

# Health & Human Rights Symposium

## Access to Treatment and the Convention

Tony McGleenan\*

### Introduction

1. When the National Health Service was established in 1948 the overarching policy aim was to secure equal access to comprehensive medical care for every individual across the country regardless of their ability to pay. It was an ambition of the system, as articulated by Aneurin Bevan, that the cost of the service would reduce as the health of the nation improved. By that rationale, conflicts about the allocation of finite resources would have reduced over time as wealth increased and health improved. This simplistic algorithm has proven to be incorrect. While the NHS helped dramatically to improve the health of the population as a whole with mortality and morbidity rates which have consistently declined for the past 50 years, the gap in health between 'rich' and 'poor' people and 'rich' and 'poor' areas has widened and the costs of treatment have continued to increase.
2. However, a comparison of the core concepts of the foundation of the NHS with the principles outlined in the almost contemporaneous Convention on Human Rights highlights the scope for deploying Convention arguments in disputes about access to treatment. While equality of access to treatment regardless of ability to pay may have been a lofty ambition outstripped by the pace and cost of technological and scientific advance, it does resonate with some of the elementary principles of Convention jurisprudence.

### Litigating Access to Treatment – pre-HRA.

3. Litigation on issues of access to treatment and healthcare resource allocation predates the incorporation of the Convention into domestic law. Typically such cases would involve a public law challenge, by way of judicial review, to an individual resource allocation decision. The prospects of success in such cases, often by their nature emotive, were constrained by the limited scope of any public law challenge. In general terms a challenge to a resource allocation decision could only be brought on irrationality grounds. To succeed an applicant was required to demonstrate that the decision to refuse to fund a particular treatment was so unreasonable that no reasonable decision maker could have so determined. A Respondent's ready answer, absent any truly irrational decision-making, was to highlight the finite nature of resource, the infinite nature of the demand and to maintain that, against such a background, consideration of resources was a material matter in any given case.
4. The classic illustration of the difficulties facing a litigant seeking access to treatment was *R v Cambridge Area Health Authority ex parte B* [1995] 2 All ER 129. The case involved a judicial review challenge to a refusal by the health authority to provide £75000 funding for chemotherapy and bone marrow transplant for a 10 year old child suffering from acute myeloid leukaemia. At

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\* Barrister-at-Law. Contact [tony.mcgleenan@barlibrary.com](mailto:tony.mcgleenan@barlibrary.com)

first instance Laws J had found for the Applicant and granted an order of certiorari quashing the decision not to fund the treatment. The learned judge stated that “where the question is whether the life of a 10-year-old child might be saved by however slim a chance, the responsible authority must do more than toll the bell of tight resources.”

5. The decision was appealed to the Court of Appeal. There Bingham MR reversed the High Court decision. The robust pragmatism of his decision echoed in arguments in many future judicial review applications where access to treatment decisions were subjected to public law challenge. He held:

“I have no doubt that in a perfect world any treatment which a patient, or a patient’s family sought, would be provided if doctors were willing to give it, no matter how much it cost, particularly when a life was potentially at stake. It would however, be shutting one’s eyes to the real world if the Court were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet. They cannot pay their nurses as much as they would like; they cannot provide all the treatments they would like; they cannot purchase all the extremely expensive medical equipment they would like; they cannot carry out all the research they would like; they cannot build all the hospitals and specialist units they would like. Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. This is not a judgment which the court can make.”

A notable feature of both the first instance and Court of Appeal decisions is that in neither case was there a single reference to the Convention articles or jurisprudence notwithstanding the relatively obvious Article 2 issues.

6. In *ex parte Coughlan* [2000] 2 WLR 622 the Court of Appeal examined the extent of the statutory obligations on the Secretary of State to provide healthcare and social services. In that case the local authority proposed closing a facility which cared for elderly patients. Woolf LJ addressed the issue of the statutory obligations imposed on the Secretary of State to provide health care services in the following terms:

24. The first qualification placed on the duty contained in section 3 makes it clear that there is scope for the Secretary of State to exercise a degree of judgment as to the circumstances in which he will provide the services, including nursing services, referred to in the section. He does not automatically have to meet *all* nursing requirements. In certain circumstances he can exercise his judgment and legitimately decline to provide nursing services. He need not provide nursing services if he does not consider they are reasonably required or necessary to meet a reasonable requirement.

25. When exercising his judgment he has to bear in mind the comprehensive service which he is under a duty to promote as set out in section 1. However, as long as he pays due regard to that duty, the fact that the service will not be comprehensive does not mean that he is necessarily contravening either section 1 or section 3. The truth is that, while he has the duty to continue to promote a comprehensive free health service and he must never, in making a decision under section 3, disregard that duty, a comprehensive health service may never, for human, financial and other resource reasons, be achievable. Recent history has demonstrated that the pace of developments as to what is possible by way of medical treatment, coupled with the ever increasing expectations of the public, mean that the resources of the N.H.S. are and are likely to continue, at least in the foreseeable future, to be insufficient to meet demand.

26. In exercising his judgment the Secretary of State is entitled to take into account the resources available to him and the demands on those resources. In *Hincks* (1980) 1 B.M.L.R. 93 the Court of Appeal held that section 3(1) of the Act of 1977 does not impose an absolute duty to provide the specified services. The Secretary of State is entitled to have regard to the resources made available to him under current government economic policy

7. Notwithstanding the negative approach adopted by the Court of Appeal in *ex parte B* and Woolf LJ's decision in *Coughlan*, judicial review proceedings have been brought which successfully challenged resource allocation decisions. *R v North West Lancashire Area Health Authority ex parte A* 1 WLR 977 [2000] is indicative of a judicial review application where the applicants successfully employed public law and Convention arguments in a challenge to a healthcare resource allocation decisions. In that case the public authority had decided to adopt a policy of not funding gender reassignment surgery. The Applicants were all transsexuals who claimed *inter alia* that the authority had erred in adopting a "blanket policy" and that their rights under Article 3 and Article 8 of the Convention were engaged. The Court of Appeal upheld the High Court decision quashing the local authority decision and requiring the matter to be considered afresh. Auld LJ considered the authorities cited above and found that:

"However, in establishing priorities – comparing the respective needs of patients suffering from different illnesses and determining the respective strengths of their claims to treatment – it is vital for an authority: (1) accurately to assess the nature and seriousness of each type of illness; (2) to determine the effectiveness of various forms of treatment for it; and (3) to give proper effect to that assessment and that determination in the formulation and individual application of its policy."

8. Interestingly, the argument adopted by the Respondent in *ex parte A* was that the refusal to provide gender reassignment surgery would be waived in exceptional circumstances. Auld LJ commented on this approach stating:

"That basic error, one of failure properly to evaluate such a condition as an illness suitable and appropriate for treatment, is not mitigated by the allowance in both policies for the possibility of an exception in the case of overriding clinical need or other exceptional circumstances. As I have said, such a provision is not objectionable, but it is important that the starting point against which the exceptional circumstances have to be rated is properly evaluated and that each case is considered on its individual merits."

9. The Court made the decision on the "blanket policy" point and did not directly decide upon the Article 3 and Article 8 arguments which had been advanced on behalf of the Applicants. Auld LJ did state that Article 8 was not designed for circumstances of this sort "where the challenge is as to a health authority's allocation of finite funds between competing demands." He also stated that Article 8 imposed no positive obligation to provide treatment. The import of these comments is tempered by the fact that they are *obiter* and the Human Rights Act 1998 had not commenced at the date of the Court of Appeal decision.

#### **Litigating Access to Treatment – post-HRA.**

10. With the commencement of the Human Rights Act in October 2000 the prospect of deploying new arguments in challenges to access to treatment decisions emerged. The most likely vehicle for such challenges remained an application

for judicial review pursuant to Order 53 of the Rules of the Supreme Court (NI). The elementary change was the ability to bring a challenge to public law decision-making without the constraints of the narrow *Wednesbury* irrationality test. In simple terms an Applicant can plead illegality in such an application. The contention is that the relevant public authority has acted unlawfully by breaching section 6(1) of the Human Rights Act 1998. The particulars of the breach can then be developed by citing the pertinent provisions of the Convention. In essence the Applicant is contending that the public authority has either failed to have regard to their Convention rights in deciding to refuse the particular treatment or has failed to strike the appropriate balance in weighing the impact upon the particular Convention right. This is of particular practical significance given the peculiarities of public law challenges under the Order 53 regime.

11. In order to obtain leave to apply for judicial review the Applicant must demonstrate an arguable case pursuant to Order 53. Where, for example, it is contended that a decision to refuse to fund treatment for a patient with a life-limiting condition is unlawful, it is a relatively straightforward matter to present an application which alleges that the public authority has failed to give due weight to the Applicant's rights pursuant to Article 2 and 3 of the Convention. While the merits of this contention will ultimately be the subject of forensic scrutiny it cannot readily be dismissed as patently unarguable. Leave is therefore often granted in such cases. The practical consequence is that cases raising Convention issues with regard to access to treatment are frequently compromised at or before the leave stage. This explains the paucity of written authority in the jurisdiction which might suggest, inaccurately, that the issue of Convention rights and access to treatment has not been litigated. It also opens up the opportunity for pragmatic compromise in individual cases.
12. Post-incorporation arguments based on Articles 2, 3 and 8 have received considered analysis in healthcare litigation in England and Wales. In *Burke v General Medical Council* [2005] 2 WLR the applicant challenged GMC guidance on the administration of artificial nutrition and hydration to terminally ill patients. In a complex and detailed judgment Munby J considered the applicability of Article 2, 3 and 8 to the argument. At paragraph 213 (1) he held that:

“A failure to provide life-prolonging treatment in circumstances exposing the patient to ‘inhuman or degrading treatment’ will in principle involve a breach of Article 3. Where the National Health Service has assumed responsibility for treating a terminally ill patient’s condition and he has become reliant on the medical care he is receiving, there will prima facie be a breach of article 3 if that care is removed in circumstances where this will subject him to acute mental and physical suffering and lead to him dying in avoidable distressing circumstances. Moreover, even if the patient’s suffering does not reach the severity required to breach Article 3 a withdrawal of treatment in such circumstances may none the less breach article 8 if there are sufficiently adverse effects on his physical and moral integrity or mental stability.”
13. The Court held that the competent patient had a right under Article 8 to require medical treatment in order to protect him from acute mental and physical suffering. In appropriate cases where the suffering in question met the

“severity” standard then Article 3 rights would also support the argument requiring treatment.

**Access to High Cost Treatment for Life Limiting Conditions: *Herceptin*.**

14. In late 2005 high profile litigation commenced in England in relation to the refusal of various health authorities to prescribe the drug *Herceptin* to early stage breast cancer patients. In Northern Ireland, the Commission was approached to consider providing legal advice and assistance to patients in Northern Ireland who would benefit from this treatment but who had been refused access to it. Many of the features of the *Herceptin* cases are repeated in other disputes about access to high cost treatments for life limiting conditions. These scenarios engage concerns about possible breaches of Article 2 and 3. I rehearse the history of these cases in anonymised form in order to identify certain key features of access to treatment cases.
15. *Herceptin* is the trade name for a medicinal product manufactured by Roche Pharmaceuticals which is described in the medical literature by the generic name *Trastuzumab*. The National Institute for Clinical Excellence (NICE) published guidance in relation to the use of this treatment for advanced breast cancer patients in 2002. NICE guidance recommended the use of this treatment *within* the terms of its license for the treatment of patients with metastatic breast cancer at Level 3 +. In effect, given that patients with HER2-type tumours have a particularly aggressive form of the disease, this meant that the treatment was only recommended for people who were already gravely, or in many cases terminally, ill. The clinical literature in 2002 did not indicate that *Trastuzumab* should be used for the treatment of early-stage HER2-type tumours. That position changed. On 20<sup>th</sup> July 2005 NICE issued a press release indicating that the Department of Health had requested guidelines on the use of this treatment for early stage breast cancer patients. The brief for NICE was to prepare a technology appraisal on the clinical efficacy and cost effectiveness of this treatment for early stage breast cancer.
16. Meanwhile scientific articles were published in the *New England Journal of Medicine* in October 2005 which indicated that *Herceptin* reduced the risk of recurrence of breast cancer by up to 50%. There were certain subtle nuances within this research. Most notably the treatment was not effective for all breast cancers but demonstrated heightened efficacy for a sub-type of tumour (HER2) which affected 15 to 20 percent of breast cancer patients.
17. Significantly, Roche Pharmaceuticals did not have a licence for the use of this treatment in early stage breast cancer patients in the United Kingdom. It is not uncommon in clinical practice for unlicensed drugs to be used in the treatment of patients. In the United Kingdom the MHRA issue a product licence for a particular drug or treatment. This product licence acts as a guarantee of the quality, efficacy and safety of medicines and the holder of that licence is responsible for these aspects and liable for any adverse effects resulting from the use of the product. However, the MHRA does not regulate the practice of medicine and a registered medical practitioner can prescribe an approved drug for any purpose deemed appropriate.

18. Unlicensed or “off-licence” drug prescribing is not uncommon. It occurs regularly in paediatric medicine where efficacious drugs are licensed for adults but are known to work well without adverse side-effects in children. The licensing process is “elective” in that the pharmaceutical companies must actively apply for a licence. There are significant costs involved (and potential liabilities incurred) in the licensing process and a pharmaceutical company may decide not to seek a licence for a particular usage. Indeed, if Roche were minded not to seek a product licence for *Trastuzumab* then there would be no mechanism to compel such a private corporation to do so. On the other hand the fact that a drug is not licensed is no bar to prescribing. The practical effect of the absence of a product licence is that the prescribing medical practitioner carries the risk of any liability arising from adverse side effects. Typically, the doctor prescribing off-licence will take care to ensure that properly informed consent is obtained from a patient and that a careful record is kept of all advices provided with regard to potential adverse effects. The doctor prescribing “off-licence” does not have the protection of the manufacturer’s product liability indemnities.
19. There was no product licence for the use of *Trastuzumab* in Northern Ireland either. However, if a clinician is given financial authorisation by the Trust he or she can prescribe the treatment for an early stage breast cancer patient regardless of the lack of MHRA licence or NICE guidance. The risk is borne by the prescriber (and the Trust) if an adverse outcome occurs. In short, if the funds are available the treatment can be prescribed. Similarly, if a patient with private resources wishes to receive treatment with *Trastuzumab* and can meet the substantial cost of same then, subject only to appropriate clinical indications, a consultant can prescribe the treatment. In other words, if resources can be found, the licensing problem can be circumvented for this treatment in the same manner in which it is routinely circumvented for others. The legal position was accurately reflected by the Under Secretary of State for Health in the June 2005 debate in the House of Commons. He stated:
- “It is possible for a doctor to prescribe Herceptin for other patients, subject to two conditions. First, as he pointed out, the PCT or NHS Trust must agree to supply it at NHS expense. Secondly, the doctor must retain clinical responsibility for the patient while prescribing the drug in question. Prescribing unlicensed drugs is the exception rather than the rule for the very good reason that the licensing process is designed to ensure that widespread use of a drug for particular conditions does not cause side effects that are so serious that they outweigh the benefits for which the drug was prescribed.”
20. The Commission was approached by two HER-2 type breast cancer patients who had been refused access to Herceptin. Both women required the drug during a period prior to NICE guidance or MHRA approval issuing. They were told that they would get the drug free at the point of delivery if their disease progressed to the advanced stage. However, at that point the utility of the treatment would be of an entirely different character as it would be used to manage a terminal disease. In summary, the clinical arguments indicated that the treatment should be provided immediately while the regulatory framework and the stance of Trusts was likely to prevent them from obtaining the drug until it was, in the starkest terms, too late.

21. These cases raised the possibility of a public law challenge involving Article 2, Article 3 and Article 8 rights. There was the further possibility of a challenge on convention public law grounds to the rationality of the decision. In light of the recent line of jurisprudence in the Northern Ireland Court of Appeal in *AR v Homefirst* [2005] NICA 5 and *Re Misbehavin'* [2005] NICA 35 there appeared to be particular strength in the Article 8 argument. The factual matrix of these cases supported an Article 8 argument given that the public authorities appeared to have given little or no weight to the fact that these women were the mothers of young families. The Northern Ireland Court of Appeal has castigated public authorities who fail to have due regard to the existence of Article 8 rights. As Kerr LCJ stated in *AR*:

“Where a decision maker has failed to recognise that the convention rights of those affected by the decision taken are engaged, it will be difficult to establish that there has not been an infringement of those rights.”

This *dicta* is of particular utility in cases where public authorities appear to have had no particular regard to the broader ramifications of a refusal to provide medical treatment. In the event it became unnecessary to issue proceedings in these particular cases because the Minister intervened and indicated that Herceptin could be prescribed for appropriate cases in Northern Ireland.

#### **Access to High Cost Treatment for Chronic Conditions: *Anti-TNF $\alpha$* and $\beta$ -interferon**

22. The question of funding for anti-TNF alpha treatment for rheumatoid arthritis, psoriatic and Crohn's disease patients in Northern Ireland raises a number of interesting public law issues. The treatment in question has been hailed as a significant medical breakthrough. However, the treatment has also generated controversy because of the significant cost attached. The two most commonly prescribed treatments have an average cost of £9000 per annum.

23. There is a clear disparity between provision of anti-TNF alpha therapy in Northern Ireland as opposed to the provision in England and Wales. The National Institute for Clinical Excellence (NICE) has published specific guidance on the use of this particular therapy for rheumatoid arthritis patients. The NICE Guidance states:

“1.1 Etanercept and Infliximab are recommended as options for the treatment of adults who have continuing clinically active rheumatoid arthritis that has not responded adequately to at least two disease-modifying anti-rheumatic drugs.

1.2. Both etanercept and infliximab **should be prescribed** in accordance with relevant sections of the British Society of Rheumatology Guidelines, April 2001 (see Appendix D) which set out criteria for eligibility, definitions of failure of standard therapy, exclusion criteria and criteria for the withdrawal of therapy.”

24. NICE guidance is legally binding on Trusts in England and Wales. In other words once a patient meets the eligibility criteria (which is solely a clinical decision) they should be prescribed the medication. That said, notwithstanding the NICE guidance, problems have arisen in England and Wales with Trusts not providing resources for the treatment. This was the subject of a recent report by the National Audit Commission in September 2005. The report entitled “The Financial Implications of Implementing NICE guidance” found that:

“85% of respondents identified that the funds available to implement technology appraisals were insufficient, particularly in relation to high-cost appraisals such as

Drotrecogin for sepsis (Appraisal Number 84) and etanercept and infliximab for rheumatoid arthritis. (Appraisal Number 36).”

The Report went on to comment that, whilst lack of funding was often perceived to be a factor in the failure to make provision for high-cost therapies:

“We found that a number of NHS bodies failed to assess the costs of implementing the guidance, and so were not in a position to make a judgment about whether they had sufficient funds to implement them.”

This factor is particularly significant in that it opens scope for a public law challenge. Public authorities must examine all relevant considerations and discount all irrelevant considerations when making a decision about funding provision. If, for example, the Boards in Northern Ireland have come to a view about funding provision for anti-TNF alpha treatment without having first conducted a cost appraisal (including an analysis of the costs involved in not funding the treatment), then the decision in question would be open to challenge on grounds of irrationality.

25. Multiple sclerosis (MS) patients face similar difficulties with regard to the provision of beta interferon. This medication is clinically proven to have a retarding effect on the development of MS. It is a high cost treatment. The Northern Health Board, for example, funds only ten patients per year with this treatment. The annual cost of beta interferon treatment has been estimated by NICE to be in the region of £10,000 to £12,000 per annum. In January 2002 NICE issued guidance on the use of beta interferon and glatiramer acetate for the treatment of multiple sclerosis. The guidance stated that, on the basis of clinical and cost effectiveness, beta interferon treatment was not recommended for patients under NHS provision in England and Wales. The guidance also stated that patients who were already being treated with beta interferon should continue to be so treated. The NICE guidance was due to be reviewed in January 2004. However, that review has now been rescheduled for November 2006. The position with regard to NICE guidance is, therefore, somewhat different in relation to the beta interferon as opposed to anti-TNF alpha treatment.

26. Refusal of treatment to patients with chronic conditions raises questions of potential breach of Article 3 and 8 of the Convention. Girvan J (as he then was) examined the issue of Article 3 breaches in his decision in *Martin v Northern Ireland Prison Service* [2006] NIQB. This was a writ action seeking damages for breach of Convention rights as a consequence of the “slopping out” policy applied at HMP Magilligan. Girvan J considered arguments alleging a breach of Article 3, 8 and 14 in the course of his judgment. In relation to the Article 3 point he held that:

“As I pointed out in paragraph 13 of Re Karen Carson in considering whether a person had been subjected to inhuman or degrading treatment one must consider the totality of the circumstances. A particular act on its own may constitute treatment but the concept of treatment generally points to a course of conduct. In considering whether the sanitary arrangements had given rise to degrading treatment the arrangements must be looked at in the overall context of the surrounding prison arrangements.”

The “totality” of the circumstances must be considered in cases of refusal of treatment for chronic conditions. In the case of the arthritis patient a relevant factor in such an analysis must be the clinical fact that the medicine is at its most effective in the relatively early stages of the disease. Patients are placed on a lengthy waiting list which, in itself, ensures that by the time they get the drug

more damage will have been done to their joints and the efficacy of the treatment will be reduced. It could reasonably be contended that, it is not just the denial of the drug which constitutes a breach of Article 3, but the totality of the arrangements for rationing the drug including, in particular, the waiting list system. While on one view waiting lists are a *prima facie* fair means of allocating scarce resources, it is also a method which does not involve consideration of individual circumstances. Similarly, the arrangements made for the provision of beta interferon for the MS patients should be examined in their entirety. It would appear that the Department of Health has given an unequivocal commitment to patients who meet the eligibility criteria that they will be provided with the drug through the NHS although this was not being honoured with respect to appropriate patients in Northern Ireland.

27. Both the anti-TNF alpha and beta interferon cases raise a potential Article 14 point. In simple terms rheumatoid arthritis patients in England and Wales are prescribed anti-TNF alpha treatment pursuant to the NICE guidelines. Relapsing-remitting MS patients in England, Scotland and Wales are prescribed beta interferon if they meet the eligibility criteria set out in the HSC Circular 2002/004. In Northern Ireland rheumatoid arthritis patients are only being prescribed anti-TNF alpha after a protracted wait on the “waiting list”. MS patients should be being prescribed beta interferon if they meet the criteria but the suggestion is that most are not. Differential treatment between provision in Northern Ireland and elsewhere in the United Kingdom does not necessarily ground a challenge pursuant to Article 14 of the Convention. A considerable number of judicial review applications have been brought alleging a breach of Article 14 where individuals are treated differently in Northern Ireland than they would be if they were resident in England and Wales. These challenges have tended to fail on the basis that Northern Ireland is a discrete jurisdiction and legislative differences are construed to be the intention of Parliament.

23. The test to be applied in an Article 14 challenge is the *Michalak* test. This was recently endorsed by the Court of Appeal in *Re Sinn Fein’s Application* [2004] NICA 4. Carswell LCJ (as he then was) stated:

“[17] It is necessary in order to establish discrimination in any field to identify comparators, that is to say, the persons or bodies by comparison with whom the complainant claims to have been treated less favourably: cf, for example, the sex discrimination and fair employment legislation. In *Wandsworth London Borough Council v Michalak* [2002] 4 All ER 1136 at paragraph 20 of his judgment Brooke LJ set out a method of approaching the issue:

“[20] It appears to me that it will usually be convenient for a court, when invited to consider an art 14 issue, to approach its task in a structured way. For this purpose I adopt the structure suggested by Stephen Grosz, Jack Beatson QC and the late Peter Duffy QC in their book *Human Rights: The 1998 Act and the European Convention* (2000). If a court follows this model it should ask itself the four questions I set out below. If the answer to any of the four questions is No, then the claim is likely to fail, and it is in general unnecessary to proceed to the next question. These questions are: (i) Do the facts fall within the ambit of one or more of the substantive convention provisions (for the relevant convention rights, see s 1(1) of the 1998 Act)? (ii) If so, was there different treatment as respects that right between the complainant on the one hand and other persons put forward for comparison (‘the chosen comparators’) on the other? (iii) Were the chosen comparators in an analogous situation to the complainant’s situation? (iv) If so, did the difference in treatment have an objective and reasonable justification: in other

words, did it pursue a legitimate aim and did the differential treatment bear a reasonable relationship of proportionality to the aim sought to be achieved? The third test addresses the question whether the chosen comparators were in a sufficiently analogous situation to the complainant's situation for the different treatment to be relevant to the question whether the complainant's enjoyment of his convention right has been free from art 14 discrimination."

We respectfully agree with and adopt Brooke LJ's four questions, pointing out only that it is only in respect of the first three questions that the answer No will cause the claim to fail; if the court proceeds to question (iv) it is the answer Yes which will be fatal to the claim. Brooke LJ also emphasised that the questions formed only a framework and that there was a potential overlap between them, so that there may be a need for caution in treating the four questions as a series of hurdles to be surmounted in turn. In particular, as Mance LJ observed in *Nasser v United Bank of Kuwait* [2002] 1 All ER 401 at paragraph 56 of his judgment, the two issues represented by Brooke LJ's questions (iii) and (iv) tend to merge into each other."

24. It is possible that there may be a strong Article 14 case in certain cases involving refusal of access to treatment for chronic conditions. For example, multiple sclerosis patients could contend that their rights pursuant to Articles 3 and 8 of the Convention are engaged and that the Department of Health should provide them with analogous services to those provided in England and Wales and cannot justify their actions by reference to jurisdictional differences because, pursuant to HSC 2002/004, they have expressly agreed to the terms of the Scheme for provision of beta interferon. The position with regard to the rheumatoid arthritis patients is slightly less clear cut. It is apparent that there is differential treatment compared to rheumatoid arthritis patients in England and Wales. However, the Boards have argued that NICE guidance creates a legal imperative for the provision of treatment in England and Wales which, because NICE is not binding in Northern Ireland, is not applicable in this jurisdiction.

#### **NICE Guidance in Northern Ireland. *Pegvisomat***

25. Prior to 30<sup>th</sup> June 2006 an anomaly persisted whereby clinicians in Northern Ireland practised evidence-based medicine in line with NICE guidance but patients could not rely upon NICE recommendations in seeking access to recommended treatments. That position altered, at least in part, with the publication of a Circular by the Department of Health on 30<sup>th</sup> June 2006. This provided that:

"Under the new arrangements, health technology appraisal guidance *endorsed by the Department of Health as applicable for Northern Ireland* will be treated as essential within the recently published Quality Standards for Health and Social Care.... HSS Boards are now required to take account of *locally endorsed* NICE guidance and any associated departmental commentary in their planning, funding and provision of services to ensure that recommended medicines, medical devices, diagnostic techniques or surgical procedures are made available to meet clinical need." [my italics]

The Circular further provided that "Departmentally endorsed" NICE technology appraisal guidance will be implemented within 12 to 24 months of its dissemination. The Department has taken care to retain for itself a residual discretion about the applicability of NICE guidance. The rationale for this approach is not readily apparent. However, this residual discretion has exposed further anomalies in a recent case assisted by the Commission.

26. The applicant wished to bring a legal challenge to a decision taken by the NHSSB not to approve funding for a drug treatment for a tumour in the pituitary

gland. He had developed a pituitary tumour which leads to an excess of growth hormone in the bloodstream. He was been treated with a drug called Sanostatin which has had limited efficacy. He had a surgical excision of the tumour but it has returned. His clinical condition was described as Acromegaly. This is a rare chronic condition which arises when the body produces too much growth hormone. This excess of hormone causes a resulting increase in the production of insulin-like growth factor (IGF-I). Acromegaly typically causes symptoms such as a marked overgrowth of the face, hands and feet. It is a debilitating disorder which is associated with a significantly decreased life expectancy with mortality being approximately doubled. The predominant cause of death in acromegaly sufferers is cardiovascular failure. If the disease is appropriately treated and controlled mortality rates return to that of the normal population.

27. A treatment with increased efficacy was available, and recommended by the consultant in charge of the case. The drug was called Pegvisomat. This treatment is licensed for use in the BNF. It is referred to in the NICE Guidelines on “Improving Outcomes for People with Brain and Other Tumours” of June 2006 as the treatment of choice for conditions of this type. As acromegaly is a relatively rare clinical condition it is not the subject of a full NICE guideline recommendation – it is endorsed in the guideline. The Applicant’s consultant wrote to the NHSSB seeking approval for funding for this drug. The Board replied by letter dated 6<sup>th</sup> October 2006 which stated that the reference to Pegvisomat in NICE does not constitute a “formal NICE technology appraisal” and cannot therefore be considered “NICE approved.” This response appeared to conceal a practice of “cherry-picking” those aspects of NICE which could be relied upon by patients and those which could not, motivated at least in part, by a concern about the resource implications. Such an approach could be facilitated by the residual discretion retained by the Department of Health to “endorse” NICE guidance.
28. Moreover, the requirement for full NICE approval has an adverse effect on patients suffering from rare diseases which can be effectively treated with “orphan drugs”. Acromegaly is itself, a very rare condition. A small proportion of those Acromegaly patients who will not respond to surgery or somatostatin will require treatment with the “orphan drug” Pegvisomant. Given the extremely small number of patients involved, randomised drug trials would be very difficult to perform and so a full technology appraisal by NICE will probably never be performed. In requiring such an appraisal as a prerequisite to approval for funding the Board appeared to be creating an insurmountable hurdle to the provision of this treatment.
29. Judicial review proceedings were drafted contending that *inter alia* the refusal to approve funding for treatment with Pegvisomant was discriminatory and contrary to Article 14 of the European Convention on Human Rights when read in conjunction with Articles 2 and 3 of said Convention. A letter before action issued. Before the matter could be lodged with the High Court the Northern Board reversed their decision. This case identified the difficulties which are likely to continue to emerge in access to treatment cases while the primary funding body retains the final say on the applicability of NICE guidance – a power which is not vested in the Department of Health in England and Wales.

**Conclusion.**

30. This paper has highlighted Convention and public law issues with regard to obtaining access to high cost treatments for life-limiting and chronic conditions. This is, of course, only a partial picture. A similar analysis could be conducted with regard to refusal of access to the entire range of health and social services on grounds of cost. The availability of Convention arguments has led to greater scope for challenge and has increased the likelihood of judicial consideration of arguments which so frequently failed in the past. However, one should not lose sight of the fact that legal challenges to access to treatment decisions themselves incur costs and, if successful, result in a redistribution of available resources rather than any increase in the total resource available for healthcare. Strategic challenges to Departmental policies which fail to have regard to Convention rights or public law principles, rather than to individual clinical decisions, may bring greater long term benefits.

**Tony McGleenan**  
**16<sup>th</sup> April 2007**