PENSION SCHEMES ACT 1993, PART X
DETERMINATION BY THE PENSION OMBUDSMAN

Applicant	Miss J Thomas
Scheme	NHS Injury Benefit Scheme
Respondent(s)	NHS Business Services Authority (**NHS BSA**)

Subject

Miss Thomas has complained that the NHS BSA have not considered her eligibility for a permanent injury benefit (**PIB**) in a proper manner.

The Pensions Ombudsman's determination and short reasons

The complaint should be upheld against the NHS BSA because they failed to provide Miss Thomas with any reasoning for their decision.

DETAILED DETERMINATION

Material Facts

1. Miss Thomas was employed as a Community Nurse. Her employment ceased on 14 August 2001 on the grounds of ill health and she is in receipt of an ill health retirement pension. Miss Thomas applied for a PIB on the grounds that her condition, Chronic Fatigue Syndrome (**CFS**), was caused by Hepatitis B vaccinations she was required to have in the course of her employment. Miss Thomas' former employer has confirmed that she received vaccinations in 1988, 1989 and 1997.

2. The relevant regulations are contained in the National Health Service (Injury Benefits) Regulations 1995 (as amended). Regulation 3 states,

> "Persons to whom the regulations apply
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> (1) ... these Regulations apply to any person who ...
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> ... sustains an injury, or contracts a disease, to which paragraph (2) applies.
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> (2) this paragraph applies to an injury which is sustained and to a disease which is contracted in the course of the person's employment and which is wholly or mainly attributable to his employment and also to any other injury sustained and similarly, to any other disease contracted, if -
>
> (a) it is wholly or mainly attributable to the duties of his employment;
>
> ..."

3. Regulation 4 sets out the scale of benefits which may be paid and provides that a PIB shall be payable to any person to whom regulation 3(1) applies whose earning ability is permanently reduced by more than 10% by reason of the injury or disease.

4. In 2000/2001, Miss Thomas eligibility for a Temporary Injury Allowance (**TIA**) was under consideration. The medical adviser to the NHS BSA at the time expressed the view that her case for receiving a PIB was weak. He said that her reported reactions to her vaccinations were likely to have arisen because of a constitutional vulnerability to become allergic rather than the nature of the vaccine itself. The medical adviser acknowledged that it was theoretically possible for Miss Thomas' incapacity to have arisen out of an interaction between her

constitution and the vaccine. However, he went on to say that CFS and/or Fibromyalgia were common conditions and there was inadequate evidence of a link between them and the vaccine to prove a causative connection. The medical adviser said that Miss Thomas appeared to be allergic to a number of things and had a history of eczema in 1994 (Miss Thomas subsequently informed the NHS BSA that she did not have eczema in 1994 and had confirmed this with her GP.)

5. Miss Thomas applied for a PIB in 2007. The Scheme's medical advisers, Atos Origin (**Atos**), issued a decision on 13 November 2007. They informed Miss Thomas that their medical adviser was unable to recommend payment of a PIB because he was unable to conclude that she had suffered an injury which was wholly or mainly attributable to the duties of her NHS employment. Atos quoted from their medical adviser,

> "Having considered a detailed submission from the applicant, information submitted in connection with her application for ill health retirement and information submitted in connection with her application and subsequent appeals regarding [TIA] … including information provided by the Manufacturer of Engerix B … The applicant has indicated that the condition for which she is requesting consideration of [PIB] is "Chronic Fatigue Syndrome/ME with elements of Fibromyalgia". She attributes this condition to an adverse reaction to the administration of Engerix B vaccine that she was required to have during her employment … In order for her application to succeed it must be accepted that her condition can be wholly or mainly attributable to the duties of her NHS employment
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> It is noted that she had her initial Hepatitis B immunisation on 14/10/88, the GP notes record that she had a reaction to this … In April 1989 she consulted her GP with symptoms of swelling of her hands and feet the GP considered that these symptoms were attributable to the contraceptive pill that she had started two months previously. In October 1989 the GP notes that she had blood and protein in her urine and had symptoms suggestive of a urinary tract infection. It is considered that these findings cannot be associated with the administration of the second dose of Hepatitis B vaccine several months before. It is noted that she had a history of recurrent urinary tract infections. There is no record in the GP notes of any particular adverse reaction to the second dose of Hepatitis B vaccine.
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> In March 1996 she commenced treatment with thyroxine; by December 1996 she told her GP that she felt as tired as she had been prior to starting thyroxine …The first mention, in the GP notes, of her perception that an adverse reaction to Hepatitis B vaccine was the cause of her symptoms … is dated to April 2000. It is noted that the GP refused to complete an adverse reaction

> form due to lack of evidence of reporting to him of any adverse reactions following the booster dose – the vaccine had been administered on 15/8/97 …
>
> A letter from the Occupational Health Nurse dated 18/4/00 notes that the applicant reported symptoms of nausea and pyrexia occurring after her vaccination on 15/8/97. These symptoms were reported by telephone and resulted in one week's sickness absence. She was seen at the GP surgery in September and October 1997 and no comments were recorded concerning the Hepatitis B booster …
>
> The reports from Dr Rickards, Consultant Neurologist, dated 2/2/00 and Dr Glover, Consultant Physician with an interest in [CFS], dated 7/8/00 are based on her self reported history. Neither Consultant had the benefit of her contemporaneous GP notes.
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> A report has also been considered from Dr Weir, Consultant Physician, … dated 20/1/6. Dr Weir offers the opinion that there was a "temporal and "probably causal" relationship" between the Hepatitis B inoculation and the development of symptoms of chronic fatigue. He cites his personal experience of this relationship in a small number of patients in his clinical practice. Evidence based medicine does not support this opinion; [CFS] is a common condition of uncertain aetiology. It is considered that an apparent association may appear to be present simply because of the large numbers of medical, nursing and dental staff immunised with Hepatitis B, inevitably a small number of these employees will develop symptoms of [CFS] irrespective of such immunisation.
>
> On the balance of medical probabilities it is not accepted that the underlying medical condition, namely [CFS], can be wholly or mainly attributable to the duties of her NHS employment."

6. Summaries of the medical reports referred to above are provided in an appendix to this document. Both parties have provided a considerable quantity of documents relating to Miss Thomas' health. It would not be practical to provide summaries for all of these documents. However, summaries of those reports specifically referred to are provided in the appendix.

7. Miss Thomas' union, the Royal College of Nursing (**RCN**), submitted an appeal on her behalf. They provided copies of reports from Dr Glover, dated 7 August 2000, 11 August 2001 and 28 August 2004, and Dr Weir, dated 20 January and 27 April 2006, 25 June 2007 and 14 February and 6 November 2008. Miss Thomas also provided a statement. The RCN made the following points:

- It was Dr Glover's clinical view that Miss Thomas' CFS was caused by her Hepatitis B vaccinations. This was supported by Dr Weir's report. Dr Weir was of the view that the 1989 vaccination was the main cause of Miss Thomas' CFS.

- Miss Thomas' GP notes record that she consulted him in April 1989, with swollen hands and feet (at the time, this was attributed to the contraceptive pill), and in October 1989, with blood and protein in her urine (attributed to a urinary tract infection). Miss Thomas did not associate these symptoms with the Hepatitis B vaccination at the time. Later, having given a detailed history to Dr Glover, she was made aware of their likely significance.

- The GP notes were sparse. This was typical of GP notes, which are rarely comprehensive. They confirm that Miss Thomas consulted her GP at the time in question with the stated problems, but told them almost nothing else. They did not contradict the history given by Miss Thomas.

- The fact that the GP concluded that the oedema in Miss Thomas' hands and feet was caused by the contraceptive pill did not invalidate the opinions of two consultants. GPs are not infallible and are not usually experts on immunology.

- When a patient is referred to a consultant, it is not unusual for the consultant to take an oral history. The history taken by Dr Glover was not inconsistent with Miss Thomas' GP notes, but obtained some additional information. The history taken supported his conclusions. It was "bizarre" to suggest that Dr Glover's conclusions were not valid because he had obtained information which was not included in the GP notes.

- Dr Weir had not based his opinion solely on the temporal relationship between Miss Thomas' 2nd vaccination and her development of CFS. He considered that she had suffered an immune complex mediated reaction to the vaccine in 1989 and that this was probably involved in the development of her CFS. His view was supported by the fact that the later severe reaction in 1997 was associated with an exacerbation of her CFS.

- It was accepted that the aetiology of CFS was uncertain and, therefore, it was impossible for Dr Weir to be certain. He had acknowledged this in his report. Dr Weir had taken account of the likelihood that CFS could be caused or exacerbated by an unregulated immune response to an antigenic challenge. This had not been conclusively proved, but was supported by the literature. Dr Weir had made a judgment based upon the balance of probabilities.

8. Miss Thomas' case was reviewed by Atos. They issued a decision on 17 June 2010 declining Miss Thomas' appeal. They quoted from their medical adviser,

> "[Miss Thomas] had the first vaccination on 14/10/1988 and the GP notes record that she had a reaction to this but do not give details as to what the reaction was. A reaction to any vaccination is very common. The second dose was given on 14/01/1989 and there is no note of any reaction at that time. The first note in her GP records after that was in April 1989 when she consulted with symptoms of swelling in her hands and feet … There is no mention of any correlation with her vaccination. In his report of 7/08/00 Dr Glover states that 'There is a probability that her Hepatitis B vaccination of 1988 caused an acute immune complex mediated problem after the second dose (actually 14/01/89). This was characterised by fever, joint swelling, haematuria and proteinuria and a skin rash'. There is in fact no medical corroboration of this and no note of any reaction in her GP records and the first note of protein and blood in her urine was in October 1989. A report from a Urologist of 2/02/1990 indicates that she had a history of Urinary Problems going back to 1980. It is therefore considered that there is no evidence that she had the reaction that Dr Glover presumed that she had.
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> She states that she saw a Private Specialist Dr Harper in 1990 who diagnosed Myalgic Encephalomyelitis in 1990 but there is no report in the records confirming this and no mention in the GP records of this diagnosis until February 2000.
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> She attended her GP on 9/07/1997 with Neck pain one month prior to having her 3rd vaccination on 15/08/1997 and it is noted that in the interim period she had been diagnosed with Hypothyroidism in 1996 and was put on Thyroxine.
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> The only note of symptoms after this third vaccination was in a letter from the Occupational Nurse dated 18/04/00 that she reported nausea and pyrexia which resulted in 1 weeks absence from work. There is no medical corroboration of this.
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> The next relevant consultation was with her GP on 12/04/1999 with Neck pain and the first mention of Chronic Fatigue Syndrome/ME/Fibromyalgia was on 8/02/2000, some 2.5 years after her third vaccination. Although both specialists state that

> Chronic Fatigue Syndrome can be 'triggered' by Hepatitis B vaccination, it is considered that there is no evidence based medicine to support this opinion and there is not a sufficient temporal association between the hepatitis B vaccination and the development of Chronic Fatigue Syndrome.
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> It is also noted that her GP refused to complete an adverse reaction form due to lack of evidence of any adverse reaction to the 3rd vaccination, which was given by occupational health.
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> On the balance of probabilities, therefore, it is not accepted that her Chronic Fatigue Syndrome can be wholly or mainly attributable to the duties of her NHS employment."

9. The RCN submitted a further appeal on 16 March and 5 April 2012. They referred to a report provided by Dr Smith on 2 October 2009 (see Appendix) and to the fact that Miss Thomas had been awarded Industrial Injury Benefit. The RCN went on to say that Miss Thomas had been awarded a pension on the grounds of ill health due to CFS, which was a direct result of a multi-complex auto-immune response to Hepatitis B vaccine. They said that her employer and the NHS Injury Benefit Scheme had acknowledged her adverse reaction to the vaccine. The RCN said that Miss Thomas' employer had continued to pay her half pay for nearly two years and, thus, had recognised her condition was wholly or mainly work related.

10. The RCN went on to point out that Atos were medical advisers to both the NHS Injury Benefit Scheme and the DWP with regard to Industrial Injury Benefit. They suggested that their findings could be expected to be consistent. The RCN argued that insufficient weight had been placed on the specialists' reports and said that the DWP Tribunal had accepted Dr Weir's view over "the non-case specific generic research" used by Atos.

11. Miss Thomas' case was reviewed by the NHS BSA under the Scheme's two-stage internal dispute resolution (**IDR**) procedure. They issued a decision on 20 April 2012 declining the appeal. The NHS BSA said that they had referred the matter to their medical advisers and quoted from the advice they had received. The key points in the medical adviser's comments are summarised below:

    - The criteria for Industrial Injury Benefit were not the same as for a PIB. The award of an Industrial Injury Benefit did not mean that the attribution condition for payment of a PIB had been met.

- The reports from the specialists had been carefully considered and weighed. It was accepted that they had offered detailed and balanced reports, with a thorough review of the evidence.
- In addition to the views expressed by Dr Glover and Dr Weir, the medical adviser referred to a report from a Consultant Psychologist, in 2000, in which she had said that she had been treating Miss Thomas for work related stress, anxiety and depression resulting from protracted perceived harassment and victimisation in the workplace, together with work overload. She had also expressed the view the Miss Thomas was exhibiting subsyndromal symptoms of delayed post traumatic stress disorder relating to a fatal accident she had attended. He also referred to a report he said had been provided in connection with Miss Thomas' ill health retirement by a Physiotherapist. She had been of the view that Miss Thomas had a long history of hypersensitivity to medical intervention and had stated that the aetiology of CFS was complex and multifactorial. The Physiotherapist had identified genetics and possibly an immune disturbance as factors in Miss Thomas' case. She was of the view that the Hepatitis B vaccination had, on balance, acted as a trigger for Miss Thomas' CFS and that occupational stressors acted as maintaining or perpetuating factors.
- It was accepted that Miss Thomas suffered reactions to the Hepatitis B vaccinations.
- The evidence indicated that the cause of CFS was multifactorial.
- It was accepted that the vaccinations acted as triggers for some of Miss Thomas' persistent symptoms. However, she had carried on working until 1999. This was after the vaccinations and there were significant stressors in Miss Thomas' life, both work and non-work related, during the 90's which had led to psychological comorbidity.

12. The medical adviser concluded,

> "The evidence base from research in to Hepatitis B vaccination and CFS has not been conclusive about there being a causal link and while it is acknowledged that such a link has been made in the specialist reports and opinion on this particular case, there have been other significant constitutional contributory factors as

> outlined by Psychologist, Physiotherapist and Occupational Physician. On balance, on careful weighing of all the evidence, both case specific and general research, it is advised that it is not accepted that the Hepatitis B vaccinations have been the whole or main cause for the CFS and any related long-term incapacity."

13. The NHS BSA said that it appeared that their medical advisers had taken full account of all of the relevant medical evidence and information presented in support of Miss Thomas' claim. They said that the rationale offered by their medical adviser appeared to be reasonable in the context of the Scheme's requirements. The NHS BSA said that it was for them to decide what weight to place on the evidence.

14. The RCN submitted a further appeal under the IDR procedure. They accepted that the DWP Tribunal considering Miss Thomas' application for Industrial Injury Benefit had not been required to determine whether her CFS was wholly or mainly attributable to her NHS employment. However, the RCN pointed out that it had considered whether, on balance of probabilities, there was a causal link between the vaccinations and the development of CFS by Miss Thomas. They said that the Tribunal had acknowledged Dr Weir as an expert in the field of CFS and had preferred his evidence. The RCN said that, essentially, the Tribunal had made a finding of fact that Dr Weir was correct which, whilst not binding on the NHS BSA, was "highly persuasive". They said that Dr Glover and Dr Weir had considered the other factors mentioned by the NHS BSA's medical adviser but had concluded that Miss Thomas' CFS was most likely caused by the Hepatitis B vaccinations. The RCN argued that Dr Glover and Dr Weir, being Consultant Physicians with a special interest in CFS, were likely to be more knowledgeable about CFS and its causes and better placed to express an opinion than any other general medical practitioner. They argued that their views should, therefore, carry significant weight.

15. The NHS BSA issued a decision, on 19 November 2012, declining Miss Thomas' appeal. They explained that they had sought further advice from their medical advisers and quoted from that advice. The key points from the medical adviser's comments are summarised as follows:

- He had considered all of the previous medical evidence and conducted an up to date search of peer reviewed medical literature.

- He listed a number of articles and summarised their findings.
- He had only been able to find one paper relating Hepatitis B vaccine to CFS and, in that case, the patient had also sustained a leak from a breast implant.
- The two leading opinions, in his view, had concluded that there was no evidence of an association between the administration of Hepatitis B vaccine and the development of CFS. This was the evidence-based position.
- The RCN was suggesting that the DWP Tribunal had determined what they should accept as being medical fact.
- CFS was a contentious area which caused heated arguments about its aetiology. There were questions as to whether it was a psychological condition, an infectious disease or a malfunction of micro-metabolism.
- It was not for the independent medical adviser to hold any particular view; rather, he had to accept and advise on the basis of the consensus of medical opinion. To do otherwise would risk a perverse outcome.
- Dr Glover's and Dr Weir's opinions were not in keeping with the wider body of medical opinion. No publication had appeared since Dr Weir's last report (November 2008) which would retrospectively support his or Dr Glover's opinions.
- He would not place much weight on the report referred to above because of the co-morbidity of the leaking breast implant and the fact that it related to a single patient.
- He advised that attribution should not be accepted in Miss Thomas' case.

16. The NHS BSA said that they took advice from professionally qualified, experienced and specially trained occupational health doctors who had access to expert resource when needed. They said that they had accepted the recommendation of their medical adviser that Miss Thomas' condition was not wholly or mainly attributable to her NHS employment.

Miss Thomas' Position

17. Miss Thomas submits:

- The NHS BSA have relied on debateable research in determining that her CFS was not attributable to her NHS employment.
- She has provided medical reports from two medical experts with acknowledged expertise in CFS, together with a judgment from an Industrial Injuries Benefit Tribunal which made a finding of fact in her favour.
- The NHS BSA and their medical advisers have been asking the wrong question; namely, whether the Hepatitis B vaccine causes CFS per se, rather than whether her reaction to the vaccine caused her CFS.
- She was told that she could not apply for a PIB until her TIA application had been decided and this was not concluded until 2006.

The NHS BSA's Position

18. The NHS BSA submit:

- They have properly considered Miss Thomas' application, taking into account and weighing all of the relevant evidence and nothing irrelevant.
- They have taken advice from proper sources; that is, the Scheme's medical advisers. They have considered and accepted that advice and arrived at a decision which they believe is not perverse.
- They can only consider applications on the basis of the documentary evidence presented. In Miss Thomas' case, there is no clinical evidence to corroborate a causal link between Hepatitis B vaccinations and the onset of her CFS.
- Medical matters are seldom black and white. A range of opinions may be given from various sources, which must be considered and weighed. The fact that Miss Thomas does not agree with the conclusions they have drawn or the weight that they have attached to any of the evidence does not mean that their conclusions are flawed.

- The Scheme's medical advisers are not experts in all medical conditions, but they are expert in carrying out a forensic analysis of the evidence and considering this against the Scheme's requirements.
- It is unnecessary for them to provide Miss Thomas with a reasoned explanation for their decision to accept Atos' recommendations over the opinions expressed by her doctors because there was sufficient explanation provided in Atos' decision letters.
- There was sufficient reasoning as to why Miss Thomas' application failed in Atos' rationales and their decision letters for her to be able to properly make an appeal. The eligibility criteria were explained to Miss Thomas and she was aware of the opinions expressed by the specialists in their reports.
- GP notes can be "scant", but they are contemporaneous rather than being reported "after the fact" or "by recollection". They are also prepared by a clinician who is familiar with the patient and in more regular contact than a consultant.
- The DWP Tribunal findings were taken into account on the understanding that IIDB awards are more often than not time limited and the eligibility criteria are different. There was no indication in the DWP reports of any measurement of attribution.
- The question is whether Miss Thomas has sustained an injury or contracted a disease which is wholly or mainly attributable to her NHS employment. This is not the same as asking whether her CFS was caused by the Hepatitis B vaccination because that falls short of any "quantum of attribution".
- Because the test they are required to use is very precise, it is not appropriate to consider attribution on the basis of phrases such as "temporal relationship" or "causal connection", as used by Dr Weir and Dr Glover. These fall well short of any measurement of attribution. Such comments may have satisfied the previous "softer" test of "attributable to", but not the "harsher" test of "wholly or mainly".

- The Atos advisers are required to provide independent advice in keeping with the body of medical opinion; that is, in keeping with what is known in the published literature. They can only make a decision on a similar basis. Miss Thomas' doctors have not offered any explanation for why she should be regarded differently from the consensus of medical opinion.
- The consensus of medical opinion is that there are numerous suggested causes for CFS/ME. No-one really knows for sure what causes it. Therefore, the proposition that the Hepatitis B vaccination is the whole or main cause for Miss Thomas developing CFS can only be regarded as conjecture; particularly in the presence of numerous other possible contributing factors.

Conclusions

19. Miss Thomas would be entitled to a PIB if her condition was wholly or mainly attributable to her NHS employment. She has submitted a claim on the basis that her CFS was caused by the reaction she had to Hepatitis B vaccinations. Miss Thomas' employer has confirmed that she received the Hepatitis B vaccinations. There is no disagreement that this was something she was required to do in the course of her NHS employment. The disagreement lies in whether her reaction to the vaccinations caused Miss Thomas to go on to develop CFS.

20. Whether Miss Thomas meets the criteria for the payment of a PIB is a finding of fact for the NHS BSA to make. They are required to weigh up all the available relevant evidence and come to a decision. The weight that the NHS BSA attaches to any of the evidence is for them to decide and it is open to them to prefer some over other, provided that they have given due consideration to all of the evidence. It follows that it is open to the NHS BSA to prefer the advice they receive from their own medical advisers to that provided by Miss Thomas' doctors provided that there is no reason why they should not. The kind of reasons I have in mind are errors or omissions of fact on the part of the medical advisers or a misunderstanding of the eligibility criteria.

21. Both the NHS BSA and Miss Thomas sought medical advice as to the cause of her CFS. I think it would be safe to say that there is currently no consensus within the medical world as to the cause of CFS. It is probably most accurate to say that a number of causes are under consideration and one of those is the

reaction in some individuals to vaccines of various types. The NHS, itself, acknowledges problems with the immune system as a theory for the cause of CFS and the DWP is prepared to accept it for the purposes of Industrial Injury Benefit.

22. Dr Glover and Dr Weir have been prepared to state that, on the balance of probabilities, Miss Thomas' CFS was caused by her reaction to the Hepatitis B vaccinations. They both work in the field of CFS and have a particular interest/expertise in the area. Dr Weir, in particular, based his opinion on research papers and his own observations. He acknowledged that the cause of CFS was unknown and that "Full scientific proof of the cause and effect relationship between this vaccine and CFS is not available". However, given Miss Thomas' reactions to the vaccinations, he was prepared to say that Miss Thomas' CFS had been "initiated by the second dose of hepatitis B vaccine administered in January 1989 and exacerbated by the booster dose given in 1997". He went on to say that work related stress had also contributed to the severity of her illness, but he was of the view that, if the hepatitis B vaccine had not been given, it was unlikely that Miss Thomas would have contracted CFS.

23. In their advice to the NHS BSA, the Atos doctors were not persuaded that the link between Miss Thomas' vaccinations and her CFS had been shown. They either did not accept that the symptoms she had reported were linked to her CFS or questioned the lack of reporting to her GP. I do think that the RCN made a valid point when they questioned the reliance on the GP notes in questioning Dr Glover's and Dr Weir's opinions. A note of caution should be sounded in questioning the existence of symptoms reported by a patient to a specialist simply because they have not first been reported to a GP; they are, of course, "self reported" in both cases. I do not disagree that the GP notes had the value of being contemporaneous, but more information may have been gleaned by the specialists simply because they knew what they were looking for.

24. I note that the third Atos doctor did accept that Miss Thomas had suffered reactions to the Hepatitis B vaccinations. Since they made no other comment, the Atos doctors also appeared to dismiss the findings of the DWP Tribunal simply on the basis that the eligibility criteria were different. This ignored that fact that one material question was the same – was Miss Thomas' CFS caused by her Hepatitis B vaccinations. Whilst the Tribunal finding was not binding on the

NHS BSA for the purposes of determining Miss Thomas' eligibility for a PIB, it was relevant evidence and should have been given due consideration. Both of these issues warranted the NHS BSA seeking clarification from their Atos advisers.

25. However, the key area of disagreement between Miss Thomas' doctors and the NHS BSA's advisers lies in the more fundamental question of whether the Hepatitis B vaccination can cause a recipient to develop CFS. Clearly, Dr Glover and Dr Weir are of the view that it can and, in Miss Thomas' case, did. The Atos doctors disagree.

26. The NHS BSA seek to distinguish between the question of whether Miss Thomas has sustained an injury/contracted a disease which is wholly or mainly attributable to her NHS employment from whether her CFS was caused by the Hepatitis B vaccination on the basis that the latter does not address the "quantum of attribution". The question of whether Miss Thomas' CFS was caused by the Hepatitis B vaccination is in fact part and parcel of the larger question of whether she has sustained an injury/contracted a disease which is wholly or mainly attributable to her NHS employment. If it is decided that Miss Thomas' CFS was not caused by the vaccine, there is no need to consider the "quantum of attribution". However, if it is accepted that the Hepatitis B vaccine was either the sole cause or one of a number of contributory factors in Miss Thomas' development of CFS, it then becomes necessary to consider the "quantum of attribution".

27. The NHS BSA submit that the test they are required to apply is precise. They take the view that the use of phrases "temporal relationship" and "causal connection" fall short of what is required because they do not offer a measure of attribution. It is true that they do not. But they do relate to the question of causation, which, as I have said, is part of the overall question to be decided. If NHS BSA mean that the phrases are too imprecise to contribute to a decision which falls to be made on the balance of probabilities, then I do not think they are right. They have to put the total evidence into the balance, every item does not have to be certain and precise.

28. It was for the NHS BSA to consider all the evidence and come to a reasoned decision as to whether Miss Thomas met the eligibility criteria for a PIB. In their responses to Miss Thomas' IDR appeals, the NHS BSA explained that they had accepted the recommendations from their medical advisers. They said that their advisers had taken account of all the evidence and had offered a reasonable rationale. The NHS BSA also pointed out that it was for them to decide what weight to place on the evidence. This is, indeed, the case. However, the responses from the NHS BSA gave no indication that they (as opposed to Atos) had weighed up the evidence. For example, they did not explain why they were preferring the opinion of the Atos doctors to that of Dr Weir, who is a specialist in this particular condition.

29. Nor did they address the concerns raised by the RCN that the Atos doctors were addressing the question of whether it had been shown that the Hepatitis B vaccine caused CFS per se, rather than whether, on balance of probabilities, it had caused Miss Thomas to develop CFS. The NHS BSA say that Atos are required to provide independent advice in keeping with what is known in the medical literature. This is the approach taken by the medical adviser at stage two of the IDR procedure. He reviewed the medical literature and provided a report outlining his findings and his opinion. However, each case must be determined on its own merits. The question is whether, in Miss Thomas' case, her reaction to the Hepatitis B vaccine contributed (and by what degree) to her development of CFS. It is not whether or to what extent there is a likelihood of any individual going on the develop CFS after receiving the Hepatitis B vaccine (although that is obviously relevant evidence).

30. The fact that a number of possible causes have been proposed for CFS (including problems with the immune system) is insufficient reason to exclude the possibility that, in Miss Thomas' case, it might be the Hepatitis B vaccine. The NHS BSA describe it as conjecture (which seems to be placing a very low value on medical opinion). It may be that the NHS BSA properly conclude that the evidence for a causal connection is not in fact there, but I do think that the NHS BSA needed to deal with the evidence rather than dismiss it. The presence of other factors in Miss Thomas' case (and I take them to mean her treatment for stress and depression) is not fatal to her case. A decision would have to be taken as to their relative contributions. She would qualify for a PIB if, on the balance of

probabilities, her reaction to the Hepatitis B vaccine contributed at least 50% to her development of CFS.

31. In the circumstances, that is, where they are opting to accept non-specialist views over the opinion offered by a specialist, the NHS BSA can be expected to provide a more detailed and reasoned response. Without the reasoning behind the decision, Miss Thomas is not in a position to understand it and either accept it or, if not, to properly prepare an appeal.

32. Put simply, the NHS BSA must have a reason to have preferred Atos' opinion. Their preference cannot have been arbitrary and so they must be able to explain it, but they have not.

33. I do not find that it is sufficient for them to say that between the rationales offered by Atos and their own decision letters there was sufficient for Miss Thomas (or anyone else for that matter) to discern their reasoning. It is not unreasonable to expect the NHS BSA to tell Miss Thomas why they prefer Atos' opinion rather than leave her to try and piece together the reasoning for herself.

34. In view of this, I am unable to find that the NHS BSA gave proper consideration to Miss Thomas' eligibility. I uphold her complaint on that basis.

35. It is not for me to come to a decision as to Miss Thomas' eligibility for a PIB; that is a decision for the NHS BSA. The proper course of action is for me to remit the decision and I have made directions accordingly – in this case requiring the NHS BSA initially to give Miss Thomas a reason for their decision rather than reconsidering it (unless that is, they find the decision is not supportable). I make no finding as to whether or not Miss Thomas should receive a PIB.

36. This has been a lengthy process for Miss Thomas. This was in some part because of delays in submitting her appeals. However, at the end of a decision making process under which her claim has been considered four times, she has still not been provided with a reasoned explanation for why she is not considered eligible for a PIB. I find that this will have caused distress and inconvenience to Miss Thomas which should be recognised by a modest amount of compensation.

Directions

37. Within 21 days, the NHS BSA shall provide Miss Thomas with a reasoned explanation for their decision to accept the Atos recommendations over the opinions provided by her doctors – or to review their decision if it cannot be supported by reasons. They will allow Miss Thomas a further opportunity to appeal the decision if she so wishes.

38. Within the same 21 days, the NHS BSA shall pay Miss Thomas £250 in recognition of the distress and inconvenience she has suffered.

Tony King
Pensions Ombudsman

16 September 2014

Appendix

Medical Evidence

Dr Rickards 2 February 2000

39. Miss Thomas was referred to Dr Rickards, Consultant Neurologist, by her GP. He wrote to the GP,

> "I do not think that there is any primary neurological problem here, nor in fact do I think that she has any significant problem with her general physical health in the sense that I can identify no features of any underlying systemic disease.
>
> I do think that her symptoms fall into the spectrum of fibromyalgia and so-called myalgic encephalitis …"

Dr Glover 7 August 2000

40. Dr Glover, Consultant Physician, wrote to Miss Thomas' GP following his referral of her case. He said that he had read Miss Thomas' file and examined her and was of the opinion that the only reasonable diagnosis was CFS with elements of fibromyalgia and regional pain. Dr Glover commented that there was a possibility that Miss Thomas had had an allergic reaction to her Hepatitis B vaccination, but that this could only be based on circumstantial, rather than objective, evidence. He asked the GP to carry out a test to exclude one possible alternative condition.

Dr Glover 21 August 2000

41. Dr Glover wrote to Dr Wort, Consultant Occupational Physician, in connection with Miss Thomas' application for ill health retirement,

> "… The accepted diagnosis in her case is that of [CFS] contributed to by the stress and pressure of her work as a nurse and aggravated by hepatitis B vaccination in 1988 and 1997 …
>
> Her history dates back to 1988 and is characterised by fatigue, muscle pains, joint pains and a variety of neurological symptoms. There is a probability that her hepatitis B vaccination of 1988 caused an acute immune complex mediated problem after the second dose. This was characterized by fever, joint swelling, haematuria and proteinuria and a skin rash. Similar symptoms developed after her booster dose of hepatitis B vaccine in 1997 …"

Dr James 1 September 2000

42. Dr James, Consultant Psychologist, wrote to Dr Wort,

> "I have been treating [Miss Thomas] for a year now for work-related stress, anxiety and depression resulting from protracted harassment and victimisation in her work setting together with work overload without adequate support. She has also exhibited subsyndromal symptoms of delayed post traumatic stress disorder …
>
> [Miss Thomas'] work meant that vaccination for Hepatitis B was required. She had the first injection in October 1988; the second injection in November 1988 was not given but administered in January 1989. Following this her health deteriorated significantly as can be seen from her medical records …
>
> [Miss Thomas] is suffering from co-morbid symptoms of anxiety, and post trauma stress accompanied by moderate depression. These effects have impaired and altered her cognitive functioning and emotions. The distress and damage to health that she has been subjected to have had a negative affect [*sic*] on her causing severe detrimental effects to her self-confidence and self esteem, quality of life, health and well being …"

Ms Wigley 10 April 2001

43. Ms Wigley, Physiotherapist, provided a report in connection with Miss Thomas' application for ill health retirement. She said,

> "Miss Thomas first came to see me for assessment and advice on 16/2/01. She gave a long history of generalised muscular and joint pains and lethargy which began in 1988 following a hepatitis B injection. She was subsequently diagnosed as having suffered an acute immune complex-mediated problem resulting in chronic fatigue syndrome.
>
> I assessed her from a functional standpoint …"

Dr Glover 11 August 2001

44. Dr Glover wrote to Miss Thomas' GP following a further consultation. He said he had reminded Miss Thomas that there was a possibility that her Hepatitis B vaccination in 1988 had caused an acute immune complex mediated problem and that this might be relevant to her ongoing chronic fatigue. Dr Glover said that, from his perspective as a General Physician and Specialist in Infectious Diseases, he could not see any alternative working diagnosis.

Dr Glover 28 August 2004

45. Dr Glover prepared a report at the request of Miss Thomas' union. Having outlined Miss Thomas' medical history, Dr Glover said,

> "I think there is a high probability that her hepatitis B vaccinations of 1988/1989 caused an acute immune complex mediated problem, particularly manifest after the second vaccination of January 1989. The presence of fever, joint swelling, haematuria and proteinuria with skin rash support this clinical interpretation. Further support to this relationship is in the onset of very similar, but more severe symptoms after her booster dose of hepatitis B vaccination in 1997.
>
> In support of this potential causal link … it is to be noted that the product information leaflet with hepatitis B vaccination includes warnings of adverse reactions such as arthritis, arthralgia, paraesthesia, paralysis, neuralgia, neuritis and neuropathy.
>
> Further support to this causal link is given in a series of papers …
>
> In summary, therefore, there is a strong clinical and temporal link between her hepatitis B vaccinations and the exacerbation of her chronic fatigue syndrome."

46. With regard to the contribution made by stress to Miss Thomas' condition, Dr Glover said that, given the level of physical investigation she had undergone and that no other firm or reasonable diagnosis had been made, he could fully endorse the diagnosis of CFS. Dr Glover concluded,

> "Although the exact mechanism or pathophysiology of this condition are not known, there is little doubt that it is related to periods of intensive stress and psychological trauma and anxiety, and that the condition can be significantly exacerbated by intercurrent viral infections or other medical events. In this lady's case the likely immune complex mediated reaction to her hepatitis B vaccination is highly relevant.
>
> Muscle pain is one of the central symptoms of chronic fatigue syndrome/ME. It is notable that her neck pain became worse at the time of the emotional pressures on her and is, I believe, intimately related to the other symptoms of her chronic fatigue syndrome."

Dr Weir 20 January 2006

47. Dr Weir, Consultant Physician, was asked to prepare a report by the RCN on behalf of Miss Thomas. He said that he had met Miss Thomas on 9 May 2005 and had read correspondence and records from her GP, correspondence from Dr

Glover, her occupational health records, correspondence from the NHS BSA relating to her application for a TIA and Miss Thomas' own notes. Dr Weir explained that he was a consultant physician in private practice with an interest in CFS. He explained that he ran a clinic which provided for the care and management of patients with CFS and the basis for a number of academics studies of the condition. Dr Weir said he had also been part of the Chief Medical Officer's working group on CFS.

48. Dr Weir began his report with a synopsis of CFS. He described the symptoms and noted that the precise cause(s) was unknown, but that research had demonstrated immune, endocrine, musculoskeletal and neurological abnormalities. Dr Weir explained that infections of various kinds appeared to act as triggers, but no known infectious agent had been proven to be the cause. He also mentioned that stress and physical injury had been described in relation to the onset of CFS.

49. Dr Weir then described Miss Thomas' medical history and her current illness and its onset. He said the diagnosis was CFS and hypothyroidism; he did not think the latter was the cause of Miss Thomas' current symptoms. In response to the question: was there a causal link between the Hepatitis B vaccine and the development of Miss Thomas' CFS, Dr Weir said,

> "a) Firstly, a temporal (and probably causal) relationship between hepatitis B inoculation and CFS has been reported in a number of other patients (see references). I have also encountered this relationship in a small number of patients in my own practice. Immunisations in general have also been reported as triggers for CFS …
>
> b) Secondly, the medical events which followed the inoculations … were almost certainly attributable to acute immunologically mediated side-effects of a type seen occasionally with other vaccinations and occasionally other non-vaccine drugs. In lay terms, Ms Thomas was <u>allergic</u> to the vaccine …
>
> c) Dr Glover … goes on to state "I think there is a high probability that her hepatitis B vaccinations of 1988/89 caused an acute immune complex mediated problem, particularly manifested after the second vaccination of January 1989. The presence of fever, joint swelling, haematuria and proteinuria with skin rash support this clinical interpretation. Further support to this relationship is the onset of very similar, but more severe symptoms after her booster dose of hepatitis B vaccination in 1997." This sequence of events is very similar to those I have

> seen in my own practice, in other patients developing CFS after hepatitis B vaccine."

50. Dr Weir concluded,

> "Ms Thomas has CFS. This was initiated by the second dose of hepatitis B vaccine administered in January 1989 and exacerbated by the booster dose given in 1997. Work related stress also contributed to the severity of her illness but, if the hepatitis B vaccine had not been given, it is unlikely that Ms Thomas would have contracted CFS …"

Dr Weir 27 April 2006

51. In a letter to one of Atos' doctors in connection with Miss Thomas' application for a TIA, Dr Weir said,

> "Although I am not Ms Thomas' treating consultant, you have raised one or two questions relating to my conclusion that Hepatitis B vaccine played a significant role in the development of her CFS. You have cited the Canadian study in which it is proposed that Hepatitis B vaccine does not play a role in the causation of CFS. This is not a universally held perception amongst practitioners in the field of CFS (see attached papers by Dr Charles Shepherd) … Full scientific proof of the cause and effect relationship between this vaccine and CFS is not available but I was asked for my opinion in the matter *with specific reference to Ms Thomas' case*, because there was an undoubted temporal relationship between the administration of the vaccine and the development of her CFS.
>
> The test I have applied to that question employs the yardstick legal phrase "the balance of probabilities". The events following the administration of the vaccine, particularly the second and third doses, suggest the occurrence of an acute immune complex mediated problem … which has lead on to the development of CFS. Antigenic challenges due to either acquired infection or administered vaccine are very well recognized as precipitants of CFS …
>
> In conclusion, I do not think that the hepatitis B vaccine given to Ms Thomas was innocuous, a view held by Dr … Glover, another clinician with an interest in CFS. The balance of probabilities suggests that her CFS was due to the Hepatitis B vaccine she received."

Dr Weir 25 June 2007

52. Dr Weir was asked, by Miss Thomas' union, to review the responses from the NHS BSA to Miss Thomas' application for a TIA. With regard to the WHO report cited by the NHS BSA, he said that the evidence considered was purely statistical and that the statistical method did not allow for causality being attached to rare occurrences. Dr Weir suggested that it was inappropriate to use statistics to decide causality in individual cases. With regard to Miss Thomas' reaction to the 2nd and 3rd vaccinations, Dr Weir said that these were "almost certainly immunological". He went on to explain that it was now widely recognised that CFS was frequently initiated by an immunological event; either an infection or a vaccination. Dr Weir asked about the NHS BSA's medical adviser's credentials. He said that the medical adviser did not appear to be aware of recent work on the immunological basis of CFS. Dr Weir also pointed out that both he and Dr Glover had experience with CFS and ran clinics dedicated to the care and management of the condition.

Dr Weir 14 February 2008

53. Dr Weir was asked to prepare an addendum to his previous reports by Miss Thomas' union. In answer to the question "Can CFS be triggered by a vaccine?" Dr Weir said that there were many anecdotal accounts of CFS developing "in the immediate aftermath of administration of a vaccine". He mentioned three other conditions where he said it was "generally recognised that vaccination can be causal". Dr Weir referred to a report by the Chief Medical Officer which had said, "It is biologically plausible that some processes seen after infections could also occur after immunisation … but this has yet to be confirmed by a good quality cohort study in the case of CFS/ME. Current advice to avoid immunisations during infections is designed to avoid such triggering." Dr Weir said that the suspicion existed that CFS could be triggered by a vaccine. He went on to say that it was his opinion that, on the balance of probabilities, there was a causal relationship between immunisation and the sub sequent development of CFS in some individuals. In answer to the question "Can CFS be triggered by an immune complex mediated response?", Dr Weir said that he had not seen any other cases, but he thought it was "biologically plausible". In response to further questions, Dr Weir said that he did not think that Miss Thomas had suffered an immune complex mediated response in 1988, but he thought she had in 1989 and

1997. Dr Weir was unable to give a percentage of people suffering such a reaction, but he did say that the Hepatitis B vaccine tended to "feature prominently" amongst reports of reactions to vaccines.

54. Dr Weir was asked if Miss Thomas was an atopic individual and expressed the view that she was. He also said that atopic individuals "probably have a greater tendency to contract CFS given the appropriate trigger". In response to the question "When did [Miss Thomas] contract CFS?" Dr Weir said the 2nd dose of vaccine, given in 1989, triggered the subsequent development of CFS and there was no precise date of onset.

55. Dr Weir acknowledged that it was possible that Miss Thomas' development of CFS after receiving a Hepatitis B vaccine was coincidental. He argued, however, that the clinical events which occurred, particularly in relation to the 2nd and 3rd doses, indicated a causal rather than a purely temporal relationship. Dr Weir confirmed that there was no evidence for an alternative event causing Miss Thomas' CFS.

Dr Weir 6 November 2008

56. Dr Weir wrote to Miss Thomas' solicitor,

> "I should state quite categorically that there are two separate and debatable issues in relation to her case. The first asks the direct question: Did the hepatitis B vaccine … cause her to develop CFS? In order the reach my conclusion on this matter I have carefully studied her records, and used the benchmark phrase "the balance of probabilities" … I have been able to draw the conclusion that in her particular case, there was a causal relationship between the vaccine and her CFS. I have also done some further literature searches.
>
> The second issue asks a different question, namely, has hepatitis B vaccine been definitely excluded as a cause of CFS in some of the many patients who receive it? In my view the answer to this question is no …
>
> Whether or not CFS can be included as a recognised side effect of hepatitis B vaccine depends on the accuracy with which it is reported from the mass of patients who receive the vaccine … The only way to conclude with any degree of certainty that there was no relationship between hepatitis B vaccine and CFS would be to follow up and examine a large cohort of recently vaccinated individuals. To my knowledge this has not been done, and it is therefore not possible to state categorically that hepatitis B vaccine does not occasionally cause CFS.

> Furthermore, vaccinations in general have been implicated in the causation of CFS, and I quote from the Chief Medical Officer's report: "It is biologically plausible that some processes seen after infections could also occur after immunisation … but this has yet to be confirmed by a good quality cohort study in the case of CFS/ME …" … This advice is supported by the suspicion that CFS can be triggered by a vaccine, and it is my considered opinion that, on balance of probabilities, there is a causal relationship between immunisation and subsequent development of CFS in some individuals, including those given hepatitis B vaccine."

57. Dr Weir then provided his responses to a set of questions which Miss Thomas' solicitor had put to him. Describing the chain of causation, Dr Weir said that the second vaccination dose Miss Thomas received caused an immune response, part of which comprised an immune complex reaction. He said a component of the immune response then caused her CFS to develop and the third dose of vaccine caused an exacerbation of her CFS.

58. Dr Weir said that CFS developed without a trigger in approximately 50% of cases. He suggested that it was likely that an underlying, but asymptomatic, infection had been partly responsible. Dr Weir explained that it was common practice to avoid vaccination in individuals with established CFS. He went on to say that the Hepatitis B vaccine seemed to be prominent amongst reports of CFS apparently triggered by vaccines and cited a letter to the British Medical Journal in 1996. Dr Weir explained that said that the vaccine stimulated an immune response which then did not "shut down" in the case of CFS.

59. Dr Weir said that the illness Miss Thomas developed after her first Hepatitis B vaccine in 1988 probably had nothing to do with the vaccine; unlike her reactions to the second and third doses. He referred to two research papers which described immunologically mediated reactions following the Hepatitis B vaccine. Dr Weir said these were "highly suggestive" of immune complexes being generated as a result of the vaccine. He noted, however, that none of the cases reported went on to develop CFS.

60. Dr Weir said that atopic individuals seemed to be more prone to developing CFS, but the biological connection was not known. He also said that the connection between CFS and allergies was not fully understood, but the association was clear.

61. Dr Weir referred to another research paper which described the onset of reactive arthritis in two patients following administration of the Hepatitis B vaccine. He said that he had been unable to find a paper in which CFS had occurred in the aftermath of a recognised episode of immune complex reaction.

62. Dr Weir said that the evidence which he considered to support the proposition that the second dose of Hepatitis B vaccine received by Miss Thomas precipitated her CFS was:

- The occurrence of characteristic symptoms described by Miss Thomas approximately one month after the vaccine was given.
- The clear evidence of a reaction occurring within this time, as evidence by her GP notes dated 15 April 1989.
- The severe exacerbation which closely followed the third dose, which suggested an adverse reaction.

63. Dr Weir referred to the opinion given by the Scheme's medical adviser that, because CFS was a common condition, it was likely that coincidence might account for the occasions when a causative role was alleged. He said he had enclosed a research paper which addressed this and quoted,

> "The results showed a statistically significant increase in the incidence of adverse reactions reported after adult hepatitis B vaccinations when compared with the incidence of adverse reactions reported … about control vaccines."

64. Dr Weir acknowledged that the paper went on to say that the Hepatitis B vaccine had not been shown to cause CFS. He pointed out that the authors had later said that some of the patients concerned went on to develop chronic adverse reactions which lasted for at least a year. Dr Weir noted that the authors had not identified the nature of these reactions and he expressed the view that some could be CFS. Dr Weir also referred to a WHO report on the putative associations between the Hepatitis B vaccine and arthritis and CFS. He acknowledged that, on the face of it, this was evidence against Miss Thomas' case, but pointed out that the report had limitations and the wording of its conclusions was "guarded".

65. Dr Weir concluded that he was still of the opinion that, on the balance of probabilities, Miss Thomas' CFS was caused by her Hepatitis B vaccination.

Dr Smith 2 October 2009

66. Miss Thomas was referred to Dr Smith, Consultant Rheumatologist, by her GP. He wrote to the GP,

> "[Miss Thomas] was perfectly well until 1988 when she had her first hepatitis B inoculation and this was soon followed by vomiting, diarrhoea, feeling hot and sweaty. These problems lasted for forty eight hours. In 1989 she had her second jab with no immediate after effects, but about a month later noticed swelling of her joints, aches and pains, nausea, malaise and fatigue. These symptoms have continued with variable severity ever since. She is incidentally a very good responder in terms of antibody levels to hepatitis B.
>
> In 1997 she had another hepatitis B immunisation and within thirty six hours had developed sweats, a "hives" rash on her trunk, abdominal cramps, nausea, widespread aches and pains and increased fatigue. She also had worsening problems with balance. All these problems have again continued since that time and she has had to give up her employment and has been pensioned off on the basis of her health.
>
> Other past history reveals that she is hypothyroid, diagnosed in 1996 … She has had Raynaud's phenomenon since her twenties.
>
> Apart from symptoms outlined above she mentioned other rather more puzzling symptoms …
>
> Her clinical picture is generally consistent with chronic fatigue syndrome. She also has evidence of Sjogren's syndrome … In addition she may have a left carpal tunnel syndrome and a right shoulder capsulitis …"