Neutral Citation Number: [2016] EWHC 1395 (Admin)

Case No: CO/4007/2015

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION
ADMINISTRATIVE COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 15/06/2016

Before :

MR JUSTICE COLLINS

- -

Between :

S (a child)	**Claimant**
By her father and litigation friend M	
- and -	
NHS England	**Defendant**

- -
- -

Mr Ian Wise, QC and Mr Stephen Broach (instructed by **Hodge Jones and Allen**) for the **claimant**
Ms Jenni Richards, QC (instructed by **DAC Beachcroft**) for the **defendant**

Hearing dates: 4th May 2016

- -

Approved Judgment

Mr Justice Collins:

1. The claimant, who has an anonymity order, is a girl who was born in February 1999 and so is now 17 years old. In September 2011 she began to fall asleep and became unable to concentrate or to participate properly in games at school or in lessons. Sleep did not refresh her and she always felt tired. After a number of doctors were unable to identify the cause of her disability, finally in March 2012 she saw a consultant neurologist, Dr Rittey. After conducting a number of tests, he decided that she was suffering from narcolepsy and cataplexy.

2. Narcolepsy is a sleep disorder which affects the brain's ability to regulate a normal sleep and wake cycle which results in excessive day time sleepiness and night time disturbance of sleep. There are other side effects, including hallucinations and weight gain. Cataplexy is a temporary involuntary muscle weakness which is brought on by strong emotions, for example laughter. In S's case, the weakness has usually affected her knees which tend to buckle. It can be readily understood why her ability to achieve her full potential, both academically and physically, has been seriously compromised. She was academically very bright and the forecast was that she would and could expect to go to Oxbridge or certainly a highly regarded university. She also enjoyed and was good at games, particularly badminton and tennis. As a result of her condition, she has fallen behind in her work, cannot compete in sporting activities and has found that she has lost friends because, albeit initially supportive, they have dropped away since she cannot engage with them in a normal way.

3. The disability is rare, affecting apparently some 31,000 persons in the country. But the statistics for those aged between 10 and 19 show that it affects some 3.84 per 100,000. Many sufferers can be treated effectively with a number of drugs which, without needing to go into detail, I shall call the usual treatment. But there are some, of whom the claimant is one, for whom the usual treatment is not effective. But there is a drug, sodium oxybate, which has a trade name Xyrem. It was developed by an American company, which holds the patent, and is available in this country through a source licensed by the American company. It is effective for both adults and children and provides a real chance of enabling sufferers such as the claimant to live a normal life. In particular, once the correct dosage for the claimant is established, it is likely, as some who have received it have said, to give her back her life.

4. Excessive cost has not been relied upon by the defendant as a ground for refusing to fund the drug for the claimant. The cost will vary according to the dosage needed for a particular sufferer and children will often require a lesser dose than adults. It seems that the full dose, which is 9 mg per day, costs about £13,000 a year. For a child such as the claimant the dose and so the cost is likely to be less and will certainly be less while the correct dosage is identified. But it could even for a child reach the maximum of 9 mg.

5. The primary legislation which governs the operation of the National Health Service is contained in the National Health Service Act 2006 as amended by the Health and Social Care Act 2012. Section 1 so far as material provides, under the heading 'Secretary of State's duty to promote comprehensive health service':-

> "(1) The Secretary of State must continue the promotion in England of a comprehensive health service designed to secure improvement –

> (a) in the physical and mental health of the people of England, and
>
> (b) in the prevention, diagnosis and treatment of physical and mental illness.
>
> (2) For that purpose, the Secretary of State must exercise the functions conferred by this Act so as to secure that services are provided in accordance with this Act."

Section 1H set up the NHS Commissioning Board (usually referred to as NHS England). So far as material, S.1H provides:-

> "(2) The Board is subject to the duty under section 1(1) concurrently with the Secretary of State except in relation to that part of the health service that is provided in pursuance of the public health functions of the Secretary of State or local authorities.
>
> (3) For the purpose of discharging that duty, the Board –
>
> (a) has the function of arranging for the provision of services for the purpose of the health service in England in accordance with this Act, and
>
> (b) must exercise the functions conferred on it by this Act in relation to clinical commissioning groups so as to secure that services are provided for those purposes in accordance with this Act."

The public health functions of the Secretary of State and of public authorities are specified in various sections of the Act. It is not necessary for the purposes of this judgment to refer to them.

6. A number of specific duties are imposed on the defendant in the Act. Section 13D requires the defendant to 'exercise its functions effectively, efficiently and economically'. Section 13G requires the defendant, in the exercise of its functions, to:-

> "(a) reduce inequalities between patients with respect of their ability to access health services, and
>
> (b) reduce inequalities between patients with respect to the outcomes achieved for them by the provision of health services."

7. "Clinical commissioning groups" (CCG) are referred to in s.1H(3)(b). Their duties are set out in Section 3. Their responsibilities include arranging to the extent they consider necessary to meet the requirements of persons for whom they have responsibility for inter alia such services or facilities as are required for the treatment of illness (s.3(1)(f)). A CCG has responsibility for those who usually reside in its area (s.3(1A)(b)). The duty set out in s.3(1) does not apply in relation to a service or facility if the defendant has a duty to arrange for its provision (s.3(1E)). Regulations have been made which require the defendant to be responsible for the provision of services for various persons. The regulations are the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 (2012 No. 2996). These include services for what

are identified as rare and very rare conditions in Schedule 4 to the Regulations (paragraph 11). Schedule 4 identifies 144 different services. Number 120 is:-

> "Specialist neuroscience services for children and young people".

8. Part 7 of the Regulations is headed "Standing rules: decisions about drugs and other treatments". A relevant body, which includes the defendant, must have in place arrangements for making decisions and adopting policies on whether a particular health care intervention is to be made available and those arrangements must include those for 'the determination of any request for the funding of a health care intervention for a person where there is no relevant NICE recommendation and the relevant body's general policy is not to fund that intervention' (paragraph 34). Reasons must be given for any decision (Regulation 35). Sodium oxybate is not recommended for children nor at present is there a general policy of the defendant to fund it.

9. The defendant was established on 1 October 2012 and took over many responsibilities which had been dealt with by Primary Care Trusts which were abolished by the 2012 Act. One of the aims of a centralised body to commission services is to provide for nationwide consistency and equality of treatment. Inevitably, cost and value for money play a significant part. The defendant's present budget is set at £100 billion per year which has to cover all NHS health activity from birth to death bearing in mind that the NHS employs more than 1.6 million people. Where, as in this case, there is no NICE recommendation or general policy to fund, there is what is called an Individual Funding Request policy (IFR). This endeavours to balance the need for consistency and the prevention of those who lobby being given undue priority. A provision in the IFR policy which excludes those whose needs would be better considered as a service development request is not now taken into account in this case and, albeit raised in the initial refusal of treatment, has not since featured.

10. IFRs are dealt with in a policy document of April 2013. Clinicians may make an IFR request if the patient is suffering from a medical condition for which the defendant "has commissioning responsibility and a commissioning position and the patient's particular clinical circumstances fall outside the criteria set out in an existing commissioning policy for funding the requested treatment" (paragraph 1.2). IFRs can be met if the patient has exceptional clinical circumstances. Paragraph 1.9 deals with cases such as the claimant's and so far as material provides:-

> "The IFR panel will use the information provided by the requester to compare the patient to other patients with the same presenting medical condition at the same stage of progression. Specifically, the panel may consider, based upon the evidence provided to it, whether or not the patient has demonstrated exceptional clinical circumstances which lead the panel to believe that the patient would benefit significantly more from the treatment than the other patients not meeting funding criteria. When making the decision, the IFR panel is required to restrict itself to considering only the patient's presenting medical condition and the likely benefits which have been demonstrated by the evidence to be likely to accrue to the patient from the proposed treatment."

There is a requirement to have regard to the Equality Act 2010 and the Human Rights Act 1998 and a prohibition on making "treatments available to individual patients, and not other clinically similar patients, on the basis of non-clinical factors".

11. The policy states that there needs to be a distinction between cases where the clinical circumstances are genuinely exceptional and those where they are representative of a small group. The latter may need a commissioning policy which will be considered where there are likely to be 5 or more in any region served by the defendant. It is to be noted that consideration is being given to the provision of sodium oxybate for those children who are not responsive to the usual treatment. There is due to be a report in June but the outcome is not of course certain. If it does recognise that there should be commissioning, cases such as this will no longer arise.

12. The policy considers what is meant by exceptionality. I do not propose to burden this judgment with the four pages which deal with this. I shall summarise. It starts by stating that 'very few patients have clinical circumstances which are exceptional so as to justify funding for that patient which is not available for other patients'. Thus the approach to exceptionality must be to require considerably more than a failure of usual treatment. But it must be borne in mind that exceptional is not the same as unique and that there should not be an approach that denies that any but an extreme case is regarded as exceptional. In its ordinary meaning, exceptional can mean no more than a case which does not meet what is normal.

13. The policy continues:-

> "The fact that a patient failed to respond to, or is unable to be provided with, one or more treatments usually provided to a patient with his or her medical condition (either because of another medical condition or because the patient cannot tolerate the side effects of the usual treatment) may be a basis upon which the panel may find that a patient is exceptional".

It is difficult to follow why there should be a difference in principle where the usual treatment simply does not work for a particular patient irrespective of the existence of another medical condition or side effects. But this statement is qualified and the panel is told to be satisfied that the patient's inability to respond to the usual treatment was genuinely an exceptional circumstance. The policy continues:-

> "If the usual treatment is only effective for a proportion of patients (even if a high proportion), this leaves a proportion of patients for which the usual treatment is not available or is not clinically effective. If there is likely to be a significant number of patients for whom the usual treatment is not clinically effective or not otherwise appropriate (for any reason) the fact that the requesting patient falls into that group is unlikely to be a proper ground on which to base a claim that the requesting patient is exceptional."

Much will obviously turn on what is meant a significant number. Is it necessary to try to ascertain the overall number of patients in question or is it a proportion of those who suffer a condition? A reasonable approach would suggest the latter, albeit there will be difficulties in making an assessment on either approach.

14. The policy concludes the section on the meaning of exceptional thus:-

> "To meet the definition of exceptional clinical circumstances there must be an NHS CB policy in place that describes the availability of the requested intervention and your patient must demonstrate that they are both:
>
> Significantly different clinically to the group of patients with the condition in question and at the same stage of progression of the condition
>
> AND
>
> Likely to gain significantly more clinical benefit than others in the group of patients with the condition in question and at the same stage of progression of the condition."

The claimant's condition is not progressive so that reference to the same stage of progression is not applicable. But a sensible approach to what is intended will mean the same failure of the usual treatment to achieve the necessary benefit to the patient.

15. It is for the patient's clinician to set out clearly the grounds for saying he or she meets the exceptionality test. The policy states:-

> "The grounds will usually arise out of exceptional clinical manifestations of the medical condition as compared to the general population of patients with the medical condition that the patient has."

16. Statements have been lodged by the defendant from the Head of Clinical Effectiveness for Specialised Services for the defendant. She gives figures which show that less than 15% of IFR applications were allowed and that in the 10 months between 1 April 2015 and 31 January 2016 74 out of 921 were allowed. There have, apparently over the period since 1 April 2013, been only 9 applications for sodium oxybate for children and two of these have been allowed. It is difficult to see that 9 is a significant number of children who are in need of sodium oxybate and so who should be regarded as meeting the exceptionality test.

17. The defendant is not responsible for adult sufferers from narcolepsy and cataplexy. Requests for sodium oxybate for adults are dealt with by the CCG in the particular area. Further, the claimant's solicitor has been instructed on behalf of some 81 patients who have suffered narcolepsy and cataplexy following the Pandremix vaccination for swine flu in 2009/2010. The Secretary of State has set up a scheme for those sufferers outside the NHS and those, both children and adults, who have needed sodium oxybate have received it. The defendant has said it is not responsible for the Secretary of State's decisions and is not the deciding body for adults.

18. The first IFR application was made by Dr Rittey on 2 June 2014. It was wrongly dealt with by the CCG. On 8 December 2014 Dr Rittey provided further information which included the observation that only a very tiny proportion of patients with narcolepsy fell into the group of which the claimant was a member who continued to have significant symptoms which severely interfered with her everyday life. Since the vast majority of patients did not require sodium oxybate, it was, he said, difficult to answer the question whether the claimant would experience greater benefit than other children. But he was clear that the lack of response to the usual treatment made her case exceptional. On 3 February 2015, the CCG refused the application on the ground

that it was not cost effective. It accepted that the claimant was an exceptional case. Dr Rittey requested a reconsideration by letter of 6 March 2015 on the basis that cost effectiveness should be judged on the basis that the treatment would enable the claimant to reach her full potential in order to be a productive member of society.

19. On 28 May 2015 the defendant came into the picture, no doubt (although this was not stated) because someone had realised that the CCG had no jurisdiction to deal with the IFR application. It refused even to put the request to its panel because, it was said, the claimant was representative of a group of patients who had a similar condition and were at the same stage of that condition so that the request was for a service development and not appropriate for consideration as an IFR. Following a pre-action protocol letter, the defendant replied on 7 July 2015. It said that the defendant's decision of 28 May 2015 did not take into account the further information submitted to the CCG after the initial IFR application in June 2014. It is difficult to identify a sensible reason for this failure. The result of the muddle by the CCG and the defendant has been the lapse of time of more than a year during which, as it has since become apparent, the claimant's condition has deteriorated and her future well being has been severely compromised.

20. The defendant asked for a fresh IFR. By letter of 20 July 2015, the claimant's solicitors sent a further PAP letter saying that a further IFR was unnecessary since all relevant information was already before the defendant. On 3 August 2015 solicitors on behalf of the defendant responded. This letter did little more than repeat the basis for refusal and that only the original request was considered. Further, the service development point was maintained. It has now been abandoned. The CCG's view on exceptionality was said not to accord with the defendant's policy. In addition, account would not be taken of clinical factors such as the particular effect on the claimant's ability to achieve as she should in her A-levels.

21. By letter of 19 August 2015, the claimant's solicitor raised section 11 of the Children Act 2004 which requires that functions be discharged having regard to the need to safeguard and promote the welfare of children. This was rejected by the defendant's solicitors who offered consideration of a fresh IFR which, they said, was all that judicial review could achieve. Since the defendant's approach had been clearly set out, a fresh application would not have achieved anything but, as will become clear, judicial review could show that the defendant had failed to reach a lawful decision.

22. The claim was filed on 21 August 2015. It raised discrimination on the basis that there was no justification for refusing to fund the drug for some but not others. There was a breach of Section 11 of the Children Act and the failure to include all the information provided by Dr Rittey amounted to a procedural impropriety. An Acknowledgement of Service was lodged on 14 September 2015. This rejected all the grounds relied on but also repeated the offer to reconsider. On 13 November 2015 on the defendant agreeing to reconsider I granted permission for judicial review and made directions about amendments if the reconsideration was not favourable.

23. On 27 November 2015 the defendant wrote to Dr Rittey informing him of its decisions to maintain its refusal of his IFR application. The decision was made by the screening group and was not put to the defendant's panel. It indicated that the evidence produced suggested that about 10% of patients would not respond to the usual treatment so that overall there would be between 70 and 157 children aged 16 or

under who might be suitable candidates for the drug. Some 180 to 200 adults and children were receiving the drug as a result of CCG and some historically approved by PCTs. But, it was said, the defendant was not bound by those approvals. It set out a number of bullet points. The three final points were:

> "▪ The application states that this patient has not responded to standard treatments and the supporting information from the school and other assessments indicate functional impairment. However, there is insufficient information on symptom severity using recognised scoring systems to enable an IFR panel to be clear of how far away from the usual response range this patient's symptoms may be and to be able to consider her case in the context of other paediatric patients with this condition.
>
> ▪ The outcome measures are not described in sufficient detail to enable an IFR panel to reach a decision on the efficacy of the treatment in this case.
>
> ▪ At present there is insufficient information in the application form to justify why this patient should have access to this intervention ahead of others with a sub optimal response to standard treatment who will await clinical commissioning policy publication".

It informed Dr Rittey that if he chose to submit an updated application, he should specifically address the points raised in the bullet points I have set out above.

24. On 17 January 2016 Dr Heather Elphick, the lead consultant at the hospital which the claimant was attending, wrote to the defendant giving the information required. This included cataplexy questionnaires and sleepiness scores of February and December 2015 which showed a deterioration in both. The claimant thus was suffering very poor symptom control despite the maximum which the usual treatment could provide for her having regard to side effects from which she was already suffering. Dr Elphick considered that the claimant's case was indeed exceptional. There followed a refusal by the defendant to reconsider further without a fresh IFR. The claimant's solicitors were unimpressed by this seemingly bureaucratic approach, but on 7 February 2016 Dr Elphick submitted a fresh IFR.

25. This stated that the claimant was on the maximum available medication and concern was expressed about the risk of potential side-effects due to the number of medications she was taking. The only remaining option was sodium oxybate. There was concern about her physical and mental wellbeing. She had put on weight and had sought psychological help because of deterioration in her mind. Further, she was currently worse than other patients for whom the usual treatment was not working because her condition was deteriorating. She was thus likely to gain a greater clinical benefit from sodium oxybate than other patients with the same refractory narcolepsy. She thus would seem to fall within the paragraph of the IFR policy referred to in paragraph 13 above in that she could not tolerate the side effects of the usual treatment. A three month trial was suggested and the improvement in the claimant's quality of life and the damage to her mental and physical health resulting from her condition if not properly treated was emphasised.

26. On 14 March 2016 the defendant rejected the fresh IFR. The comparator group of patients was considered to be those with severe narcolepsy whose symptoms were not

adequately controlled by the usual treatment and it was, it was said, 'unclear how this patient would be different to other patients with the same condition and at the same stage of progression'. Again, inappropriate reference is made to the stage of progression. It was recognised that the claimant was 'at the severe end of the scales and experiencing serious and deteriorating symptoms' but 'this in itself does not demonstrate clinical exceptionality'. While the claimant had poor symptom control it was agreed that there would be other patients with this condition who would also be in the same position as this patient and there was no information provided to demonstrate how this patient could be considered clinically exceptional to those patients. The effect on academic achievement was a non-clinical aspect which could not be taken into account. This was stated:-

> "There was insufficient evidence to support an argument that the patient would experience greater clinical benefit than other patients who were refractory to first line treatment. The fact that her condition was currently deteriorating was not sufficient as this information could not indicate what absolute benefit she might expect to receive nor how absolute benefit would compare with other patients, some of whom might be experiencing a deterioration".

27. A statement from Dr Elphick dated 18 March 2016 was sent to the defendant to deal with the defendant's request for "further clinical information as to clinical exceptionality". In it, she underlined with clinical results the severity of the claimants' condition. In paragraph 8, she said this:-

> "I note that to be clinically exceptional under the IFR policy, she has to be 'significantly clinically different to the group of patients in question and at the same stage of the progression of the condition'. I consider she is clearly significantly clinically different on the basis that all the existing attempts to manage her symptoms have not been successful and even on medication her sleep study results are consistent with someone with severe narcolepsy – as could be seen in someone unmedicated. This is a rare and extreme type of narcolepsy. Narcolepsy is not a progressive condition and therefore the issue of the progression of the condition is not applicable".

In paragraph 7, Dr Elphick had drawn attention to the worsening of the claimants' symptoms. Thus the claimant was, Dr Elphick said, clearly an exceptional case.

28. The defendant replied to this fresh information through its screening group. In essence, the reasons given in the letter of 14 March 2016 were repeated since the new information was "not sufficient to substantially change the original decision and your request should not go forward for consideration by the IFR panel". Before obtaining leave to amend to challenge the March refusals, the claimant's solicitors suggested a three month trial of sodium oxybate but that was rejected on the ground that it breached the principle of equal access for equal clinical need. Further, it was said that there was a need to guard against "patients, patient groups or services who lobby being given undue priority and warns that a decision to treat some patients but not others has the potential to be unfair, arbitrary and possibly discriminatory". This comes perilously close to undermining the IFR policy since the whole point of it is that there will be patients who are entitled to a particular treatment not available generally to others because of their exceptional needs.

29. In her claim as amended, the claimant relies on three grounds. First, it is said that there has been unlawful discrimination. The discrimination alleged is between those on the Pandemrix group and between children and adults since adults can receive (subject to CCG's approval) sodium oxybate. Secondly, it is said that there has been a breach of Section 11 of the Children Act 2004 coupled with the need pursuant to Article 3 of the UN Convention on the Rights of the Child to treat the claimant's best interests as a primary consideration. Thirdly, it is said that there has been a failure to apply the IFR policy correctly.

30. It was decided that I should hear argument first on the third ground, namely the failure to apply the IPR policy correctly. Since I decided that there was such a failure, I did not need argument on the other two grounds.

31. For obvious reasons, there has been emphasis placed on the claiamnt's academic expectations and her need to do as well as possible in her current A level examinations. But every child will need to do their best since otherwise their future life will be severely blighted. This is however a non-clinical factor. Ms Richards relies on the decision of the Court of Appeal in R(Condliff) v. North Staffordshire PCT [2012] PTSR 460. The case concerned the criteria set for determining exceptionality because of the difficult ethical and practical questions in deciding, as between patients competing for limited resources, what circumstances should be taken into account as potentially exceptional. Toulson LJ, who gave the only reserved judgment, referred to and cited extensively from a paper published in 2008 by Dr Daphne Austin, a consultant in public health with many years experience. The approach to be adopted must be to ask 'on what grounds can the PCT justify funding this patient when others from the same patient group are not being funded?' The ratio of the decision in the case was that it was lawful to adopt a policy that IFR's should be considered and determined exclusively by reference to clinical factors.

32. I recognise, as Ms Richards has submitted based on the evidence of the Head of Clinical Effectiveness for Specialised Services for the defendant, that the defendant has finite resources and, as the courts have recognised (see for example R v. North Devon H.A ex p Coughlen [2001] QB 213), cannot fund every treatment for every patient. It has to make decisions, which may sometimes seem extremely harsh for individual patients, to ensure the best possible outcome for all patients. The defendant's official policy makes the point that 'there should not be a parallel system operating which allows individual treatments on patients to bypass prioritisation.' The policy states:-

> "A Commissioner should not give preferential treatment to an individual patient who is one of a group of patients with the same clinical needs. Either a treatment or service is funded in order to create the opportunity for all patients with equal needs to be treated or, if this cannot be afforded, it should not be commissioned as part of NHS treatment for any patients. The NHS CB considers that if funding for treatment cannot be justified as an investment for all patients in a particular cohort, the treatment should not be offered to only some of the patients unless it is possible to differentiate between groups of patients on clinical grounds. A decision to treat some patients but not others has the potential to be unfair, arbitrary and possibly discriminatory."

33. While accepting that the approach of the defendant is not unlawful, it must be borne in mind that there is an IFR policy which must be given some effect. Equally, I am conscious that it is not for me to strike down the decision in this case because I believe that it was too harsh and I have, as anyone would, enormous sympathy for the claimant. Mr Wise has contended that the cohort to be considered should be all those suffering from narcolepsy and cataplexy. Ms Richards submits that that cannot be right since all for whom the usual treatment is not effective would be regarded as exceptional. This would be contrary to the policy of the defendant and would in any event widen to an excessive extent the test for exceptionality. I am inclined to agree with Ms Richards but in any event I think I should regard the appropriate cohort as those who do not respond to the usual treatment.

34. The key evidence in this case is that of Dr Elphick emphasised in her letter of 18 March 2016. The claimant is not only not responding to the usual treatment but is deteriorating. This shows that she is suffering from a particularly severe form of her condition. Her condition is rare, and her failure to respond to the usual treatment is also rare. But she is in a very rare situation in that she suffers from a particularly rare form of the condition. This aspect is not dealt with in the response of the defendant's panel or screening group. Since exceptional cannot mean unique, it is in my view difficult if not impossible to see that the claimant should not be considered to meet the exceptionality test. If she is not exceptional, who is? I should add that in her case there is clear evidence that her mental and physical health is suffering and will get worse. Thus she will benefit from the treatment with sodium oxybate to a greater extent than others who are not receptive to the usual treatment. This means that, as Dr Elphick said, there is cost effectiveness in that she will not be likely to need medical care to the extent she will if not treated with sodium oxybate.

35. As I have said, I must not substitute my own judgment for that of the panel. But I have not done this since, as I have set out, there were in my view failures by the defendant to have regard to all the matters raised by Dr Elphick and an altogether too restrictive application of exceptionality. The claimant qualified within the IFR policy referred to in paragraph 13 above.

36. Normally in cases such as this, as the defendant's solicitors stated, the remedy would be to quash the decision and to require reconsideration in accordance with the judgment given. But I am satisfied that this case is indeed exceptional to the extent that a decision to refuse the treatment could not be supportable. Accordingly, I took the unusual step of making an interim order that the defendant should fund the provision of sodium oxybate to the claimant for a three month trial period to be administered under the control of Dr Elphick.

37. I have no doubt that anyone reading the circumstances of this case would be surprised that sodium oxybate is not available for children generally and for the claimant in particular. But I recognise the constraints under which those responsible in the defendant have to act. I wish to make it clear that there is no suggestion that any of those involved in the decisions lacked compassion or knowingly refused treatment they should have permitted. The difficulties facing them cannot be underestimated and I am sure that they regret the need to make decisions which result in suffering by individual patients. Nonetheless, I am satisfied that this is a very rare case in which the decision making has gone wrong.

38. I would only add a hope that this particular problem and a case such as this will go away when the decision is reached whether sodium oxybate will be recommended and in principle available for children. No doubt the need for children to be able to achieve as they should is of fundamental importance and to that end s.11 of the Children Act may be material. But I recognise that it is no part of my function to consider that aspect.