed to be prescribed thyroxine because these days PCT supervise the prescriptions coming out of GPs.

Dr JEFFRIES: I think, with respect, that is more guided by price than anything else, but those are the only questions I have.

THE CHAIRMAN: Thank you, Dr Jeffries. Mrs Pond is a non-medical or lay member of the Panel.

MRS POND: Good morning, doctor. Two things I wonder if you can help me with understanding a little bit better, please. You were talking about guidelines, there was some discussion with yourself and counsel. Are there guidelines for prescribing these medications

A Yes.

Q There are?
A Yes.

Q Can you tell me what those guidelines are?
A Where the thyroid function test clearly shows that the amount of hormone produced by the gland is low, below the reference range, and the hormone coming from the pituitary is raised, that is so clear that the guidelines says you must treat, you must replace thyroid.

Q I think I have perhaps asked the wrong question. Can you tell me what the actual guideline is? Does it have a name? Is it a publication? Can I find it on a piece of paper somewhere?
A You can if you access Google and there is treatment of hypothyroidism, you get several guidelines.

Q Again I am just trying to understand as a lay person, is this something that is published?
A Yes.

Q Who by? Is it a National Health Service document?
A No, by various bodies. You get BMA, you get *Lancet*, you get various other journals and some of them are not just local, the *European Journal of Endocrinology*, you get the *American Journal of Endocrinology*, it is widespread.

Q Okay. In terms of those guidelines, how rigid are they for a practitioner? Are they optional or are they mandatory?
A It is best advice. In fact, a doctor can ignore those guidelines if he so wishes though it is unwise to do so, because then if something happens to that patient the blame is unequivocal and this is why so many of us try to respect established published guidelines.

Q If I can just make sure I have understood what you are saying. I think you are saying that the guidelines are there as advice, best practice perhaps?
A Well, yes, advice based on best practice.

Q They do not have to be followed?
A No.

Q The risk of not following them lies with the clinician?
A There is no compulsion that if you do not do it you will be instantly dismissed.

Q Okay.
A The restriction is if you do it and that patient comes to harm then you cannot escape blame.

Q As a lay person that sounds like quite a worrying statement, really. If I understand you correctly you are saying that there might be guidelines but any doctor can choose to give any treatment to any patient and as long as they are willing to take the risk of nothing happening to them that is fine. Is that correct? Is that how it works?
A They can take risk but this is also supervised by various bodies. I know that PCT are very strong on this because they have the interests of their patients at heart, so some PCTs – after all, there are pharmaceutical and medical bodies – and the GPs know sometimes I cannot give it. A good issue will be some of the drugs we use in divertology; some GPs will say, "No, I am not giving that, it is not in the guideline."

Q You are talking about PCTs but we are obviously considering the practice of a doctor who works in private practice, so is there a role for a PCT in that car?
A Well, unfortunately, whether private or public the patient still belongs to the GP who is still governed by his PCT. Inside the hospital they now have pharmacists going round all the wards and looking at the prescription charts and the pharmacist will say, "This one is on warfarin, he should not be", and it will be noted on the drug Kardex. The doctor's prescribing habit is supervised right, left and centre, both for in-patients in hospital and out-patients.

Q Okay, thank you. Again, it is still on the same sort of theme but just help me with my understanding. If a doctor is prescribing an unlicensed medicine or an unlicensed prescription, are there guidelines or safeguards around how and when that may be done?
A Yes. I think most pharmacists are also aware of this. Most pharmacists are aware of what the clinician can prescribe or cannot prescribe. Sometimes the pharmacists may have erroneous beliefs when they can take it up with the consultant. I do not know if I can give an example here.

Q I think I probably would just like to try and stick more to the actual process and the procedures as opposed to perhaps what happened. I am trying to understand, again as a lay person, the idea that unlicensed medicines can be prescribed sounds quite alarming. I would like to understand if there are any guidelines, restrictions, rules around that.
A There are guidelines and I did say earlier on in my presentation that many of the GPs refer patients for treatment of thyroid disease to Dr Skinner knowing they can actually take it as self-referral and prescribe the thyroxine. They know they can do that. It is only areas where there are doubts as to the indication of thyroxine that they do not have the authority, the belief, call it what you like, to prescribe. The GP probably prescribes thyroxine hundreds of times in the year. Now, the one that comes in looking like this patient might need thyroxine they are not going to prescribe it, they will refer

this patient elsewhere. There are probably fears of, you know, conflicts with the guidelines or established guidelines.

Q Okay, thank you, I think that is all I have got on that area. I just want to check if I have got other questions that came up during your evidence have been answered or not. *(Pause)* If I could just take you to your report and again it is page 6 of your report, the paragraph around concerns.

A Page 6. Yes, I have found page 6.

Q Thank you. You make a statement six lines down to say:

> "The use of Armour Thyroid is controversial. It is not licensed in the UK."

Is that why it is controversial or is the use of it controversial for other reasons?

A A lot of people have written about Armour Thyroid and the reservations on their use is that you have got a drug with a mixture of active components. We know two of those, we know there is thyroxine there, we know there is triiodothyronine in there and there are also other chemicals. The reason I am sure it is not licensed is because of that, that you have got components, very potent components all mixed together and like this triiodothyronine we call it T3 and thyroxine we call it T4, it has been well documented now that replacing thyroxine, treating hypothyroidic patient you do not need to give a mixture and rarely need to give thyroxine and triiodothyronine in the clinical setting. That applies to Armour Thyroid. The lack of sufficient knowledge about the quantities of these potent chemicals – in fact it is believed that there are some other potent chemicals that have not been documented.

Q Okay. Do you know if that particular Armour Thyroid is licensed elsewhere or is it licensed as a treatment for another condition?

A In the UK?

Q In the UK.

A I do not think so.

Q Not licensed at all. Do you know if it is licensed elsewhere, internationally?

A I think most operators in the business just use thyroxine.

Q You are not aware of it being licensed ---

A Occasionally triiodothyronine where you have got severely hypothyroidic patients so you are talking of Myxedema Magnus and some severe forms of hypothyroidism where you want faster action.

Q Okay, thank you. One final question. You were answering a question from Dr Jeffries about changing opinion in terms of treatments for these conditions and you said that there is no revision of the reference range and that you were aware of other publications that have been written about this.

A Yes.

Q Again, as a lay person I understand there are formal medical published documents

but there is also other noise, you know, other information that comes through perhaps from patients, perhaps a drug company that is developing a new product, there might be other information available through the Web, through the Net and wider circles that might raise the profile of an issue that is under discussion and perhaps may come up for revision in the future. Does that apply to this condition and these treatments or not so far as you are aware?

A There is constant review by various bodies of established reference ranges and the laboratories. I mean, the consultants in charge of the laboratories are duty bound to look at these and alter their reference range as it needs to be. As far as I am aware, I did mention in response to Dr Jeffries's question that I go to different Trusts when they need extra pair of hands as locum so I am privileged that I can tell you what happens in about half a dozen Trusts in the UK and current as well because, as I will say, I was working as a locum in north east of England until end of October and comes New Year I will be going elsewhere to work. You have to know the prevailing reference ranges in all those places, so I can say confidently that for thyroid it has not changed.

Q Outside of the medical profession, so in the wider community?
A Yes.

Q Are you aware of pressure, support for a movement that is becoming persuasive around reviewing these reference ranges for this condition?
A Pressure? I am not aware of any pressure.

MRS POND: Okay, thank you. That is all the questions I have.

THE CHAIRMAN: Thank you, Mrs Pond. I am a medical member. I do not have very much to ask you. First, can I just take you to page 580 in your report? It is a copy of one of the papers that you have put in. The paper "Thyroxine treatment in patients with symptoms of hypothyroidism…" Have you got that? Page 580 in the bottom right hand corner?
A *(Pause)* Yes. The study, okay, sorry. Thank you.

Q You have got that? The paragraph headed "Introduction"?
A Yes.

Q It says:

> "…classic symptoms of hypothyroidism are wide ranging and non-specific, therefore biochemical testing has become the cornerstone of diagnosis in patients for whom there is a clinical suspicion of thyroid dysfunction."

A Yes.

Q Do you agree that it is the cornerstone of a diagnosis or is it really more a helpful adjunct?
A I agree but because so many conditions mimic under active thyroid, doing a biochemical test that points to as to whether this condition – I will give you an example, sir. Obesity can mimic under active thyroid and of course we do blood tests on obesity

first to make sure that obesity is not due to under active thyroid and, two, the diagnosis of under active thyroid hinges very strictly on these blood tests.

Q Could it not be argued that if it is taken as the cornerstone you end up either treating or not treating a laboratory condition rather than a clinical condition?
A Well, again it comes back to evidence-based medicine. If somebody has angina, chest pain, first of all you prove that this is due to bad circulation to the heart and it is not due to acid coming from the stomach or it is not due to any other thing that can cause chest pain, so you will need the evidence for coming round to saying this is angina and then you prescribe appropriately for that condition. It is the same in thyroid or any other condition, you look for proof that these several different symptoms, depression, lethargy, weakness and all those things are due to thyroid.

Unfortunately, in medicine – this is what this particular article also mentions in its conclusion – you give a patient treatment. You never can be sure whether the first positive response is due to that drug working or what they call placebo effect, which is well known in medicine. The fact that the patient feels better on this drug is not a proof of correct treatment, correct diagnosis, it is a matter of only time will tell the situation. I would like to submit here that I, as the physician, because this happens every day, presented with a patient that looks like under active thyroid will never dream of giving that patient thyroxine replacement if that patient has normal result. Then I repeat it. If I am surprised by it I may repeat that blood test to be sure. I will then often do an endocrinology anyway to get to…

Q In such a situation you would be content and you would think it absolutely correct to consider a chemical diagnosis rather than a possible clinical diagnosis?
A I think there is a chance for me as a physician. You do not say to the patient, "Cheerio, your thyroid test is normal." No. I look for other possibilities. Is this patient depressed? Has this patient got some viral illness?

Q Are you saying, then, that if the biochemical test is normal there is never any possibility that the patient could be hypothyroid clinically?
A This is…

Q It has always got to be something else?
A Yes. This is an established field in medicine. A good example is HRT. If some woman comes to me anxious, by night sweating and I think, I wonder if you are reaching menopause. If I do not have biochemical tests and test the oestrogen, I will say to the patient, "First you are not menopausal yet," so I look for other causes of her symptoms. It could be simple anxiety, it could be other things.

Q It could not be what it might be as far as the patient is concerned?
A Well, if we use this example of menopausal anxiety there is no way that somebody will get HRT prescription from me if her biochemistry is normal. The same goes for thyroid.

Q One of the reasons, the main reason I think, for not giving thyroid to euthyroid patients that you put forward is that it may cause untoward consequences, particularly with regards to bones and heart. Is that right?

A That is correct, yes. You are increasing the patient's ---

Q Yes, you have explained why. You mentioned the possibility of osteoporosis and that unnecessary thyroxine replacement may cause irregular heart beat. I want to know how likely it is that if one gives thyroxine to a euthyroid patient how likely is the possibility: is it a probability or is it a slight possibility or what? How probable is it that you would cause an irregular heart beat. How likely are these symptoms to occur?

B

A In the setting up a definite under active thyroid patient, when you are giving thyroxine you will have to be careful.

Q Yes.

A Because a small dose for A will be a big dose for B, so you still have to watch. You never know which patient will react to the small dose of 50mcg you prescribe, for instance. It may be all right for Patient D, Patient B might go into irregular heart. This is even for normal well diagnosed under active thyroid, not an individual with normal levels so you are adding to it. Answering your question, sir, it is difficult to quantify what the possibilities are and this is why people avoid it.

C

Q If it is difficult to quantify, have any studies been done to show the likelihood of these effects occurring in the patients that you have told us that a small dose for A may be a big dose for B in the patients who you would give thyroxine to?

D

A Well, the reason we bring patients back, "Oh, you have been diagnosed with this, cheerio," is because you still have to monitor levels. Every now and then the level comes back on the same dose it has been taken for. In a few months ---

Q The extrapolation of what you say would appear to be that if these untoward events are likely to occur in a treated hypothyroid patient, a biochemically hypothyroid, that they are more likely to occur in a treated biochemically euthyroid patient. Is that what you are saying?

E

A Yes, sir.

Q What evidence is there for that?

A I am not aware of any article that I have read that actually quantifies. The feeling is based on the opinions of, I cannot use the word elders, but the opinion of experienced physicians in the field who actually say and write about this that you do not do it.

F

Q How can they have written about it if they have not been treating them in the first place?

A Well, I cannot answer that question, but it is a piece of practice, consensus, that you do not give thyroxine to somebody with normal levels. It is the same thing, sir, with iron. Somebody looks pale and tired, you say Let us give this lady maybe some iron replacement but the serum iron is absolutely normal so you do not give that lady iron replacement because her levels are normal. If you give it on top of normal levels then you are likely to increase the iron load in the blood, which is not very healthy. This is the opinion about many conditions that when levels are normal you do not add more.

G

Q Can I put a suggestion to you? Would you agree that any doctor who has developed a new treatment or a new approach to treatment would wish that as many patients as possible might be allowed to benefit from that treatment? It seems to me a

H

perfectly reasonable suggestion to make. After all, we are in the business of curing people.
A Yes.

Q If we have something to cure people with then we want to cure as many people as possible. Would you agree with that?
A The issue is the word cure, sir.

Q Well, improve the health of.
A Yes. I will not do it on the basis ---

Q No, no ---
A On the basis that the patient has ---

Q Sorry, I am not talking about the specific fact of giving thyroxine to biochemically euthyroid patients but in general would you agree any doctor who has developed a new treatment or a new approach to treatment would wish that as many patients as possible might be able to benefit from that treatment? A general hypothesis.
A If that new treatment is evidence-based, if that treatment is accepted as a consensus, then there may be, but if I give the treatment to somebody without evidence-based but I think ---

Q You are jumping the question, I am coming on to that. The answer is yes, if the treatment is evidence-based?
A Yes.

Q Would you agree that if such a treatment was unknown and appeared to a degree to run counter to mainstream medical practice and therefore probably not evidence-based that it is more than ever important that the doctor takes steps to ensure not only its efficacy but particularly its safety are taken into consideration? It is particularly important under those circumstances that the efficacy of the treatment is there and that steps are taken to ensure that treatment is safe. Would you agree that that is particularly important?
A Yes, it is very important but the question is steps and safety.

Q I am not trying to use the words to trip you up I am just trying to use them in normal English usage.
A We have had some wonderful pills. I think we all in this room have heard the story about rosiglitazone. This is a wonderful tablet for diabetic patients. On a ward basis large studies were done and it was shown that it can cause heart attack. This drug has been used for at least five years before it got withdrawn but the monitoring is international large scale intensive, so if that is done with any new treatment and it is shown there is no side effect whatsoever I may be convinced.

Q Anybody who introduces a new treatment, and particularly if it is unorthodox, should take steps to ensure that it is safe? That is what you are saying?
A Yes. Not just the use of treatment, body of investigators must check.

Q You are agreeing with my hypothesis that steps should be taken building to the

treatment?
A Yes.

Q Whether or not you, as an expert witness, consider Dr Skinner's approach to the treatment of clinical hypothyroidism, biochemically euthyroidism to be safe, do you consider that Dr Skinner has taken appropriate steps to ensure its safety judging from the 662 patients that you have reviewed?
A Unfortunately, sir, we do not have results of published work for the safety of this treatment. If there was we would not be having warning from some leaders that say this is dangerous and ---

Q Have you seen, in the 662 documents that you have reviewed, evidence of the fact that Dr Skinner is taking into consideration the safety of his treatment, particularly with regards to the possibility of osteoporosis and whether it may cause irregular heart beat?
A To be fair to Dr Skinner, the paperwork I was given, which consists of consultations, referral letter from GP and his own letter out, does not show checks on safety of the drug. I do not have a long term documentation about these patients.

Q No. Have you been able to form any view on the way in which Dr Skinner has been able to organise in the treatment plan, build into the treatment plan, steps for ensuring safety? Have you been able to identify those within the 662 patients?
A There is a paucity of documentation about what happened to these patients. It is not there on this record that this patient was followed up not just once or twice but three times and all these investigations, like we wondered about bone density, osteoporosis, I do not see comments about their bone density ---

Q I was going to ask if you were looking for steps what steps would you be looking for to ensure that safety was uppermost?
A I think what one does in this situation is not just one solo effort to follow up the patient clinically. There are investigations that can be done to monitor side effects, like ECG, electrocardiograms, bone density measurement, but it is also important for large scale study to be done to monitor complications.

Q When you are treating your hypothyroid patients with thyroxine do you regularly institute bone scans and regular ECGs in order to assess whether they are in danger of running the risks that you have described?
A If these patients are routinely brought back every six months.

Q Yes.
A If there are risk factors that convince me to check – if the patient is complaining of palpitations, the viral level was low, he was given normal dose of thyroxine and he says, "Oh, doctor, I sometimes get palpitation," then I will investigate the heart. The same is true if somebody says to me, "Doctor, you know I have been on this thyroxine for three years, I get some back ache, I get symptoms that make me…" I do not investigate every patient on thyroxine for complications.

Q Because you feel it is not necessary to do it on a routine basis?
A It is not necessary, it is very expensive.

Q It would be perfectly satisfactory, you feel, that if a patient produced a symptom which might alert you to heart or bone problems then you would investigate them to see if things were happening?
A *(The witness nodded)*

THE CHAIRMAN: Thank you. I do not think I have got anything more. Dr Jeffries has another question for you.

DR JEFFRIES: I know you have been there a long time, it is just a short follow-up from the Chairman's question. You have treated hundreds of hypothyroid patients with thyroid replacement I assume?
A Yes.

Q What percentage of those – I am not asking for precise but a ball park figure – has developed adverse effects requiring further investigation in the way you have just described? Are we talking 50%, 20%, 5%, 1%?
A Probably less than 1%, sir.

DR JEFFRIES: That is all I wanted to know. Thank you.

THE CHAIRMAN: Do either counsel wish to come back after our questions?

MR ATHERTON: No, thank you.

MR FOSTER: Yes, please, sir, very briefly, if I may.

<u>Further cross-examined by MR FOSTER</u>

Q First of all, Dr Akintewe, in relation to the paper from the BMJ which we have beginning at 580 in the bundle – have you got that in front of you now?
A Yes.

Q The 2001 paper produced by you in support of the proposition that treatment with thyroid replacement where there was normal thyroid count should have a question mark over it. It is a very small study, is it not, first of all?
A Yes.

Q Twenty five symptomatic patients, 19 controls?
A Yes.

Q The conclusion we see on page 584…
A Yes.

Q 895 of the BMJ itself are results that require confirmation in a larger study. Do you agree with that observation?
A Sorry?

Q This is under the "Conclusion" in the left hand column:

> "We can find no support for the hypothesis that people with symptoms of hypothyroidism but thyroid function tests within the reference range benefit from treatment…However, our results require confirmation in a larger study."

A Okay.

Q Then they emphasise the need for that to be a randomised control trial because of the placebo concern. Do you agree that the results require confirmation in a larger study?
A Yes. However a small study is a stepping stone to doing a larger study.

Q Of course. A controlled study of this was precisely what Dr Skinner and colleagues had been agitating for from the 1990s, was it not, as you have indicated by your inclusion of his earlier letters to the BMJ? Yes?
A Yes.

Q That BMJ paper which we have just been looking at is 2001. In fact, there has been no subsequent control study of this issue, has there, which is why you did not include it?
A That is probably true although I may not notice, but I will accept that maybe there has not been further studies.

Q One might conclude, therefore, that the work that Dr Skinner has done since 2001 amounts to one of the best bodies of evidence that we now have, that thyroid replacement therapy in these circumstances does produce a benefit. Yes?
A I would not conclude that, because we have not got the situation of large scale study that bodies in medicine have looked at and no-one knows they will announce it, with new jabs you can do that, you can give thyroxine to people with normal thyroid function tests.

Q You repeated a number of times the mantra that one should only do that which is justified by the evidence base. Let us be clear about it here, the evidence base that we are talking about is this 2001 paper, is it not? There is nothing subsequent.
A This 2001 paper actually does not claim to be the gospel. It is probably even react to the controversy that followed the publication of Dr Skinner's letter and I think that is probably to see whether this practice of giving thyroxine to people who are euthyroid can be sure to be beneficial in terms of cognitive function and lifestyle improvement. Their conclusion is that it is not any more than placebo effect. I am not going to say that is the gospel truth, one needs larger studies and more prolonged studies to be able to do that. In the meantime I would not do it.

Q The evidence base to which you constantly refer says simply this: in 2001, on the basis of a very small study, we do not think there is an effect but we really do not know. That is the height of it, is it not?
A We do not have evidence.

Q It would be wrong, would it not, for any clinician to use the entirely proper evidence-based approach to justify failing to use his or her clinical acumen in treating the patient in front of him or her?

A I think I can say here that most clinicians in UK will not give thyroxine to patients who are euthyroid on the basis of just symptomatology.

Q It is, of course, entirely accepted that there are risks in prescribing thyroid replacement therapy to any patient and that accordingly there has to be follow-up. In relation to all the patients that you have singled out there were provisions, were there not, for that follow-up? Let us take at random out of the smaller bundle, that is C6, page 31.
A The right hand side, page 31?

Q That is right. An entirely typical letter, bottom of the page:

> "I think this lady would indeed benefit from thyroid replacement and I have provided her with a prescription for two months…and will review her in two months time and hopefully have her well on the way to optimal health by mid-summer. It would be very helpful if you could perhaps repeat the thyroid chemistry in six weeks time if you felt that to be appropriate…"

Follow-up?
A Yes, in two months. Yes.

Q We see that ---
A I do not dispute that patients were asked to come back but there was no documentation of what happened at two months, at six months and twelve months.

Q We see that same follow-up formula repeated, do we not? "We will see you again, we will check how you are and please repeat the thyroid biochemistry".
A I am sorry, I did not dispute that. I said there was no comment as to what happened like the two months that patient came back or six months or twelve months.

Q Yes.
A There was no comment on what happened.

MR FOSTER: You do not have outcome data it is agreed. Thank you very much.

THE CHAIRMAN: Have we finished with Dr Akintewe?

MR ATHERTON: Yes.

THE CHAIRMAN: Thank you very much for attending and giving us your helpful advice and evidence, Dr Akintewe. You may now be released. Thank you.

THE WITNESS: Thank you very much, sir.

(The witness withdrew)

MR ATHERTON: Sir, that is the evidence that the GMC propose to present to you for the purposes of this review.

THE CHAIRMAN: Thank you, Mr Atherton. In that case it seems to be a perfectly reasonable time to break for lunch. If we have an hour we will come at twenty to two.

(The Panel adjourned for lunch)

THE CHAIRMAN: Mr Foster.

MR FOSTER: I call Dr Skinner, please.

GORDON ROBERT BRUCE SKINNER, affirmed

THE CHAIRMAN: Make yourself comfortable Dr Skinner. I will not go through the rigmarole of introducing us, I think you will know by now who we all are. I will hand you straight over to Mr Foster.

MR FOSTER: Thank you, sir.

Examined by MR FOSTER

Q Dr Skinner, the Panel have seen that in 1997 you wrote a letter to the BMJ which the Panel has at the annex to C2, which is Dr Akintewe's report, it is page 579 of the continuous numbering. That letter was a plea for an incremental three month trial of thyroxine treatment in clinically hypothyroid but biochemically euthyroid patients. Yes?
A Yes.

Q We have seen the 2001 trial which was referred to in the BMJ.
A Yes.

Q Does that 2001 trial give you what you wanted?
A You are referring to the one by Pollock, I think?

Q Yes.
A Well, it is the easiest thing to criticise but I did feel there was some serious shortfalls in it, some to which you have already alluded, so I do not feel that that negated the hypothesis.

Q Does the work which you were advocating in 1997 still need to be done, in your view?
A Yes.

Q Dr Akintewe criticised you for failing to adhere to guidelines in relation to the prescription of thyroid products to biochemically euthyroid patients. What guidelines do you understand are pertinent?
A As you said and as was shown, there are not any formal guidelines and only NICE, the National Institute of Clinical Excellence, are empowered to make these guidelines. Various bodies have made guidelines, various papers, as Dr Akintewe said, have advanced their views on the matter. There are no formal guidelines at the moment.

Q In 2007 a Fitness to Practise Panel imposed a number of conditions on you. In the main bundle, that is C1, you will find the relevant conditions at page 19 and the pages that follow. Can you turn that up, please.
A I can remember them.

Q It will be helpful if you have them in front of you, please.
A Somebody help, please. I do not know where they are. *(Pause)* Thank you. Sorry, what was the page?

Q Page 19, please.
A Apologies, everyone.

Q I am particularly interested at the moment in conditions 5, 6 and 7. Condition 5:

> "You must only accept new patients for endocrine treatment if they have been referred to you by a fully registered medical practitioner."

Was that your practice before these conditions were imposed?
A For about five years before. It has always been my general practice but it was not a rigid practice prior to, say, 2002.

Q If this Panel were to conclude that no conditions were justified now, would you continue to feel bound by that stipulation?
A I would continue to feel bound but it has been beneficial, it has been a good thing to have a referral from usually a family practitioner. I will continue that that practice, most certainly.

Q Condition 6:

> "Prior to initiating or varying any treatment regime, you must ensure that you have communicated your diagnosis and suggested care plan to the patient, his or her GP, and any other referring medical practitioner."

Would you continue doing that absent of direction from the Panel?
A Yes.

Q The conditions imposed various administrative burdens upon you, for example, condition 7, the contemporaneous log book and six monthly provision to the GMC of various types of information. How onerous have those accounting obligations been?
A That is quite onerous, that. It needs a great deal of secretarial time copying and paginating and so on. Keeping a log book is not a problem but sending a great pyramid of stuff every six months is very time consuming.

Q What effect have these conditions had on your life and practice?
A On the conditions we have discussed so far I hope no effect on the medical care, if I understand your question.

Q Yes. Have any of the other conditions imposed had any effect, or the mere fact

that any conditions at all were imposed?
A Yes. The condition is kind of onerous in the sense that if I wish another post I think you could say fairly straightforward you would not get, if any, some rather obscure job because of that condition. You would not keep it a secret anyway if you had to work with the GMC but I think at square one that conditions rather rules out any possible application for another appointment.

Q Have there been over the condition period jobs which you would like to have applied for but have not felt able to do so or been turned down for because of these conditions?
A Yes, there have been. About three, I would say.

Q Have these conditions had any effect on the number of referrals?
A I am not very sure of that, it is very hard to judge in retrospect. They do not seem to have made a significant difference. Well, 692*(sic)* referrals, as Dr Akintewe pointed out, he ratified.

Q Are some medical insurers reluctant to finance treatment provided by a doctor with conditions?
A I do not think reluctance, I think just a plain refusal so to do by BUPA and PPP. Other insurance companies seem to have taken a more flexible view of the matter.

Q The Panel will be concerned that your private practice is overseen by somebody. Is there any oversight?
A Yes. The Care Quality Commission is empowered to oversee private practitioners and other professionals. Secondly, I have a very good element of overseeing in that all the patients are referred by family practitioners usually who I then write back to, so there is a sort of auto overseeing as I work closely with the family practitioners.

Q What in practice does the oversight of the Care Quality Commission mean?
A Well, when you start in private practice there is a very fairly onerous set of things you have to abide by. They then can inspect or come in at any time. I should have said you had to register with them originally and be accepted, which I have been. They can inspect your premises or your work. Now, they have not actually inspected in the last year; I am assuming that that is because they are happy with what is going on.

Q In addition to the patients who Dr Akintewe referred to in his 662 snapshot there are a number of other patients who over the course of many years you have treated, are there not?
A Oh, yes. Yes.

Q The Panel will have seen a number of testimonials from patients which are in the bundles in front of them but there is also a big pile of red books there *(indicates)*. What is that?
A That is approximately 2,000 testimonials from mainly patients and some from dental colleagues, I suppose what you might call non-patient testimonials.

Q We have not burdened the Panel with those but of course the Panel is very welcome to look at them should they wish to do so. In 20 out of the 662 patients

Dr Akintewe identified patients who were prescribed thyroxine in spite of having normal thyroid chemistry. How useful a guide do you think that thyroid chemistry is?
A I think it is a useful guide and, contrary to what has been put before the Panel, I do not disregard it; I would like to correct that. It is really what might be called the mis-assumption of the reciprocal. If thyroid chemistry is wayward then the patient is almost certainly unwell. However, the reciprocal, if thyroid chemistry is in 95% reference intervals in my experience in many patients that does not mean the patient is well. Perhaps to expand a little bit if, let us say, a reference interval is ten to 22 and there is a value of 21.999 versus a value of 22.0001 it would be insecure to declare a patient was hypothyroidic or not hypothyroidic on that basis, which is advocated by other workers in the field.

Q When a patient is referred to you by a general practitioner is any questionnaire filled in by the patients identifying their symptoms and signs?
A Yes. I hope it is available.

Q Yes, it is.
A Yes. Every patient fills in a questionnaire where they mark their symptoms.

Q We have got a copy of that questionnaire. I wonder if a copy could be handed to you and to the Panel. My learned friend has seen this already. Perhaps this can be D1.
(Same handed to the Panel)

THE CHAIRMAN: The questionnaire is D1.

MR FOSTER: Thank you, sir. The Panel have heard from Dr Akintewe that thyroid supplementation has dangers associated with it. Do you agree that it does?
A Yes.

Q Do you agree with Dr Akintewe's description of those dangers?
A Sorry, could you clarify that.

Q Dr Akintewe talked about palpitations, he talked about the dangers of osteoporosis, for example. Do you agree that he enumerated reasonably well these dangers?
A Well, these are the perceived adverse effects if someone takes too much of the medication so in a sense the question was self-answering. I would say before saying any more that the dangers of not treating a patient are indeed appalling. However, the evidence of osteoporosis, there has been a recent meta-analysis which did suggest that on balance there could be osteoporosis or osteopenia in a patient who was treated recklessly over a long period of time but that did not take account of a patient who is not thyrotoxic during that period of time. These studies have rather ignored that critically important point. Then there is a large body of evidence to gainsay or may say there is osteoporosis complication. I personally have not seen it in my practice. Dr Akintewe has a very interesting point which is difficult for clinicians, you cannot do densitometry on every patient and he expressed, I thought, a very sensible position on that. If there is any reason so to do one would do it or arrange with the family practitioner to do it. Cardiac complications, I have actually never seen this. Palpitations, it is important to say, is a notable feature of hypothyroidism. If you crassly over treat a patient for some reason or

A

another, which you should not do, then palpitations can develop. The palpitations point, if the patient is aware that they can telephone you or make contact with someone, can simply be dealt with. You would not cavalierly say to a patient carry on with your palpitations.

Q Let us consider that point with the procedure you have for review. First of all, are patients given any information about possible complications from the treatment?

B

A Yes. I discuss this with them and they are actually also given a sheet. My apologies, I have somehow lost that on the journey from Birmingham to here, I am getting it faxed through, hopefully, in time. That enumerates these I think quite clearly.

Q From where is the list of possible complications on that sheet taken?

A Through literature and from those skilled in the art, as they say. I think it is fairly standard.

C

Q So far as follow-up is concerned, what is the procedure?

A The procedure is fairly clear. The patient is asked to return in two to three months, depending a little bit on the regime. The family practitioner is of course advised of every patient and asked if the family practitioner considers it appropriate – remember we are dealing with an adult qualified doctor here – to take thyroid chemistry in six weeks prior to the return to the clinic. Some patients do say they would like to see the family practitioner in six/eight weeks, which is fine, and that point is addressed in the letter to the family practitioner.

D

Q Do you feel it is important to keep a record of any communications over the telephone or otherwise that you have with patients?

A Yes, I do.

E

Q Is a sheet available in your practice for the logging of precisely those communications?

A Yes. When a patient phones and wants to speak to me the secretary puts name, date and then the conversation is recorded below that and then that sheet is put into the patient's notes.

F

Q Just for the sake of completeness, I think it will be helpful if that sheet is handed out. It is headed "Telephone call sheet" so perhaps this can be D2. *(Same handed to the Panel)* Is that the sheet that you are referring to, the telephone log sheet?

A Yes, that is it.

G

Q It may be that one of the concerns about prescriptions is that a prescription is written by you which is then repeated *ad nauseam* without the chance for you to see how the patient is doing. What is the procedure about repeat prescriptions?

A Prescriptions are done for three months and then the patient is sent a pink sheet, if the patient is not coming back at that time, further down the line. The patient then advises if they have seen the family practitioner or any other carer in the last three months and no prescription is given out without that safety factor. If a patient has not been seen in six months the patient would really have to come and see me or, more usually at that stage, the family practitioner, so no-one is left adrift having prescriptions with no monitoring.

H

Q We will be looking at a document which I am going to hand up in a moment, it is called "Prescription request form". Is that the document you are referring to?
A Yes. It is usually pink but I think ---

Q That has been a casualty of the photocopying.
A Right, yes.

Q Perhaps I can hand that round as well, sir. Perhaps that can be D3. *(Same handed to the Panel)*

THE CHAIRMAN: D3.

MR FOSTER: That will be D3. Just talk us through how this form works, please, and when it is used.
A If someone requests a prescription they receive this form and indeed the patient is telephoned. We are interested to know when they last had a blood test, perhaps by the family practitioner or myself, they state what medication they are taking and then a prescription, if all is well and there is no cause for any anxiety, is sent to the patient.

Q I would like to look now, please, at the patients specifically identified by Dr Akintewe. For this you will need bundle C6.
A Yes.

Q Patient 1, please. The notes for that patient begin on page 1. Dr Akintewe's complaint was that the TSH was 0.8. It seems that he drew that from page 3, which is your letter back to the GP. Paragraph concludes:

> "…the TSH is more than three times the average for healthy patients which runs at 0.8 on account of the skewed TSH values."

I do not want to deal with this in any detail but the reference ranges in the US and the UK you refer to there and in a number of other places. What is the difference?
A Well, averagely and roughly in the UK it would be 0.5 to 5 and in the US they re-sampled the population, they have excluded patients who had antibodies or who had relatives who were hypothyroid and have come up with, or suggested, that 0.5 to 2.5 is amore accurate reflection of the sampled population.

Q Has that led to any revision of the relevant guidelines in the US?
A Again, I am not quite sure if there are formal guidelines but there are various associations have argued on this basis that the levels should be considered 0.5 to 2.5. That has been a bit of an evolutionary process in the last eight years, and stepped.

Q Dr Akintewe is unhappy about you prescribing thyroxine given this biochemistry. Why did you do it?
A I do not know, perhaps you do not want to launch into the whole business about thyroid chemistry. In this particular patient, because I thought the patient was hypothyroid according to the symptoms and signs which have been written here in my clinical notes. Basically if I might say the thyroid chemistry has never been validated. It

A was based loosely on the old protein bound iodine at the time and there are so many authorities, which I do not quite agree with Dr Akintewe who has vociferously pointed out, including the government of England, that clinical signs should be pivotal in the diagnosis, I am perfectly clear on that. As I say, there is over 100 papers in the literature and, in actual fact, dare I say it, the unorthodoxy does not lie with me, it lies with those who adhere rigidly and inflexibly to this belief that the thyroid chemistry will give you the diagnosis. That was why that patient was treated.

B

Q Broadly because it was clinically justifiable?
A Yes.

Q Patient 2, please. The notes begin at page 4. Normal thyroid chemistry but a prescription of thyroxine. If you go, please, to page 6 bottom right hand corner, you will see your letter to the GP. The substantive paragraph there talks about the thyroid levels. Is this normal thyroid chemistry?

C

A Yes. If it was 2.4 it would be within the 95% reference interval.

Q What is the significance of your contention about the left sided skewed distribution of TSH value?
A It is mis-assumed that the average will lie between the two numbers at equal distance, which would be a median value not an average. If it is skewed to the left the average will be down towards the modal value, which is about 0.8 or 0.9. That is what I am saying there. It is not distributed according to the class of Gaussian distributions. This patient, by the way, had a thyroid removed.

D

Q Patient 3, notes beginning at page 8. Dr Akintewe rightly observes that the TSH is 2.53, nonetheless thyroxine is prescribed. Why?
A Again, it is the same, the driving motivation was how the patient was and I have enumerated the clinical features there. 2.53 would be outside the US reference interval but it was hardly contentious.

E

Q Patient 4, the notes begin at page 12. Normal thyroid test per the GP but thyroxine, nonetheless. Why was that?
A This patient's thyroid chemistry was not controversial or not even marginal and that is the basis of the matter. I discussed with the GP or wrote to him the basis that it should be on clinical grounds and I think if you look at that you will see – I think we all understand that fatigue or whatever could occur in many, many different diagnoses but it is the combination that is the important thing, combination of symptoms or signs.

F

Q Patient 5, please, beginning at page 15. TSH of 2.9 according to Dr Akintewe but if we go to page 16 we can see that it was not always 2.9.
A No.

G

Q Does that make any difference?
A TSHs have a certain variability but nevertheless there are two values of 3.1 and 2.9. I would say it was the clinical features that was fairly persuasive.

Q Patient 6 beginning at page 19. We are agreed that we have got normal thyroid tests here, so why thyroxine?

H

A In this particular patient I ran out of space for the clinical features, which I think speaks for itself.

Q Patient 7, beginning page 23. Normal thyroid tests according to Dr Akintewe. You will remember that I quizzed him about that by reference to page 25.
A Yes.

B

Q Third paragraph down in that letter:

> "…she has a TSH reading well above the average for healthy patients which runs around 0.8…"

A I wonder if I am in the wrong… This is 25?

C

Q This is page 25.
A Right.

Q Are you there?
A Yes. That TSH reading will of course be in the documentation that would not be available to Dr Akintewe.

D

Q Indeed.
A In many laboratories now, which must put a practitioner in a difficult situation, they essentially do not carry out the FT4 if the TSH is deemed to be within reference intervals. That is just flagging up a problem.

Q The FT4 is the free thyroxine?
A Yes, free thyroxine. A little bit caught both ways if you are a practitioner there.

E

Q Patient 8, beginning at page 26. We read here that the TSH was 3.42. Why thyroxine?
A Again, the answer to all those questions, by the way, is a clinical feature because treating patients whose TSH is abnormal and they do not have symptoms gets into a whole controversial area of sub-clinical hypothyroidism. However, 3.4, even UK range-wise would raise eyebrows, I would have thought, with most practitioners and indeed endocrinologists.

F

Q Patient 9, beginning at page 29. Normal TFT. Why teat?
A Well, I mean, I am almost tempted to say the opposite. You would be heard put to know what to do if you did not treat some of these patients, this is a textbook of hypothyroidism.

G

Q Patient 10, page 33. Normal TFT per the GP. Why thyroxine?
A This documentation does not tell us. Sometimes normal is pretty close to being out and so on but we do not know that because we do not have this documentation but, again, the clinical features, I would have thought, were very persuasive here.

H

Q Patient 11.
A Notice that this patient had palpitations prior to treatment, that is an important

point in managing these patients.

Q How does that impinge on your management?
A It impinges very much because if a patient says that they have palpitations I would take it seriously but it is important to know if they had them before the treatment started for the assessment of any patient. It is a well recognised feature of hypothyroidism.

Q Patient 11, please, beginning at page 37. Dr Akintewe commented normal TFT but if we go to page 38 we can see a comment a slightly elevated TSH of 6.4 and an elevated peroxidase antibody with subsequently normal TFTs.
A I am not quite sure why Dr Akintewe made that assertion. That TSH was actually eight times the average, which is clearly raised. I am not quite why actually the GP said it was slightly elevated, but there we are, he said it was elevated anyway.

Q Just to be clear: in this patient is there, in your view, biochemical justification for thyroid supplementation?
A Yes.

Q Patient 12 beginning at page 41, please. Normal TFT according to Dr Akintewe. If we go to page 42 we can see a reference in the top paragraph to consistently normal TSH tests and a normal Free T4 but then, jumping a paragraph down:

> "He has had five checks of his TSH over the last five years and all tests range from 0.9 to 1.26. His free T4 done last month came back with a reading of 8 which is normal."

What are we to make of that? Is that biochemical justification for thyroid supplementation?
A Not as an isolated entity but in conjunction with the clinical features. I think we have to discriminate between something that is low within the 95% reference interval and something that is outside it. Let us say the 95% range was 6 to 20, someone with a value of 8 is hardly the same as someone with a value of 19, so to lump them all into the one bag is, I think, insecure.

Q Patient 13, please, beginning at page 45.
A 45?

Q Please. Dr Akintewe commented normal TFT, that is not disputed from the figures that you have got.
A Yes, I actually flag up that very matter: here is a dilemma that the clinical features suggest this and the thyroid chemistry which is presently available does not.

Q Where do we see that flagging up?
A Sorry, third paragraph, page ---

Q 47, is it?
A Yes.

Q Can you explain that dilemma to the Panel.

A Well, the very dilemma which has become a controversial dilemma. Should you exclude the diagnosis on the basis of thyroid chemistry that is within 95% reference intervals? I do not think you should but I respect other people's views. There is an extra dilemma I think here, I have not got the full notes which is a problem that also Dr Akintewe had, but I think the thyroxine reading basically the laboratory do not want to do it so you are left with a TSH value alone and that is certainly not a secure way of excluding the diagnosis.

Q Patient 14, please, beginning at page 48. Normal TFT according to Dr Akintewe. If we go to page 51:

> "The findings are consonant with his thyroid chemistry where the TSH indeed has been notably above the new upper value of the TSH 95% reference interval which has been set at 2.5 by our colleagues in the US."

A Yes, that is the position there, really. That patient also has abnormal thyroid chemistry.

Q Patient 15, beginning at page 53, normal TFT according to Dr Akintewe. If we go to page 55 we can see your letter back. The third paragraph deals with the thyroid chemistry. Is this a biochemically euthyroid patient?
A I do not know, really, because I do not think the tests are available – I might be wrong here – in this documentation and they would be in other documentation that was not given to Dr Akintewe either, this is just a snapshot. Anyway…

Q We do not know?
A Well, I hope I did at the time and did not just say consonant for diagnosis off the top of my head. I would not do that.

Q Patient 16, please, beginning at page 56.
A 391? My paginating has stopped.

Q I think it is just buried by the photocopying. What you are referring to as page 391 is actually page 57. The notes begin at page 56.
A We have gone slightly out of kilter. Right.

Q Normal TSH but you treated. Why?
A Again the clinical picture here, very strong family history. This patient was not started – you must remember a lot of these patients, I did not start this patient on treatment, a number of the patients were already on treatment and this was… Unless I am getting mixed up here, that was the situation with this patient. The family practice had initiated the treatment but wanted advice on its efficacy of where we were going with it.

Q Patient 17, please, beginning page 61. Again you will find the 61 is actually cut off but it bears a big number 8 at the bottom. Yes?
A Yes, yes.

Q Normal TSH according to Dr Akintewe. We can see that documented, in fact.

A No, it is not documented.

Q We have got a reference to the philosophy of treatment on the basis of normalish TSH on page 64.
A 64, yes.

B Q That does not necessarily reflect what the TSH say.
A No. I mean, that is a situation where I asked the family practitioner if he could perhaps lean on the laboratory to carry out this test of FT4 but I felt it was perfectly reasonable to institute treatment, which you do at a low level anyway so you are not actually putting the patient into any danger and if you get the results in the near future that has saved time.

C Q Patient 18, please, beginning at page 65. Normal thyroid tests according to Dr Akintewe and that seems to be the case per the GP as well. Why treat?
A I believe we are not actually seeing the test because there is a big flexibility in "normal", the adjective. Again this patient has many, many symptoms and was an unwell person.

Q Patient 19, beginning at page 70.
D A 70 is my clinical notes.

Q I think you probably want to look at the pathology results which you will find on page 71.
A Yes.

Q You have got a serum TSH of 2, that is two inches down and then…
E A An FT4 value of 7.2 which you will note the laboratory actually says is abnormal.

Q Indeed. Then at the bottom of the page can you help me with this, we have got serum TSH level 2.22 and serum free T4 9.40.
A Yes. Yes.

Q What are we to make of that picture?
F A The first thing to emphasise is the intrinsic variability of some thyroid hormone tests, it depends when they are taken and they do seem to just basically have quite a large standard deviation. I think the question you are asking is should the 9.4 have dissuaded treatment even though it was a 7.2 before and I would have said no to that given the patient seems to be hypothyroidic.

G Q Fin ally, in relation to this cohort of patients, Patient 20, beginning at page 73. We have got a TSH of 1.07, we can see that on page 74. She has had a thyroidectomy.
A Yes.

Q Why treat?
H A I am not not answering your question but it is very rare to find a patient who has had a thyroidectomy and does not require treatment. That does not answer your question, I realise that. Again there is as long as your arm symptoms. The same answer, I am afraid. These cases have been selected, that will tend to be the same answer throughout.

A I just want to make one point. The concept that the TSH and the FT4 negatively correlate is not secure, we have graft TSH values against FT4 values and the correlation is very poor, there is a broad correlation. If you are hypothyroid it affects all the body organs, that includes the pituitary, and I have seen quite a few patients where you give thyroxine instead of the TSH coming down it initially goes up a bit. One assumes a kind of lay explanation that the pituitary, like all the other organs, have been jollied up a bit or something, stimulated. I think that is an important interpretation of these results.

B

Q Thank you. Let us just go back a bit and talk about the broad principles that you used when deciding whether to prescribe thyroxine to anybody and how you should prescribe. Dr Akintewe said that it was important that you started low and then titrated up. Do you agree with that?
A Yes.

C

Q What would be the increments of racking up the dose or would that depend?
A Could depend. It would usually be 25mcg per day of thyroxine. Yes, per day and then three weeks up another 25 would be the kind of average approach.

Q I suspect the answer is obvious but how do you decide the dose needs to go up?
A The answer is if the patient is not returning to full health.

D

Q We have got twelve patients who were treated with Armour Thyroid. That is twelve patients out of the 662. We did not look at these patients in any detail with Dr Akintewe and I am not proposing to do so with you but, broadly, what is the justification for prescribing Armour Thyroid as opposed to the more conventional thyroxine supplementation?
A The strategy in my practice, if that is the question, is to use thyroxine and if a patient gets to a level where they do not seem to be improving then you would introduce perhaps tri-iodothyronine or Armour Thyroid. As a personal observation I have noticed that patients who have had a thyroidectomy seem to do well on Armour Thyroid.

E

Q Very quickly, the justification in each of these patients. Patient 1 of this series, page 76 in the bundle. We can see your letter back to the GP at page 78. Why Armour Thyroid rather than thyroxine?
A Essentially because she was not improving at all on thyroxine.

F

Q That is paragraph 2, is it?
A Yes.

Q Anything to add to that?
A She said, which is the most important thing on consultation, that she was having adverse effects with taking T4.

G

Q Patient 2 in that series, Let us begin at page 80. So far as justification is concerned of course draw your answer from anywhere in this document or nowhere in these documents, but the referral letter is at page 81.
A Yes. The family practitioner—well, it is not a family, it is a consultant chemical pathologist who referred the patient, basically is saying that thyroxine is not working and, indeed, this lady had tried on thyroxine and T3, had reached a kind of cul-de-sac in the

H

management of the patient.

Q She is keen to consider Armour and wishes to discuss this. Patient 3, Let us begin at page 84. She has been seeing Dr Sarah Myhill in Wales who has been treating her with Armour Thyroid. She cannot prescribe it any more, would you consider doing so. Why Armour Thyroid in this patient?
A Essentially the patient was doing quite well on it. I may say, I know you did not ask me this but there never has been a proper formal trial comparing synthetic versus desiccated thyroid preparations and these have been around for 100 years.

Q The Panel might be concerned that when you get a letter like this saying the patient is on Armour Thyroid already, for such and such a reason she cannot continue to get it from her existing clinician but you just uncritically write out a prescription. First of all, is that right?
A No, sir, that is not correct.

Q If you go to page 86, the final paragraph of your letter.
A Yes.

Q It sets out the discussion that you had with the patient. Can you outline very briefly what that discussion would have involved. You say you set out the options. What would the options have been that you talked about?
A I mean, there are limited options in a way. One would have been to revert to thyroxine or triiodothyronine. The critical issue was the patient still had a slew of symptoms notwithstanding the I think it was two grains of Armour Thyroid she was taking at that time, she was seeking help. Many patients do not want to take the synthetic preparations or do not want to take a preparation from an animal and given the paucity of evidence I think we should allow some informed choice in the matter, really.

Q Patient 4, beginning page 87. The referral letter is at page 88. We have got all the thorough biochemistry there. Then on page 89...
A Yes, that is my letter.

Q In the final paragraph we see the statement of your default position, which is thyroxine, but by reference to the history you conclude that Armour Thyroid might be a better option for this patient. Can you explain how you arrived at that conclusion?
A I think the critical matter here was that the patient which, which I emphasise is tremendously important in medicine, that she did well taking Armour Thyroid and, given there is no contraindication to it, it seemed a perfectly reasonable way forward.

Q Patient 5, page 91. This is another Sarah Myhill patient. This is page 92, final paragraph:

> "As you know…I can now prescribe thyroxine, I am not allowed to prescribe generic thyroid."

That is why this patient is in your hands. We have your referral letter at page 93. Did you immediately fall in with that suggestion without any valuation yourself?
A I did not fall in. You will see my clinical notes which assess whether the patient

was in health or not. The patient would hardly have come if she was not, I think. I would not just fall in "please prescribe this", there seemed to me a perfectly good reason for doing so.

Q We see that basically in the final paragraph on page 93, do we?
A That is right.

Q Anything to add to the justification there?
A No, I do not think so.

Q Patient 6, page 95.
A Right.

Q A rather perplexing patient, you say on page 96, paragraph 2.
A Yes.

Q Why?
A One of the most difficult problems in this is patients who do not improve but do not have adverse effects – I have addressed this issue in my book which was put before a previous Panel – and the question, which is a very difficult question, is how to proceed with the matter having assured yourself that there is not another problem there, like diabetes or anaemia, something like that. An option, of course, is to use another thyroid preparation, perhaps because the patient requires T3, although a lot of the evidence for T4/T3 conversion is a little bit sloppy. That would be the justification there: getting nowhere with thyroxine so I reduced the T3 and introduced the Armour Thyroid.

Q At the foot of page 96 you talk about a therapeutic dilemma.
A Yes.

Q What was that dilemma?
A The dilemma is a patient who seems to be clearly hypothyroidic, indeed that seemed to be the case when she came to see me, is not improving at what seems to be a reasonable dose level. That is a major dilemma in medicine.

Q You make no secret about the unlicensed status of Armour Thyroid.
A I have talked to the Department of Health on that matter and they say we are perfectly happy that you responsibly use it.

MR ATHERTON: I am sorry, this is not admissible evidence.

THE WITNESS: Is it not?

MR FOSTER: He is saying what he said not telling you what they said so I do not see the problem.

MR ATHERTON: He is not saying what he said - he is saying what they said and he is saying that they were perfectly happy. That is not admissible.

THE LEGAL ASSESSOR: It is, strictly speaking, hearsay.

MR FOSTER: I was not going to take that further anyway, but there we are. There have been discussions with the Department of Health about this?

A Yes.

Q Patient 7, please.

A Where are we now?

Q Page 98.

A 98, right.

Q Page 99 is the referral letter.

> "[She] has been seen by specialists at Russells Hall Hospital and The Queen Elizabeth Hospital who have suggested very high doses of Levothyroxine… Even on this dose she is still not well controlled."

A Yes.

Q What are the options?

A It is important to know that this patient's thyroid chemistry was appalling. TSH of 54 and FT4 of 4.3, which is important background information, it is regrettable that she was allowed to get to that stage. She had also had a thyroidectomy and, essentially, the levothyroxine was not doing the job. That is consonant with my experience in patients with thyroidectomy. I suppose because if you have all the hormones and the thyroid taken away it is not a huge jump to say they might need all the hormones to go back again. I know that is rather pragmatic but it seems to make sense.

Q On page 100 we see your letter to the GP. In the final paragraph you say that you have provided her with a private prescription for Armour Thyroid for the first three weeks. That is a fairly short prescription. You then invite the GP to consider prescribing beyond that three weeks. Why that short prescription from you?

A I have not quite got my head round this.

Q This is page 100, final paragraph.

A Final paragraph, right. I think in this case, I cannot remember every detail of every case, but I think the patient was going to ask the practitioner if he or she would prescribe this after three weeks, this is a financial point, to save her money. I gave her a private prescription for the first three weeks and would have continued it if the family practitioner declined to provide it through the NHS.

Q Patient 8, please, page 102. The referral letter is at 103:

> "She has requested to remain on the treatment she was given in Canada which is Armour thyroid and is currently taking a dose of 70."

A Right.

Q

"Her results are consistent with T3 over-replacement."

Why here is Armour Thyroid appropriate?
A I suspect I did not agree she had been over-replaced and her symptoms would seem to nay-say that contention. Basically she said she was improved and at that time Armour Thyroid was being replaced by f-thyroid, which is a Canadian version, I think it is exactly the same, and has a product licence in Canada so it is not quite unlicensed, I suppose. I asked for the product literature on the matter and again thyroxine did not seem to be doing the job so I increased the level of extract and asked her to let me know how she was doing in three weeks' time by telephone and asked the family practitioner if he would check the thyroid chemistry.

Q Patient 9, please, beginning at page 106. Your referral letter begins at 107. A history of non-toxic multinodular goitre.

"She attributes a lot of her symptoms to a lack of thyroid hormone. She was treated with 50 microgram's*(sic)* of thyroxine in 2005 to see if it would shrink her goitre but I don't recall it making any significant difference. …she saw an endocrinologist in 2007 who did not think that there was a hormonal basis TSH…always been normal range except when she was taking over the counter armorthyroid last summer."

What is the justification here?
A This patient was hypothyroid on the basis of her clinical features.

Q Patient 10, please, begins at page 112.
A This patient was referred to me while she was taking levothyroxine which was not doing the job.

Q We can see that from page 113, can we not? Unwell on levothyroxine. She feels generally unwell on thyroxine. Penultimate paragraph: biochemically under-replaced. Your justification is on page 114. Anything to add to that?
A I would agree with the family practitioner that on the biochemical that she was under-replaced notably and still got symptoms so I thought it was a fairly clear cut case. Very clear cut.

Q Patient 11, beginning at 115. We see your letter back on page 116 which sets out the history. She has had Armour Thyroid provided by Dr Hanebury who works in Bristol.
A Page? Sorry.

Q Page 116 is your letter back to the GP. Why Armour Thyroid here?
A This patient was taking thyroxine and was already taking Armour Thyroid. As far as I can see I did not increase the Armour Thyroid, I put the thyroxine up. I do not know if it is germane to this particular bundle.

Q Finally, patient 12, begins at page 118. Your referral letter is at 119.

"She stopped taking Thyroxine replacement therapy eighteen months prior and commenced Armour thyroid treatment. She felt a marked improvement…continued to take 1 gram twice daily."

You prescribed Armour Thyroid.
A Well, she was taking it.

Q She was.
A Quite a high dose.

Q What you did we can see on page 120 in the penultimate paragraph.
A Yes, I added a half grain and she still seemed to be under-treated. Then a further grain and then I arranged to see her in two months and asked the practitioner to re-check the thyroid chemistry.

Q In the patients that you have seen on your regimes, do you have any recollection of any patients coming to harm?
A None whatsoever.

MR FOSTER: The Panel can view for themselves what patients say about their outcomes. If you just wait there there will be some more questions.

THE CHAIRMAN: We did start at 20 to two, of course I was thinking we started at two o'clock, we have had an hour and a quarter. I think it is time to give Dr Skinner a short break. Let us come back at ten-past three.

THE WITNESS: Thank you.

THE CHAIRMAN: Of course you stay incommunicado during this period.

(The Panel adjourned for a short time)

MR FOSTER: Sir, I said that a document about possible side effects was being faxed through, I am glad to say it has arrived. My learned friend has seen this, perhaps the Panel can be handed copies. I think it is going to be D4.

THE CHAIRMAN: *(Same handed to the Panel)* D4, yes.

MR FOSTER: Could Dr Skinner be handed a copy as well, please. What is that document? *(Same handed)*
A This we have available in the clinic and all the patients are given the document. I think we also send it out with all our prescription.

MR FOSTER: Thank you very much. Just wait there, there will be some more questions.

<u>Cross-examined by MR ATHERTON</u>

Q Is there any record kept of the patient's receipt of this document?

A The patients are handed it at the clinic.

Q What happens to it then? Do they take it away?
A They take it away.

Q Is it recorded anywhere whether the patients have in fact received it?
A Do you mean the patient writes down "I have received it"? *(Disturbance from the public gallery)* I am sorry, I am not trying to misunderstand your question.

MR ATHERTON: Sir, I am sorry to say I am, frankly, not prepared to conduct a cross-examination against a background of laughter from the public gallery.

THE CHAIRMAN: I think this must be regarded as a final warning. I apologise on behalf of whoever laughed at Mr Atherton, I was not aware of it myself, but we must not have any interference from the public gallery. It does no good to anybody, particularly Dr Skinner.

MR ATHERTON: What system do you have in place for ensuring that each patient receives this document?
A They are given it when they come to the consultation.

Q By whom?
A The secretary.

Q Your secretary?
A Yes.

Q On arrival or on departure?
A On arrival.

Q Can we look together at the bundle marked as C1, please, and the determination of the Fitness to Practise Panel in 2007 at page 15? Can you see the second paragraph from the bottom of the page beginning, "The Panel has not made its judgement"?
A Yes. Yes.

Q Can I just remind you of what the Panel said.

> "The Panel has not made its judgement based on your personal beliefs as to methods of treatment save in so far as these beliefs have shown disregard of clinical responsibilities towards patients. The Panel notes that ever doctor who has given evidence at this hearing has indicated that they would undertake blood tests when assessing the patient's condition and deciding on future management. You have indicated in your submission that you believe it is not always necessary to check thyroid chemistry prior to initiating or changing a patient's medication. You have also indicated that you believe biochemical thyrotoxicity is a misconception. No other clinician at this hearing has supported this position. The Panel is most concerned that your rigid approach has put patients at risk of harm.

> The Panel has found that you have repeatedly breached the above principles contained within *Good Medical Practice*."

Have your views changed in any way since that determination was given, Dr Skinner?
A The first proposition that I indicated that I believe it is not always necessary, I was trying to indicate to the Panel that not every patient will agreed to have thyroid chemistry taken and I do feel that rather got talked up into something I did not actually say. I know you did not ask that question, sir. The question of biochemical thyrotoxicity ---

Q I think, as you say, you have given me an answer to a different question. Has your position changed or was that never your position?
A That was never my position as it is so written there.

Q It has never been your position that it is not always necessary to check thyroid chemistry?
A It is not possible with some patients.

Q That is a different point, is it not? If a patient refuses to have a blood test …
A Yes.

Q … then clearly you cannot.
A All right.

Q If a patient either agrees or is not asked is it your belief that it is not necessary to ask?
A That was never my belief and I think either the family practitioner or I will always have thyroid chemistry available. I do want to add one caveat to that, as I indicated earlier, that some laboratories will not carry out FT4 readings, which one can do nothing about.

Q The Panel went on to say:

> "You have also indicated that you believe biochemical thyrotoxicity is a misconception."

Do you agree that you did indicate that to the Panel?
A I did indicate that and gave supportive evidence from a large consensus in the world.

Q Do I take it from that that you remain of the view that biochemical thyrotoxicity is a misconception?
A Yes, sir.

Q Does the fact that apparently no other clinician at the hearing supported that position caused you to reflect on it in any way?
A I know we should be reflecting. I am not trying to be obtuse, sir, but I do not agree with that statement anyway, that no other clinician supported the position. I have reflected on it many and many a time, read extensively and talked to people. I have reflected and I still believe it to be the case there is an increasing volume of agreement

from the professional world.

Q The Panel got it wrong in two respects, then, in that single paragraph and your answer is that since that hearing in 2007 you have undertaken further research as to views about biochemical thyrotoxicity?
A Yes.

Q You have found support for your proposition that it is a misconception?
A Yes.

Q Where?
A From literature.

Q Are you able to point the Panel to the literature that undermines this assertion?
A Yes, of course.

MR FOSTER: Sir, I hesitate to rise as counsel always do, but this is not, as we established on the first day of this hearing, an inquiry into the supportability of the belief in this prescribing protocol. This is not an inquiry into the supportability of the orthodoxy. Were it to be so it would require a new allegation and it seems to me that we are going down that line now.

THE CHAIRMAN: Legal Assessor.

MR ATHERTON: May I say in response, sir, that the Panel then went on to say that it was most concerned that your rigid approach has put patients at risk of harm. When I opened the case I referred to this paragraph and to the criticism of the need for reflective practice. If, indeed, the doctor has reflected on this matter then you may think that it would help him if he is able to produce for you evidence of his reflections.

THE LEGAL ASSESSOR: That is a matter for submissions. I see nothing wrong with your line of questioning because, as you say, the Panel having quoted Dr Skinner's beliefs about biochemical thyrotoxicity being a misconception then went on to say that they were concerned he has put patients at harm, so I see nothing wrong in the question "Have you reflected on it?" Obviously, if he has not produced any further evidence in relation to whether there is a body of opinion then obviously that is a matter for submissions to establish the point.

MR ATHERTON: With respect, I think I am entitled to test an assertion that he has reflected in this way and to ask for the evidence of it.

THE LEGAL ASSESSOR: You have asked and he has said, "I have not produced it."

MR ATHERTON: He said he has got it and he appeared to be reaching for it.

THE LEGAL ASSESSOR: Sorry, I missed that.

THE WITNESS: What is the position, Chairman, please?

THE CHAIRMAN: Do you have any further comment to make?

MR FOSTER: If you accept the ruling of the Legal Assessor then there is nothing else I can say.

THE CHAIRMAN: I am confident that rigidity of approach is behind the paragraph that is written down there and it is perfectly reasonable to go along the lines that Mr Atherton is going and having said that he can back up the statements he has made Dr Skinner should be allowed to produce it to us.

A My first reflection was an observation that the biochemical validity had never been validated ever. There was one paper which has been quoted that I can go into in detail, but I am concerned to be over tedious which was quoted by Dr Akintewe, it was a totally flawed publication and I can indicate why. The reference intervals were introduced by a Professor Gräsbeck in 1969 from somewhere in Scandinavia. He pointed out, having done this excellent work, that they were not intended to be a pivotal criteria of diagnosis of hypothyroidism. The 5% or 95% reference interval was loosely based on a kind of wild assumption from protein bound iodine studies, I apologise for mentioning this earlier, with no validation whatsoever. I will not go through the over 120 papers which my reflections have focussed on. I can find about three in total, one of whom*(sic)* was indeed from the clinician to whom you were referred, Professor Weetman. Professor Weetman, however, has said, and I have the literature references, the opposite on a number of occasions. Shall I find that or shall I go on?

MR ATHERTON: Perhaps I can ask you this, first of all, for those in the room who do not profess your level of expertise in the matter. What do you understand biochemical thyrotoxicity to mean?

A What is meant by aficionados of the term is that irrespective of clinical features one or both of the usual thyroid hormones that are measured will be outside a 95% reference interval; it makes no statement about how the patient is, is my understanding. That is something I do not agree with and the literature supports that.

Q Thyrotoxicity may suggest to the lay person that it is a poisoning of some sort, a toxicity poisoning brought about by excessive levels of thyroxine. Would that be correct?

A That would be the contention of these people.

Q The contention would be, then, that this poisoning gives rise to an illness. Is that right?

A Yes. It is *de facto* any poison would give rise to an illness, surely.

Q Doctor, there may be people here again for whom you have to explain this. What is the illness that would be represented by thyrotoxicity?

A Ah, that I can answer. Thyrotoxicity indicates that there is evidence in the body that there is too high an effective level – not a level in a laboratory – of thyroxine and you get various clinical features pursuant to that matter. The definition of toxicity rests on the patient being toxic not on a laboratory finding. I have seen high levels in patients happy as Larry and the opposite, so I would stick to that contention and I feel the literature is supporting me in this. I have not gone through it all, you would cut me off in my prime.

Q I would not do that, doctor. If you want to produce 120 papers you have

obviously spent a great deal of time looking at since 2007 then I am sure the Panel would be interested to hear what they are.
A Okay. I think there was doubt, I am not going to read out ---

THE LEGAL ASSESSOR: Before you go on, what are you reading from?

THE WITNESS: I am reading from notes which I have prepared for this hearing, which is the main papers. Obviously I have not the stash although I have some highlights here. I have referred to the historical. 1996 I would say was the first shot across the bows, if you like. I am looking at what you might call good papers with evidence, not kind of someone's throw away opinion, by a gentleman called Fraser from the city of Glasgow who said there is little value in thyroid hormone estimations; absolutely extreme view. Then there is a paper: Zaluski, Shackleton. Professor Weetman himself and Professor Toft who was quoted there have published indicating that TSH has a poor correlation with clinical status. Professor Toft, who is a doyen of the subject, has changed his position on that with a measure of grace.

MR ATHERTON: Sir, can I suggest that Dr Skinner might do better to listen to and answer my question rather than, in response to any question, read pre-prepared notes which do not seem really to be answering the point I am putting to him.

THE CHAIRMAN: Yes, I agree, although I think he did open the floodgates there himself.

MR ATHERTON: I agree and the difficulty here is one might expect that as part of the demonstration of reflection this material could have been pre-prepared and handed to the Panel. I do not want to put Dr Skinner at a disadvantage by causing him on the hoof to start to think about 120 papers but if he has done that and can support the proposition he may or may not wish to present it to you, but that is a matter for him.

THE LEGAL ASSESSOR: You have made your point.

MR ATHERTON: I have, thank you. *(To the witness)* Before I leave the thyrotoxicity can I just establish that you have agreed that there is such a condition?
A As?

Q Thyrotoxicity.
A It is very clear. Absolutely.

Q Biochemical thyrotoxicity you do not believe there is such a concept.
A Am I allowed to put a caveat in or not? It is perfectly obvious I have indicated, I hope persuasively, that you cannot diagnose toxicity from the biochemical results; no. It is obvious to anyone with a measure of common sense that if biochemical results are through the roof you would take cognisance of that. I do not agree that if someone's FT4 is slightly above the 95% or above the 95% reference interval and the patient has no symptoms that that patient is toxic. That is the position I have been trying to put over for ten years.

Q Am I understanding correctly, then, that you agree that biochemical results are an

aid to the diagnosis of thyrotoxicity?
A Yes. I made that clear in my opening remarks to the Panel, it was the reciprocal I was concerned about.

Q I am sorry?
A It was the reciprocal I was concerned about.

Q Perhaps you would like to explain that.
A Yes. As I said before, the reciprocal is that if the tests are within 95% reference interval the patient is not necessarily well. If the results are wildly wayward they would be helpful. I have seen thousands of patients clearly hypothyroid with thyroid chemistry within 95% reference intervals, I acknowledge that that is anecdotal.

Q The Panel went on to say on page 15 that it was concerned that throughout the hearing you had shown a lack of insight into your behaviour which was:

> "…clearly demonstrated by the statement you provided to the Panel, dated 7 September 2007 in which you set out your reasons for refusing to accept the findings of the Panel. For example, you state 'In fairness to myself, the text should be rewritten and the term biochemical thyrotoxicity, which is a non-concept, removed…' This approach has not been supported by any other clinician…"

The Panel's concern there seemed to be one of a lack of insight. Do you understand why there have been these concerns about your practice?
A Yes.

Q Have you taken any steps since 2007 to acknowledge those concerns and change your practice?
A Have I taken steps to acknowledge the concerns? I understood the concerns first time round. I have not changed my position following my long reflection and research and discussion with people on the question of how patients should be treated.

Q Are you able to point to any change in your practice as a result of the findings in 2007?
A Yes.

Q Could you help the Panel with those changes?
A Yes. I keep a log book. I only see patients by referral, which was indeed my practice before. I make absolutely sure, which I always did, that the family practitioner referring persons is advised of my treatment plan and should I make application for a post I would tell the person to whom I am making the application.

Q Do you now ensure that you have blood results before prescribing thyroxine?
A I always did unless the patient will not supply a blood sample. That was wrongly written in the Panel in 2007, I regret.

Q It has always been your practice to ensure that you had blood results before prescribing?

A If it is possible.

Q Of course. If the patient refuses then you cannot, can you?
A Yes.

Q Although you could, I suppose, withhold the prescription having regard to the uncertainty?
A You could.

Q You would not?
A I have tried to follow the Hippocratic oath. The patient's welfare comes first before possible trouble with regulatory authority.

Q That would also outweigh any potential risks to the patient of prescription of thyroxine?
A Potential risk to the patient?

Q Yes.
A I do not accept that the responsible prescribing will engender a significant risk otherwise I would not do it.

Q Would prescribing in the absence of a blood result be responsible prescribing?
A Yes, if it was done sensibly, if it was necessary. Much more responsible than leaving the patient ill for the rest of his or her life and as you start with low dosage and increase in integers there is a *de facto* built in safety factor.

Q Can you help us as to the nature of your practice. We understand that it is private practice. Do you work as an employee of a company or are you a partner in a firm? What is the structure?
A You mean as regards my practice?

Q Yes.
A No, I am a sole practitioner is how I am described by the Inland Revenue.

Q As such, do you trade under a name other than your own name?
A No.

Q If you feel that blood tests need to be obtained, how do you go about doing that?
A I would take the blood sample. Sometimes my secretary phones the family practitioner up if they have omitted to put them in, or sometimes requests the family practitioner to carry out the blood test.

Q If you took a blood sample, would you send it to a lab for analysis?
A Yes.

Q You have an arrangement, do you, with a lab for that purpose?
A Yes.

Q By this stage I am understanding that the patient is no longer an NHS patient but

is now your private patient. Is that right?
A Yes. It has been almost always referred from the NHS practitioner.

Q The responsibility once you take a blood sample and the cost of it, the sampling, would be your cost, effectively, would it? To be passed on, obviously, to the patient later.
A Yes. Yes, I am afraid so.

Q How often do you do that? To be more specific, over the past three years, say, in how many cases approximately would you say that you have sent blood samples off for testing?
A These are ones where the GP, the family practitioner, has not sent the thyroid chemistry or has not done the thyroid chemistry, I think that is your question. I do not know is the short answer to that. I would guess, a wild guess, I would say – I can get that information from the laboratory of course, I would say about 20% of patients I require to take the thyroid chemistry. I try to avoid it in a sense because the patient has to pay for it and they are already paying. It is good if it is already dealt with, and it usually is, by the family practitioner.

Q How recent do you like the blood test to be, or does it not matter? It obviously matters if it is years and years. I would say four or five months would be probably acceptable.

Q The Panel went on, on page 19, at the top of the page, to express the concern about prescribing thyroxine without taking blood tests and without regular review and monitoring. If you have prescribed thyroxine whose responsibility then is it to review and monitor? Is it yours or the family practitioner?
A That is a question which I would very much welcome the answer to in a shared care arrangement which nearly all the patients are. I would have thought it was a joint responsibility.

Q How do you discharge that responsibility? What procedures do you have for follow-up?
A As Mr Foster indicated to the Panel, patients are asked to either come back two, two and a half months, or the family practitioner will follow the patient. I normally ask the family practitioner to take a follow-up thyroid chemistry at about six weeks if the patient is coming back in two months.

Q Can you take any steps to ensure that that is done? Do you have a follow-up system with the family practitioner?
A Yes, because if a patient is supposed to be coming back and does not come the follow-up system there is it is in the appointments book. If the patient does not go back to the family practitioner is your question, how do I know?

Q In either event, how do you know?
A I know if they have not come at the appointed time if they were coming back to me. I think that is a sensible and reasonable point. I think it is something we might look into the practice: do I know if the patient has not gone to the family practitioner? I acknowledge that point.

Q Has your reflective practice over the last three years not caused you to acknowledge that point?
A It does not seem to have. I acknowledge that as a defect.

Q Why is that? The Panel was clear about its concerns about monitoring, was it not?
A Yes. I did not actually agree with what they said there either but I am trying to think through this question. First of all, nearly all the patients come back to see me in two to three months. Your question is would I know if the patient has not gone to the family practitioner? I think that is the bones of your question.

Q The bone of my question is what procedure do you have in place to follow up the consequences of your prescribing?
A I have told you if they are coming back to me. In other words, the patient defaults a visit to the family practitioner, that is the question. Given the patient is not getting a prescription from us I think I would be prepared to admit – and thank you for raising it – that I would not know that immediately.

Q Is it not important, though, for you to have the information about follow-up so that you are can assess the effectiveness of your treatment and whether any unwelcome consequences have flowed from it?
A I have indicated that this is a very unusual event. Adverse consequences, the patients are told very clearly to let me know. I am available on the phone at all times if there is any adverse effects and it would be surprising if they did not go to the family practitioner as well to report. The patient is asked to let me or the family practitioner know. I think it would be most unusual for a patient to have adverse effects and not flag it up.

Q Could thyrotoxicity be an acute condition?
A It is an acute condition often; thyroid storm or something.

Q Would it require hospitalisation?
A This is an untreated patient who has become acutely ill, you are asking?

Q I am asking whether a patient who is thyrotoxic would demonstrate symptoms that require hospitalisation?
A Certainly it could happen. It is unusual not to be a bit more insidious than that.

Q If that was the case it may be that you would not know anything about it, would you?
A It is conceivable but I think it is extremely unlikely.

Q Why?
A Because a patient who is starting to get thyrotoxic symptoms would almost certainly contact me or the family practitioner. That applies in all medicine, a patient can suddenly have a stroke. In every branch of medicine an unexpected emergency can occur.

Q You might be able to understand that the family practitioner would be aware of it

but not necessarily that you would be aware of it as a private practitioner.
A If the patient did not tell me and the family practitioner did not advise me, which would also be unusual, that would be true.

Q You could have a system of asking the family practitioner for follow-up, could you not? Whether there had been any adverse events?
A You mean the patient does not report it? The family practitioner will tell me if there is some adverse outcome.

Q He will?
A Yes.

Q How do you know that? What system do you have in place to ensure that he does?
A It is not a system in place in a sense, it is a question that you have to trust your colleagues in family practice. What system would you have? Please tell me if a patient comes to you with – they are responsible people the family practitioners, they are qualified practitioners, they are not students or something.

Q Is it the case now, then, just for clarification, that every patient you see and for whom you prescribe thyroxine or Armour Thyroid, for each such patient you would have seen a blood result before prescribing?
A Not absolutely every patient.

Q Every patient who was prepared to consent to a blood test?
A I think you will see, if you remember the evidence I have previously given, that a patient can come who seems seriously hypothyroid which, as you have pointed out, could be an emergency and in collaboration with the family practitioner I have on occasions prescribed a lower dose pending the blood result. I think that is perfectly responsible practice.

Q On occasions. How often would that occur?
A Twelve times in a year, maybe.

Q Maybe?
A I am just taking a guess. You asked me to guess.

Q You seemed very clear about it, I wondered if you had actually done the research on it.
A No, sir.

Q Can I just try to clarify shortly, without descending into the detail of it all, look at the schedule that Dr Akintewe has produced on the front of exhibit C6. If we could just run through these. He prepared these references because he believed he had seen patients being prescribed thyroxine where there was a normal thyroid chemistry. I would just like to be clear which of these patients you say did not have a normal thyroid chemistry.
A Perhaps the easiest way is to start on page 2 and then further examine the ones that there may be dubiety. Would that be reasonable?

Q As you wish.
A Thank you. 3.

Q Do you mean page 3?
A Sorry, Patient 3.

Q Patient 3. You say that this was an abnormal chemistry, do you?
A Yes.

Q You accept the reading TSH 2.53?
A Yes.

Q You say that is abnormal?
A Yes.

Q By reference to what value?
A 2.5 is, I think, an excellent re-sampling of the US population.

Q This is a US value, is it?
A Yes.

Q By reference to the British value or the UK value that Dr Akintewe was applying do you say that it is normal or abnormal?
A Dr Akintewe believes that it is normal. He said that very clearly this morning.

Q Yes, but I am asking for your view.
A I thought that was in before the Panel already.

Q I would like clarification, if you do not mind.
A I do not want to comment on Dr Akintewe's evidence.

Q I am not asking you to do that.
A You are.

Q I am asking you to give your view by reference to UK standards whether 2.53, in your view, is normal or abnormal.
A The UK reference interval adopted by most but not all practitioners is something like 0.5 to 5.

Q That would be normal, then?
A It is within these reference intervals.

Q Let us not fence with each other, Dr Skinner. If it is within the reference intervals is the use of the word normal troublesome to you?
A Yes, it is not good. That has been very clear from the November hearing where it was in fact formally removed. Normal has an implication of good health.

Q Yes.
A That would be my problem with understanding.

Q Can you bear with me, then, from my lay position if I invite you to adopt the word normal if it is a value within the range?
A I am prepared to say it is within the range. It would be grievous to say it is normal.

Q Forgive the grief but I am going to use normal to mean within the range. Do you understand?
A I understand what you are going to do.

Q Thank you. I would be grateful if you could bear with me however upsetting it might be for you. 2.53 would be normal, that is within the range in the UK? *(Pause)* Is that right?
A It is within 0.5 to 5.

Q Thank you. We have gone straight to Patient 3, can we just look at Patients 1 and 2. TSH 0.8 in UK ranges: normal or abnormal?
A We do not know the value here.

Q He has ---
A He says three times the average. It is more than three times 0.8. I assume it is not greatly more than a sensible assessment of it, so if we call it 2.4 it is indeed within the US range.

Q I am not asking you about the US range, you understand that, I am asking you about the UK range. Within the UK range is it normal?
A Yes, of course it is because that is wider. Yes, it has to be. It is not normal, it is within that interval.

Q By my use of the term normal you understand it to be normal, do you?
A I would ask you to concede to me in this matter. I think this term normal is having a bad effect all round.

Q Forgive me ---
A Could we not just say within the reference interval?

Q Dr Skinner, no. I think everybody understands what I mean by normal and I think you do, too. Is it normal, Patient 1?
A It is within the reference interval, as I said.

Q Thank you. Patient 2. Did that patient have a normal thyroid chemistry within the UK range?
A Can you give me the page reference, please?

Q It begins on page 4 and the letter from you is page 6.
A Page 6. Now, this one, three times the 0.8 would be within the UK and US range.

Q Thank you. Patient 4, page 12. *(Pause)* Page 13 might help.
A Yes. Yes, it is. As Mr Foster pointed out, according to the family practitioner

here he believes it to be a normal T4 and TSH. We need more data from the notes for this one.

Q Did you seek to obtain more data?
A I always do.

Q You would do?
A I always do.

Q What would you do?
A I would ask the family practitioner for the numbers.

Q Can we assume that in the absence of any correction he confirmed that the numbers were normal T4 and TSH?
A I do not think so.

Q You cannot assume that?
A I do not think so, no.

Q What value, then, did you have before you prescribed thyroxine for this patient?
A It will be in the notes but this is a snapshot.

Q I think we have your handwritten notes on page 12. Would that help us?

THE CHAIRMAN: I am sorry to interrupt, but surely page 13 shows this:

> "I enclose her most recent blood tests which does include a normal T4 and TSH."

It would seem the blood tests are enclosed and on page 14 Dr Skinner writes in the fourth paragraph:

> "The thyroid chemistry is well within 95% reference intervals…"

MR ATHERTON: Thank you.
A Thank you, sir.

Q Normal, then. Patient 6, it starts at page 19.
A *(Pause)* I have not found anything yet. *(Pause)* The family practitioner says these are normal.

Q You are looking for that at page 20. Is that right?
A The difficulty is that Let us say it was 3.4 we would be caught in the UK/US dilemma.

Q Can you just point to the passage on page 20 that you are referring to when you say the GP said it was normal?
A We are on page 20?

Q I think that is what you were looking at.
A Yes. He says, I quote:

> "I have voiced my concerns about her taking these medications…"

that is stuff above,

> "…especially in view of the fact that her thyroid function tests when checked her in surgery have always been normal. I have also voiced my concerns about using Cortisol."

Q Thank you. That is also then the evidences suggests was normal. Patient 7, beginning on page 23. I think it may be page 25, actually, we need to look at.
A My view there was that the TSH – again, I do not think we have got the numbers because of the snapshot – was well above the average for healthy patients which runs around 0.8 and, as quite often happens, we do not have an FT4 reading.

Q Do you not need an FT4 reading before you prescribe
A First of all you cannot usually get one nowadays but I would say… Well, it is what we have been saying for the whole afternoon, if there are clinical features and TSH reading it is perfectly legitimate and good medical practice.

Q What is the difficulty in getting an FT4 reading? What do you need to do?
A Generally speaking laboratories will not do it unless commissioned by a consultant endocrinologist. Many family practitioners complain to me they cannot get this done.

Q When you send it off for a private blood test …
A Oh, yes, you can get it done then.

Q … you can ask for it?
A Yes.

Q It seems here that you did not do that and nobody else had done that?
A The patients will not agree to a private blood test if the NHS have not carried it out. They will occasionally but by and large they will not and I can sympathise.

Q That may be very interesting but in this case you did not, did you?
A I think we have established that.

Q Yes. Neither do you actually give the value for the TSH reading, you simply say well above the average?
A How do you know I do not give it?

Q I cannot see it there.
A We have established that we have only got a small piece of document ---

THE LEGAL ASSESSOR: Mr Atherton, the point is that he has not done this blood test. On page 24 it says:

"I enclose copies of all [so and so's] recent blood tests."

The letter from Dr Skinner at page 25 does indicate that she had a TSH reading well above the average healthy patients but he does not actually say where it is, so that is as much information that we have.

MR ATHERTON: I think that is the point we had reached.

THE LEGAL ASSESSOR: Yes.

MR ATHERTON: *(To the witness)* I am asking whether this is one of those cases where you have thought it appropriate to prescribe without having those values first?
A But we do have the values. The family practitioner ---

THE LEGAL ASSESSOR: The point I am making is if ---

MR ATHERTON: Yes, I understand ---

THE LEGAL ASSESSOR: Then the values surely are there.

MR ATHERTON: I understand that. *(Pause)*

THE LEGAL ASSESSOR: We might not know what it is but certainly there is evidence before the Panel that when instructed all recent blood tests were sent.

MR ATHERTON: We can see from this that the blood tests showed the TSH reading but not the FT4 reading. I will invite Dr Skinner's help as to whether or not the FT4 reading is one that you now say you take into account before prescribing.
A If a reading is available of course I take it into account; yes.

Q If it is not available you do not ask for it?
A Yes, I do ask for it, actually, if the patient can pay in the private sector, which is a big problem. I always ask the family practitioner. For example in this case he sent. He had the blood test and that is why I do not enumerate it particularly as he has already got it.

Q We can say that was normal, then, on the evidence we have?
A It says she has a TSH reading well above the average. We do not know it. It is in excess of something and the family practitioner who has written to me will know of the reading, he can make his own judgement.

Q If it is outside the range you would say so, would you not?
A Not necessarily.

Q Patient 9. Do you accept that this was a normal TFT?
A Sorry. I do apologise, I am getting all mixed up.

Q Patient 9, page 29.

A Yes. Is this Dr Westwood? Page 27?

Q Page 27 I think ---
A Is the referral letter, is it?

Q You may be right, thank you.
A Is it page 27?

B

THE LEGAL ASSESSOR: Page 27 is Patient 8, which you have not been asked about.

THE WITNESS: That is the one that has a high TSH?

MR ATHERTON: Patient 8 I was just asking about, in fact.

C

THE LEGAL ASSESSOR: I thought you said Patient 9.

MR ATHERTON: I was just moving on to Patient 9 and the previous questions related to Patient 8, I believe.

THE LEGAL ASSESSOR: You were Patient 7 then I presume that you did not ask about Patient 8 because that was 3.42 and above, the clearly obvious what that was. That is my assumption.

D

MR ATHERTON: I am grateful.

THE LEGAL ASSESSOR: Correct me if I am wrong.

E

MR ATHERTON: No, I will accept that. *(To the witness)* Patient 8 we can take is normal, can we?
A Patient 8 is a Stafford Gnosall patient identified from the…

Q Sorry, what does that mean?
A I am just trying to identify the patient without really quoting the family practitioner's name.

F

THE CHAIRMAN: Yes, it is page 27.
A Yes, that is right, yes.

Q The doctor's reference letter.
A I would gainsay that contention about being normal.

G

MR ATHERTON: Why is that?
A Because the best evidence, on my reflected focus on the matter, is from the United States.

Q Yes, but you know that I am not asking you about the United States, I am asking you about the UK range.
A Well, it is obvious it is not, then. If you take 0.5 to 5 it is well within it.

H

Q Is your answer it is normal, then, or within the range, as you prefer?
A I cannot accept it is normal if a better evidence suggests that 2.5 should be the upper value. I think that would be disservice to my position as a doctor.

Q That is because you want to adopt US guidance on it. I am asking you about UK guidance.
A I am sorry, Mr Atherton, I am not trying to be obtuse, I do not want to adopt the US. The work they did was a very precise sampling of the population, it would be a negation of my duty to suddenly say we do not believe that good work, we are going to go back to that. It is manifestly obvious it is within the UK reference interval.

Q Thank you. Can we move on to Patient 9, then, page 29. I am asking you to agree or disagree with Dr Akintewe's conclusion that this patient was within the normal UK range.
A Yes. I think, I do not know – again it will be in the notes – I have made the point that in my view it was consonant for diagnosis, which probably means it was low. I have acknowledged it is with the reference intervals.

Q The doctor, the GP, page 30, enclosed thyroid test blood results which were satisfactory.
A Yes. I think it probably was lowish, slightly grudging satisfactory.

Q Can we agree that it was normal? That is within range, probably?
A I do not know. I have not got it.

THE LEGAL ASSESSOR: I understood that Dr Skinner had answered already that on page 31 he says the thyroid chemistry is within reference intervals, that is the penultimate paragraph on that page. Presumably it means it was within the range 0.5 to 5.
A For the avoidance of confusion, the UK/US thing does not apply to FT4 so we need not get into semantic difficulties there.

MR ATHERTON: Patient 11, then, please. Do you agree that this was a normal TFT as Dr Akintewe says?
A The same problem, we do not have the actual numbers. I have said in my letter it is consonant with the diagnosis. I accept that does not give a value but I have said, albeit within the reference interval, if that would answer your question.

Q Thank you. Patient 13.
A Is this page 37 foot of page?

Q Patient 13's handwritten notes begin on page 45.

MR FOSTER: You have jumped a patient again. It may be relevant.

THE WITNESS: That is the one with the high TSH? Yes.

MR ATHERTON: I am told I have jumped a patient so we should be on 12, I think.

THE LEGAL ASSESSOR: You were on 9, you skipped 10, then you went on to 11, then

you went to 13. I do not think we have done 10, if that is what you want to ask him about.

MR ATHERTON: Thank you very much. Page 33 is Patient 10. Page 34 refers to normal TFTs.
A I have said I thought it was raised but it was within the reference interval.

Q Thank you. Then I think we dealt with 11 and going to 12 on page 41… Page 42, the GP says consistently normal TSH tests, normal Free T4. Do you accept that?
A No. I cannot imagine a practitioner would not draw attention to this low FT4. We do not know if it is within or without the reference intervals because they were not given, they would not be available now.

Q Where a GP is saying consistently normal TSH tests, what are you understanding that to mean?
A I understand that, while the numbers are not given, they are within the reference interval.

Q We can take that as normal, then, can we?
A I am not going to say this normal thing. I am really sorry, I am not being obtuse, we can think it is within the reference interval.

Q Thank you.
A I would like to see the numbers ---

THE CHAIRMAN: They are all there. On the third paragraph:

> "He has had five checks of his TSH over the last five years and all tests range from 0.9 to 1.26."

THE LEGAL ASSESSOR: If you go on to page 43, in the fourth paragraph Dr Skinner says:

> "…although his FT4 is clearly on the low side and reference intervals are…"

on the low side. I do not know if that is coming from the reference intervals or what, whether that reading is within that, but there is certainly reference there to it.

MR ATHERTON: Patient 14 begins at page 48.

THE CHAIRMAN: Have we done Patient 13?

MR ATHERTON: I thought we had, just - or not?

THE LEGAL ASSESSOR: You started it then you went back.

MR ATHERTON: All right, thank you. Page 45 for Patient 13.
A This patient had clearly a TSH value some years ago, as I noted, outside I would

imagine the UK reference interval and I indicate the dilemma there. I prescribed thyroxine on the basis of that.

Q You go on to say in that paragraph after "dilemma":

> "…the thyroid chemistry of what is presently available does not and is within normal limits but I believe that clinical features should transcend thyroid chemistry which is a good servant but a bad master,"

again. It looks as though that was normal, does it not?
A Yes, it does, but not the TSH.

Q You are referring to a TSH value of some years ago, are you?
A Yes, particularly as it was notably high and that, I think, is an important observation.

Q You would want something more recent than that, would you?
A Preferably, yes.

THE CHAIRMAN: Is there not evidence of that in the third line:

> "The thyroid chemistry is within 95% reference intervals although she had one spectacularly high TSH value some years ago…"?

That indicates that he has taken into consideration recent results and comparing it with the previous ones.

MR ATHERTON: Thank you. Page 48 is Patient 14. I think page 51 might help you.
A Yes. If you are referring to the UK it was obviously within that. As I have indicated, I felt there was better information than that available for doctors now. May I be excused just one thing to say to the Panel? It says here: "Referred to endocrinologist…Dr Skinner." My colleague always writes to any family practitioner to indicate I am not an endocrinologist. Just, like, posing as an endocrinologist or something.

Q Patient 15, begins on 53.
A It is the same issue: US/UK difference.

Q UK within range, US not. Is that right?
A I think so. I cannot be absolutely certain from this paragraph, although I suspect that was…

Q Patient 16, page 56.
A This patient, as applies to a lot of patients curiously enough in this folder, was already taking thyroid replacement.

Q I think the values appear at the bottom of page 57, do they not?
A Yes. Perceived wisdom among the endocrinologists, I do not know how good the

evidence is to back this, is that FT4 should be towards the upper value of the 95% reference interval which is probably, I do not know this, about 22, 24.

Q So that we are not blinded by the science, is this patient correctly described as having a normal TSH by UK standards
A Yes. The patient is already taking the medication which would lower that.

Q That may be so.
A Yes.

Q Is she properly noted as a normal TSH?
A It is not a normal TSH. It is below the lower value of the 95% interval. It is emphasised by Professor Toft that we should probably aim for zero TSHs in patients treated.

Q Move on to Page 17, page 61. You refer to a normalish TSH on page 64.
A This is a patient where I have asked the GP to use his good office in fact to get laboratory chemistry. Some other tests I thought were appropriate. I was quite prepared, on the clinical position, to institute thyroid replacement at a low level, remember, 25 or something, and I think that is good medical practice.

Q Patient 18.
A I just do not know here. The GP seems to have sent the bloods but I do not comment on them here.

Q The GP refers to routine bloods.
A Yes.

Q U&Es, LFTs, TFTs and full blood count were normal. Does that give you what you need to know?
A I do say myself notwithstanding the thyroid chemistry, which would be consonant with your position, that that would be within the reference intervals.

Q Thank you. Patient 19.
A My letter on page 72?

Q Yes. There are some values given on page 120.
A Yes. The FT4 the laboratory vouchsafe it is abnormal.

Q Where are we looking there?
A About ten down from where it says “Pathology results”.

Q Do you agree that it is abnormal, 7.2?
A Well, the arithmetic of the matter on this occasion is 7.5 to 21 is the range, so it is out the reference interval as the laboratory say.

Q That is T4. what about TSH?
A It is more than double the average but within reference interval.

Q Finally ---

THE LEGAL ASSESSOR: Hang on. Doctor, can I just clarify something for the benefit of the Panel. You have been saying that the UK range is – and I think Dr Akintewe said this – 0.5 to 5 but on page 71 someone has written on the penultimate line in brackets 0.3 to 5.6. Where does that come from?
A Different laboratories, following their sampling, do vary the reference interval and construct the 95% reference interval. Some laboratories it is 0.5 to 5, 0.2 to 4. It is just variable, it depends on the sampling procedure.

Q Thank you, I just wanted to clarify that.
A Okay.

MR ATHERTON: Finally, Patient 20. Page 75, thyroid chemistry.
A Yes, yes.

Q Not remarkable. TSH 1.07, within the range?
A That is correct.

Q Thank you. Can I just ask you about your preference for the United States work. Is this a work that has been generally published in the United Kingdom?
A It has been published in international journals.

Q It seems not to have been adopted by anyone but you in the UK. Is that fair?
A No, sir, I do not think that is true.

Q Can you help us, then, to understand the extent of its acceptance?
A A very difficult question. A number of family practitioners accept that. I talk to endocrinologists who do. I have the references for that issue, the issue you raised. It is the Centre for Disease Control in 2002 first, the survey of patients for four years. This was confirmed in – the American Association of Clinical Endocrinologists encouraged that we should look at 3 to 3.5 and then the National Association of Clinical Biochemists in 2006, in a very assertive statement, said that 95% of the population they sampled – one understands there could be differences there – lie under 2.5, thus they advocated that reference interval.

Q How would those values in your view change practice in the United Kingdom?
A I think people should take cognisance of the fact but I would not sway away from the central criterion that the clinical features tell you if a patient is hypothyroid or not. If you found a patient with suddenly enormously high FT4 or something then you would take cognisance of it. I think it will change practice, I believe it is changing practice now.

Q What is the evidence for that? Has there been anything published in the UK in the recognised journals on this issue?
A Oh, yes.

Q Can you help us with that?
A Yes, I can. Let us go to TS3 intervals wrong. I am sorry about this delay, very complicated pieces here and there. There has been a fairly considerable body of work. I

did emphasise the person that developed them, by the way, they should not be used for that.

Q Sorry, I do not follow.
A I did emphasise that Professor Gräsbeck could develop his 1969, argued very rigorously, that there should not be a criterion of diagnoses. I have got a list of references. Is it worth giving them out or is that tedious?

Q It remains to be seen how this will help the Panel. It seems that you are preferring the use of the United States ranges to the use of the UK ranges and I am just trying to get a feel for whether you consider yourself to be out on a limb in that respect or whether you consider that it is a generally accepted practice to use the US range.
A I think acceptance is growing all the time, Europe as well as the United States, because the science should win through. The science is that the excluded patients who might already be hypothyroid, because of antibodies, because of a family history or a number of these parameters, they did a very clean investigation and certainly the work in the United States, which is supported in general, has indicated that this should come down to 2.5.

Q Has it been peer reviewed in the UK or by UK experts?
A The publications are rigorously peer reviewed. I think I can help there, I am trying to think of where to help from. We have talked about Professor Toft, I think, and he has changed his position on this, he is the doyen of the subject.

Q Changed his position in what respect?
A The TSH intervals as they were are unreliable, going up to this level to say that patients with a TSH of 4.4 are therefore not hypothyroid.

Q That is an assertion you make. Presumably there is a paper…
A Yes.

Q …published here which says that?
A Oh, yes, there is quite a lot of papers on this.

Q I see. Are you aware of any other private practitioners like yourself who are practising in this way?
A I do not actually know many other private practitioners but a number of NHS – you mean in this way, the thyroid chemistry issue?

Q Yes.
A A number of NHS consultants do this and I can provide the Panel with the actual figures here which I prepared for the November hearing. This was a survey of all endocrinologists. FT4 levels within the 95% reference intervals ---

Q I am sorry ---
A May I not read this out?

Q This is a reference to a document that I do not think any of us have seen.
A I can answer without the document, if you want.

DR JEFFRIES: I have seen the document.

THE CHAIRMAN: Can you point it out to us?

DR JEFFRIES: No, I cannot; no. I have read this earlier on but somewhere in here there is ---

THE LEGAL ASSESSOR: If it was evidence before the previous Panel then clearly it is admissible.

MR ATHERTON: Does it have a heading, doctor?
A Yes. A survey of endocrinologists 23.07.07. I have gone and lost my second page now. I am only trying to help answer your question.

Q I understand that but it is important if you are referring to a paper that we can follow it ourselves.
A It was a paper I wrote. I mean, it has not been published ---

MR FOSTER: I wonder if it is page 75 of C1.

THE WITNESS: No, these are eponymous responses.

MR ATHERTON: Is that what you are referring to, page 74?
A There should be two pages, eponymous and anonymous responses.

Q Yes, it is on page 75.
A Sorry about this. Yes, here they are.

Q This is dated 23 July 2007 and I presumed this was a paper that you placed before the original Panel. Is that right?
A Yes.

Q I see.
A I think it makes interesting reading. Shall I speak to it or not?

Q I am not going to ask you any more questions about that, thank you.

THE CHAIRMAN: Mr Atherton, do you have many more questions?

MR ATHERTON: No, sir, I have finished now, thank you.
A With respect, you did actually ask me for that information and I have it for you.

Q You have pointed it out and no doubt if my learned friend wants to re-examine you about it or the Panel ask questions they will do.
A Yes, I am sorry.

THE CHAIRMAN: Thank you very much. I think it has been a long afternoon for Dr Skinner and I think it would be reasonable to break now.

MR FOSTER: Very good, sir.

THE CHAIRMAN: In the morning we will resume with Mr Foster coming back to ask you any questions that may have arisen as a result of Mr Atherton's cross-examination of you, then the Panel may have some questions for you as well but in the meantime of course you may not speak to your legal team about the matter overnight.

THE WITNESS: Okay.

THE CHAIRMAN: We will resume again at 9.30 in the morning.

THE WITNESS: Thank you, sir.

(The Panel adjourned until 9.30 am on Wednesday, 16 November 2011)

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