PROPOSED JUDICIAL REVIEW OF NICE

Letter before claim

Our Ref: MCX/KBV/05115984-00000001

National Institute for Health and Care Excellence
10 Spring Gardens
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07 March 2014

DRAFT LETTER BEFORE CLAIM FOR JUDICIAL REVIEW
RESPONSE REQUIRED BY 4PM ON XX MARCH 2014

Dear Sirs

OUR CLIENT: EDWARD BARKER (D.O.B- 15/08/1848) OF 224 BRADFORD ROAD, MILES PLATTING, MANCHESTER, M40 7BT
We write pursuant to the judicial review pre-action protocol to give formal notification of a proposed claim for judicial review. We are instructed to act on behalf of Edward Barker, a 64-year-old man with a diagnosis of hypopituitarism. We are instructed to act on EB's behalf in relation to a challenge against National Institute for Health and Clinical Excellence's (NICE) failure to include important information regarding the high risk of hypopituitarism occurring in patient following a brain injury in their updated Head Injury Guidelines (CG56) published on 22 January 2014.

Please note that a response to this letter is required by 4pm on XX March 2014.

Please note that in the absence of a satisfactory response within this timeframe, we are instructed to take steps to issue urgent judicial review proceedings against the proposed Defendant without further notice. Should such a step be necessary, we also place you on notice of our intention to seek to recover our costs in accordance with the guidance in *Bhata & Others v SSHD [2011] EWCA Civ 895*.

1. Proposed Defendants

National Institute for Health and Care Excellence, 10 Spring Gardens, London SW1A 2BU. We are unaware of any external solicitor acting or reference numbers.

2. The Claimant

Edward Barker, who currently resides at 224 Bradford Road, Miles Platting, Manchester, M40 7BT.

Please note that Irwin Mitchell acts for Mr Barker and all correspondence regarding this matter must be directed to the address and reference shown at the top of this letter. The solicitor with conduct of this matter is Mathieu Culverhouse.

3. The Details of the matter being challenged

On 22 January, NICE published their updated guidelines regarding brain injuries and brain injury rehabilitation (CG56). The proposed Defendant is being challenged regarding NICE's failure to

include important information as to the high risk of hypopituitarism occurring following a brain injury the associated risks that stem from this medical condition and possible treatment options which are available to manage this medical condition.

4. Factual Background

Mr Barker is a 65-year-old man who was diagnosed with hypopituitarism in April 2009. Mr Barker suffered brain injuries in 1972, 1985 and 2002, and his symptoms included dizziness, chronic fatigue, vertigo, heart disease, and sleep problems.

As you will be aware, hypopituitarism is a medical disorder in which the pituitary gland either fails to produce, or produces insufficient levels of one or more hormones. The pituitary gland is a small gland situated at the base of the brain, which, despite its size, secretes hormones that influence nearly every function of the body and mind, including growth, sexual function, mood and an individual's ability to respond to stressful conditions.

There is a considerable body of research establishing that around 30% of survivors of traumatic brain injuries develop hypopituitarism as a direct result of their brain injury *(Thompson C, Traumatic brain injury-induced hypopituitarism: whom and when to test. Endocrine Abstracts, European Congress of Endocrinology 2007*). We understand that if the condition is diagnosed it can be effectively treated with hormone therapy. However research has shown that most cases remain undiagnosed and untreated. *(Agha, A.; Phillips, J.; Thompson, C J., Hypopituitarism following traumatic brain injury (TBI). British Journal of Neurosurgery, Vol 21, issue 2 April 2007 pp. 210-216)*

Research puts the annual incidence at between 30 and 50 per 100,000, and it is thus, in the words of one systematic review "of major public health importance." *(Schneider HJ et al, Hypothalamopituitary Dysfunction Following Traumatic Brain Injury and Aneurysmal Subarachnoid Haemorrhage: A Systematic Review, 2007, JAMA; Fernandez-Rodriguez E et al, Hypopituitarism following traumatic brain injury: determining factors for diagnosis, Front Endocrinol 2011).* We understand that the current number of undiagnosed PTHP patients in the UK has been estimated to be up to one million. *(BBC Radio, Inside Health April 9th 2013)*

Symptoms of hypopituitarism do not necessarily appear immediately and can develop many years following an individual's brain injury. Medical evidence demonstrates that if left undiagnosed and untreated, hypopituitarism can have a significant and potentially fatal impact on a person's life. Untreated hypopituitarism leads to heart disease and premature death, and there are strong indications that it may contribute to the well documented tripled/quadrupled risk of suicide after traumatic brain injury. *(Simpson G., Tate R., Suicidality after traumatic brain injury: demographic, injury and clinical correlates. Psychological Medicine 2002 May; 32: 687-98.)*

We note that various submissions and petitions were submitted to NICE during the consultation period prior to the publication of the CG56 guidelines, requesting that the guidelines include reference to the significant link between brain injury and hypopituitarism. We understand that this has included requests for NICE to update their template hospital discharge advice so that patients who have acquired brain injuries are made aware of the possibility of developing hypopituitarism and are informed of what steps they should take if symptoms occur. There was also a request that the guideline should advise that cortisol levels and urinary output should be monitored during the acute stage in view of the risk of adrenal crisis and diabetes insipidus, two consequences of pituitary dysfunction that can be life-threatening during the acute stage.

We understand that NICE reviewed their brain injury guidance recently and issued the updated guidance notes on 22 January 2014. We note that NICE have failed to include any advice or information regarding the significant link between brain injuries and developing hypopituitarism whatsoever and did not include advice regarding cortisol and urinary output measurement. Nor is there any easily accessible information provided to the patient or carers in the template hospital discharge advice. As a result of this failure individuals with acquired brain injuries risk not being informed of the potential risks that they face. We submit that this failure to include any reference to the association between brain injury and hypopituitarism despite the evidence set out above is irrational and therefore unlawful.

5. Grounds

Irrationality

The Defendant's failure to provide any information in the updated NICE guidance notes regarding brain injuries, detailing the associated risk and link between sustaining a brain injury and developing hypopituitarism as a direct result, is so demonstrably unreasonable so as to constitute 'irrationality' or 'perversity' on the part of the Defendant. You will be aware that the benchmark decision on this principle of judicial review was made as long ago as 1948, in the *Wednesbury* case:

"If a decision on a competent matter is so unreasonable that no reasonable authority could ever have come to it, then the courts can interfere... but to prove a case of that kind would require something overwhelming..." Lord Greene Associated Provincial Picture Houses Ltd v Wednesbury Corporation [1948] 1 KB 223, HL.

We submit that the Defendant has acted unreasonably in the *Wednesbury* sense because the decision amounts to one that no reasonable ombudsmen would make in these circumstances. A significant body of research and medical evidence confirms the association between brain injuries and developing hypopituitarism. There is also significant evidence which highlights that head injuries which lead to a diagnosis of hypopituitarism can lead to an increased risk of suicide should it not be diagnosed and/or properly treated.

We submit that the Defendant has acted irrationally in failing to fully inform patients who have acquired brain injuries of the associated risks which they may potentially develop when they produced their updated guidance notes on 22 January 2014.

6. Steps which the defendant is required to take

We request that NICE confirm in writing by no later than by **4pm on XX March 2014** that it will agree to:

1. The NICE guidance notes on brain injuries (CG56) shall be amended within 14 days from the date of this letter to include advice regarding the link between brain injuries and developing hypopituitarism at the acute stage:

2. The discharge advice and standard precedent letter of discharge for patients who have sustained brain injuries shall be amended within 14 days from the date of this letter to include the following:

   Discharge advice (Appendix O, 0.6.1 for patients over 16 years) to end as follows:

Most patients recover quickly from their accident and experience no long-term problems. However some patients only develop problems after a few weeks, months or in rare cases years. If you start to feel that things are not quite right (eg mild headache, feeling sick, problems concentrating, poor memory, irritability, tiredness, problems sleeping, lack of appetite, sexual and fertility difficulties, weight problems) then please see your GP so that he/she can make sure you are recovering properly; occasionally, further investigations (eg pituitary blood tests) may be required.

Discharge advice (Appendix O, 0.6.2, for carers of children,) to end as follows:

Most children recover quickly from their accident and experience no long-term problems. However, some may develop problems after a few weeks, months or rarely years. If you start to feel that things are not quite right (eg mild headache, feeling sick, problems concentrating, poor memory, irritability, tiredness, problems sleeping, declining school performance and lack of appetite) then please see your GP so that he/she can make sure your child is recovering properly. Occasionally young adults with a history of previous head injury may develop other problems eg weight gain, sexual and fertility difficulties that warrant further investigations (eg pituitary blood tests).

3. The discharge advice (Appendix O, 0.6.3, for carers of adults) shall be amended within 14 days from the date of this letter as detailed above.
4. The 'Admissions and Observations' section shall be amended within 14 days from the date of this letter to include instructions to measure basal cortisol levels and urinary output.

7. Details of the legal advisors dealing with this matter and the address for reply and service of court documents

Mathieu Culverhouse
Solicitor
Irwin Mitchell LLP
Bauhaus
27 Quay Street
Manchester
M3 4AW
Telephone: 0161 838 2390
Fax: 08701 973 515
Email: mathieu.culverhouse@irwinmitchell.com

8. The details of information sought and documents considered relevant and necessary

In the event that the Defendant does not agree to undertake the steps outlined at 6 above by the stipulated deadline, then we require the following documents by no later than **4pm on XX March 2014**.

1. Written submissions detailing why the proposed Defendant is of the view that the information detailed above regarding hypopituitarism should not be included in the NICE guidance notes on brain injuries (CG56).

9. Proposed reply date

A response to this letter is required by no later than 4pm on XX March 2014.

Should you fail to respond within this timeframe, we are instructed to take steps to issue urgent judicial review proceedings against the proposed Defendant without further notice to yourself.

Yours faithfully

IRWIN MITCHELL LLP

Response from NICE's solicitors to letter of claim

DAC beachcroft

Our Ref: SH/aed/NAT120-0923674
Your Ref: MCX/KBV/05115984-00000001
24 March 2014

Irwin Mitchell Solicitors
Bauhaus Rossetti Place
27 Quay Street
Manchester
M3 4AW

By post and email to: Mathieu.Culverhouse@irwinmitchell.com

For the Attention of Mathieu Culverhouse

Dear Sirs

Our client the National Institute for Health and Care Excellence
Your client Mr Edward Barker

This letter is a formal reply to your judicial review pre-action protocol letter dated 10 March 2014.

The claimant

1. Edward Barker care of Messrs Irwin Mitchell solicitors

From

2. The National Institute for Health and Care Excellence of 10 Spring Gardens London SW1A 2BU

The details of the matter being challenged

3. The Claimant seeks to challenge the content of a clinical guideline published by the Defendant, entitled *CG176 Head injury: Triage, assessment, investigation and early management of head injury in children, young people and adults.* ("The Guideline") (The reference to CG56 in the Claimant's letter is incorrect, that guideline has been republished and partly updated by CG 176). Specifically the Claimant argues that it is irrational for the Guideline not to make reference to the possibility that a patient who has suffered a head injury may go on to develop hypopituitarism.

Response to the proposed claim

4. Briefly, the Defendant says the claim is profoundly ill founded for the following reasons:

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4.1. The Guideline focuses on the immediate management of patients who have suffered head trauma. Hypopituitarism is not present in such patients and is therefore not diagnosable. Further the scope of this Guideline in this regard has been settled since 2003 and so the claim is entirely out of time.

4.2. It is apparent from the extensive citation of scientific literature in the Claimant's letter that this is at best a scientific rather that a legal dispute (in contrast to the five scientific papers cited, the substantive legal content of the letter is one cursory reference to the *Wednesbury* case). The Guideline is not Wednesbury unreasonable in not discussing hypopituitarism.

4.3. The Claimant has no standing to bring the claim.

5. Scope of the Guideline: First, the fact that the guideline covers only the immediate care of patients with head trauma is apparent from its very title, ***Triage***, ***assessment***, ***investigation*** *and* ***early management*** *of head injury* (emphasis added). This is also clear from the scope of the guideline, published at paragraph 2.4 of the Guideline as regards the original 2003 work, 2.6 as regards the 2007 update, and paragraph 2.5.1 as regards the 2014 update. Paragraph 2.5.2 of the Guideline, entitled "*What the guideline does not cover*" clearly states that the Guideline does not include:

Rehabilitation or long-term care of patients with a head injury.

6. Further it is apparent from the detailed content of the Guideline that it deals only with the immediate aftermath of injury. It should be sufficient merely to scan the Guideline's table of contents to make good this point. This is also clear from the Introduction, para 1.1, which reads:

...emergency departments see a large number of patients with minor or mild head injuries and need to identify the very small number who will go on to have serious acute intracranial complications.

7. The Claimant's letter concedes that:

Symptoms of hypopituitarism do not necessarily appear immediately and can develop many years following an individual's brain injury

8. In fact this concession does not go far enough. Symptoms of hypopituitarism necessarily do not appear on the timescale covered by the Guideline, or anything close to it. First, the pituitary must suffer harm. Then that harm must lead to a reduction in the production of hormone, which in turn must lead to a reduction in the level of hormone in circulation. Finally that reduction must lead to a medically observable effect. A timescale of months may be expected. This is far outside the timescale for guidance addressed to "emergency departments".

9. Finally on this point, this very same argument was put to NICE during the process of public consultation on the update to the Guideline. This material is published on line. For example the Pituitary Foundation commented:

It is disappointing that there is no reference to the important issue of pituitary dysfunction after traumatic brain injury in the updated discharge advice for patients and carers. Though the true incidence of traumatic brain injury and hypopituitarism remains unclear, the poor outcome for patients who go unrecognised may be devastating, with morbidity and the potential for mortality. As such it is crucial that patients and carers are made aware of this risk when they are discharged from hospital.

10. NICE replied:

Thank you for your comment. ***The scope of this guideline is early management of head injury and focuses on management in the emergency department. Pituitary dysfunction is impossible to diagnose in the early post head injury phase****. This condition is more applicable to admitted patients in high dependency or intensive care units who, once damage to the brain has been confirmed by a CT brain scan, are outside the remit of this early management guideline.* ***The section you refer to is text from the 2003 guideline*** *and as such we are unable to amend this text or make any recommendations regarding the management or prevalence of hypo-pituitarism.* (Emphasis supplied)

11. It can be seen from this material that NICE has consistently understood the scope of this Guideline to exclude the material your client believes should be included, and has done so since 2003, which in addition to the substantive point made above time bars your client's complaint in any event.

12. As to this being at best a scientific and not a legal dispute, and/or to the Guideline not being irrational, a court of law will not wish to adjudicate on the rationality of not including paragraphs such as the ones you suggest. This would require a view to be taken as to the prevalence of hypopituitarism following head trauma, which was not even a topic considered in the Guideline review, still less an issue for legal determination. We have already quoted the Pituitary Foundation above that the incidence is "unclear".

13. Further it is very far from obvious what the overall effect of providing the information you suggest would be. On the one hand would be the benefit to patients who experience the symptoms explained, who would but for the information provided not have presented themselves to their GP, and who on presentation receive treatment of benefit to them. On the other hand would be the disbenefit to patients who find the information worrying and who are needlessly concerned for "*months or rarely years*" that any one of a near universal list of symptoms ("*Mild headache... tiredness...*") requires them to visit their GP in case it is a sign of hypopituitarism. As the Guideline notes, Emergency Departments see a "*large number of patients with minor or mild head injuries*", and yet your client asserts not only that it might be desirable to provide these patients with potentially alarming and very probably irrelevant material, but that it is "*demonstrably unreasonable*" not to do so. We disagree. Where the net benefit lies is at best open to debate. This is par excellence a matter requiring specialist expertise on which it is possible reasonably to reach a wide range of conclusions.

14. If there remains any doubt on this we invite you to review the consultation responses to the draft Guideline, noting the large number of expert bodies which commented on the Guideline none of whom raised the point now being raised, and none of whom stand behind your client's challenge. If no concern was raised in consultation by the Association of British Neurologists, College of Emergency Medicine, Faculty of Intensive Care Medicine, or the Royal College of

General Practitioners, to name only some of the professional consultees, we suggest it is highly unlikely that a Court will be persuaded by your client alone that the content of the Guideline is so unreasonable that no reasonable body could have published it. Furthermore, we note that even the bodies which did raise this issue in consultation are not seeking to challenge the Guideline.

15. On standing: this appears to be the relatively rare case where a claimant lacks standing to bring a challenge. The Claimant says that he is a 65 year old man diagnosed with hypopituitarism in April 2009 (ie, before the publication of this guideline). The Defendant infers, although the Claimant's letter does not state, that the Claimant has been advised by his medical advisors that his hypopituitarism has been caused by past head trauma. (Your letter refers to "brain injury" which might encompass, eg, a cerebrovascular event, anoxia, or many other forms of non-violent injury. As the Claimant complains about a guideline concerned only with head trauma the Defendant assumes that it is physical trauma that he has been advised caused his hypopituitarism).

16. The Claimant's letter does not explain what legal interest he has in the Guideline that would provide standing for a judicial review. He is not affected by it in any way. He does not aver that the Guideline will have any relevance at all to his future medical treatment, nor could it have any such relevance as it does not concern the treatment of hypopituitarism. (For the avoidance of doubt, if it is argued that the Claimant might suffer a further head injury, not only would this not amount to an interest over and above that of any other member of the population, but the matter complained of would still be irrelevant to him as he already has a diagnosis of hypopituitarism.) He does not claim to be acting on behalf of any patient group. The Defendant has no record of his having participated in any way in the creation of the Guideline, whether by submitting comments in the public consultation or otherwise. With respect to him, he appears to have no interest in the matter at all. Furthermore, there are bodies who would appear to have standing, who, unlike your client, did raise the issue at the appropriate time during Guideline development, and who are not seeking to bring a challenge.

Details of any other interested parties

17. None

Address for further correspondence and service of court documents

18. DAC Beachcroft LLP of 100 Fetter Lane, London EC4A 1BN, for the attention of Stephen Hocking.

Conclusion

19. As to the Claimant, the Defendant understands why, given his stated medical history, this is a matter on which he has an opinion. It trusts he finds the explanation given above satisfactory.

20. As to the idea that this matter should be pursued by way of a legal claim (rather than, say, by having submitted a comment in consultation on the draft Guideline) the Defendant is with regret less sympathetic. It is difficult to see who can benefit from this other than lawyers. In common with all public sector bodies the Defendant manages its resources with care, and funds spent on legal costs are not available to improve patient care. The Defendant

Sir Andrew Dillon's earlier email sent 2 July 2010 conceding that life-threatening adrenal deficiency occurs in 12% of head injury patients during the acute stage, showing that he was well aware that pituitary damage could show its effects immediately.

Dear Ms lane,

Thank you for your email.

I agree that the systematic review which you cite refers to evidence that the incidence of **biochemically identified** hypopituitarism is higher in the acute phase. The figure of 80%, which you refer to, is for LH/FSH (gonadotrophins) only, and only in one of the two studies. The rate of ACTH deficiency, which if severe would be the only life threatening complication, is cited as 12%. The clinical significance of these biochemical findings is not clear. The review itself states that: *'Early posttraumatic pituitary dysfunction can be transient in many cases and conversely, hypopituitarism can evolve over several weeks or months after injury.'*

In addition, the abstracts of two papers listed at the end as citing this paper include the following two statements:

'By applying strict diagnostic criteria to an emergency-department-based cohort of TBI patients, it was shown that anterior pituitary dysfunction is rare (<1%). Routine pituitary screening in unselected patients after TBI is unlikely to be cost-effective.' *van der Eerden et al (2010)*

The reported variations in the prevalence rates of hypopituitarism after TBI are in part caused by differences in definitions, endocrine assessments of hypopituitarism, and confounding factors. These methodological issues prohibit simple generalizations of results of original studies on TBI-associated hypopituitarism in the perspective of meta-analyses or reviews.' Kokshoorn et al (2010).

We do have to take informed decisions the best way to allocate our limited resources and I remain of the view that the best approach to this topic is a clinical guideline which addresses the question as to whether routine screening of patients following traumatic brain injury for pituitary dysfunction is clinically and cost effective.

Yours sincerely,

Andrew Dillon
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Professor Chris Thompson's email sent 3 April 2014

Dear Joanna

Once again NICE have not researched this issue.

Histological data

It has been known since 1969 (Kornblum and Fisher, 1969) that 35% of patients surviving 12 hours after TBI have evidence of infarction of the pituitary. (Infarction is cell death due to lack of blood supply). This was reinforced in 2007 (Salehi, Brain Injury 2007) by data which showed that there was no sign of infarction in 12 patients who died at the scene of TBI, but in 43% of patients who died within the first seven days, and who were studied at post-mortem.

Our own data has shown that 30% of patient studied at 7-14 days post TBI have evidence of subnormal pituitary function (Agha et al Clin endo 2004) and more recently, a more comprehensive daily assessment of 100 patients with TBI showed that EIGHTY PER CENT HAD SUBNORMAL CORTISOL LEVELS AT SOME STAGE DURING HOSPITAL ADMISSSION (Hannon MJ et al JCEM 2013).

We have also presented data showing significant sequelae of acute pituitary injury, including hyponatraemia, hypoglycaemia and hypotension (Agha et al QJM 2005).

Therefore

1. There is evidence of structural damage occuring within the first week

2.There is clear evidence that this leads to pituitary dysfunction

3. The pituitary dysfunction leads to measurable clinical deficits.

In addition, the long term sequelae are no longer disputed.

It seems that NICE are acting in a deliberately delinquent manner in ignoring expert opinion - I wish you luck with the judicial review

Chris Thompson

Legal aid refusal

Legal Aid Agency

LEGAL AID AGENCY
High Cost Civil Team

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IRWIN MITCHELL LLP INC:ALEXANDER HARRIS
DX 14368
MANCHESTER 1

Our Case Reference:
QLBCFEE8F57 A/W/1

Date: 08/04/2014

Your Ref: MCX/KBV/5115984-1

Dear Mr. Culverhouse

Re: Mr. E Baker

Thank you for your App6 and subsequent App1 on behalf of the above. Unfortunately a copy of the relevant NICE guidance which you are seeking to review was not enclosed.

However, on the basis of the information provided:

1. It would appear that the applicant lacks standing.
2. Even if he had standing, I am unclear as to how amendment of this guidance would benefit the applicant – and as such it would appear that the costs are disproportionate to the likely benefit.
3. The guidance that you are seeking to review specifically states that it does not cover rehabilitation or long term care. From the information provided hypopituitarism is not something which is diagnosable within the early stages of a head injury and as such I cannot see that it falls within the remit of this guidance. Whilst it is clear that this issue was raised and considered by NICE during the consultation period; NICE's response setting out what the guidance is intended to cover appears clear, logical and reasonable. It would therefore appear that the prospects of success are poor as this is not an early management /emergency care issue.

For the reasons above - namely lack of standing, insufficient benefit, and poor prospects - this application is refused. I am sorry that this will be disappointing to your Client.

With kind regards,

Yours sincerely

Rhiannon Williams-Clarke
Solicitor
High Cost Civil Team