

Memo

To: NICE appeal panel  
From: [REDACTED]  
Office/Location: London - Fetter Lane  
Extension:  
Date: 14 May 2010  
Matter:

1. The purpose of this note is to record the legal advice to be given to NICE's appeal panel on the application of the Human Rights Act to this appeal.
2. It is alleged that the guidance prepared breaches the following Articles of the ECHR:
  - a. Article 2, the right to life
  - b. Article 3, the prohibition of torture, or inhuman or degrading treatment
  - c. Article 8, the right to respect for private and family life
  - d. Article 14, the prohibition on discrimination in the enjoyment of a convention right.

#### Summary of advice

3. For the reasons given below the advice is that there is no breach of Articles 2,3 or 14. Under Article 8, the Panel must decide if the guidance is "necessary" for one or more permitted purposes set out below. If it is, there is no breach. If it is not, the appeal should be allowed.

#### Article 2

4. As to Article 2, universally referred to as the right to life, this is something of a misnomer. There can be no right to life as such, not least because, however much care is taken and whatever level of medical and other resource may be given, eventually every life comes to an end. The right is instead a right to have life protected by law. Art 2 is substantially a negative right: outlawing the taking of life. However it does impose certain positive obligations, notably the obligation to investigate death and to take action to discourage the taking of life.
5. The cases on Art 2 do not support an argument that it requires the provision of any particular level of state funded healthcare, other than, perhaps, at a fairly basic level. Probably the

strongest case for the appellants is *Scialacqua* , which hypothesised an obligation to fund “treatments that are essential to save lives” but without deciding that such an obligation existed.

6. The advice to the panel is that Art 2 may arguably require the state to make available an overall health service in some form, achieving at least a minimal level of healthcare benefit<sup>1</sup>, and (read with art 14) may well require non-discriminatory access to whatever facilities which the state has decided to provide (see *NHS Trust A v M, Nitecki*.) The UK government by way of the NHS does provide such a health service. The overall scope of the NHS would amply satisfy any obligation there might be under Art 2 to provide minimal healthcare. (See below for a consideration of the art 14 point). But the author is not aware of any authority which suggests that global decisions on allocation of resources within a health service would fall within the ambit of Art 2, and would find such a position surprising. We noted above that even the most generous provision of healthcare imaginable would at best delay the end of life. In this case it is common ground that the effect of the drug is to delay death from the illness treated, rather than to cure the illness outright. Of course, the delay must be greatly valued, but sadly the issue is not death or cure, but rate of progression towards death. This suggests Art 2 cannot be of assistance. The Institute’s role may be analogous to the position in *Scialacqua* where the court ruled that Art 2 “cannot be interpreted as requiring states to provide financial covering for medicines which are not listed as officially recognised medicines.” Here the issue is not official recognition, but a judgement on acceptable cost effectiveness, but the principle must be the same. It may well be true that once a decision has been taken to make a life saving treatment available in certain circumstances, Art 2 may apply to any individual failure to provide it in those circumstances. But Art 2 does not seem to apply to the decision as to whether the treatment should be available in the first place. Therefore the advice is that the article is not engaged or breached in this case.

### Article 3

7. As Art 3 outlaws inhuman or degrading treatment, the objection that these drugs are not life saving (and indeed that the end of life is inevitable at some point) falls away. However the same essential problem with the form of the right remains. Art 3 states that “no one shall be subjected to...inhumane or degrading treatment or punishment” and is principally concerned to outlaw the deliberate infliction of suffering. (Again, there is also a positive obligation, not merely not to inflict suffering, but also to take steps to avoid a person being subjected to ill treatment. But the issue is still avoidance of the positive infliction of ill treatment.)

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<sup>1</sup> A number of cases doubt even this minimal protection, but against a backdrop where all contracting states do in fact provide some form of healthcare system the court has never had to turn its mind to the question in anger, and not too much should be read into passing remarks

8. Although it is the case that these patients suffer severely, the suffering is caused by their illness, not the state. The complaint is rather that the state could reduce that suffering but chooses not to. That goes beyond the case law. In the *Pretty* case, Ms Pretty's illness caused her severe suffering, but the court concluded there was no positive obligation to take steps to reduce that suffering (in her case, by facilitating an assisted suicide, but the argument would also seem to apply to provision of treatment).
9. For similar reasons to Art 2, Art 3 may require the provision of at least a minimal form of publicly funded healthcare. And the cases would support the argument that if a drug was generally available (ie, it had been decided to fund it), then deliberate withholding would breach article 3. If, say, a doctor has a painkilling treatment funded and available which would be clinically suitable for a patient, but does not provide it, and instead leaves the patient to suffer, Art 3 could well be breached. But this begs the question of whether the drug is to be generally available, which is the very decision to be made by NICE. (Strictly, it is whether the drug is to be more or less generally available, since NICE neither licenses nor bans drugs). It would be surprising if a decision of a health service to focus its resources on securing more cost effective treatment for its population engaged Art 3 rights for those who hoped to enjoy the less cost effective treatment which could not be provided as a result. In fact, the Art 3 argument seems to point to the opposite conclusion. It might be argued that Art 3 could require some sort of process akin to NICE technology appraisals, as the overall intended purpose is to maximise the health benefit from a given budget. If less cost effective treatments took the place of more cost effective treatments, that would result in the state failing to reduce inhuman and degrading treatment to the fullest extent possible, which, it could be argued, would be a breach of Art 3.
10. The advice is that there appears to be no authority that would suggest that Art 3 is engaged and/or breached in the way argued for by the appellant.

#### Article 8

11. It is necessary to set out Art 8 in full:

*8(1) Everyone has the right to respect for his private and family life, his home and his correspondence.*

*8(2) There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others*

12. Article 8 requires respect for private and family life. Although it may not seem obvious, aspects of medical treatment may indeed be within Art 8.
13. *Passannante* was a case in which it was held that delay in providing medical treatment may engage Art 8, although on the facts there was no breach. (The argument assumed that the treatment was in principle generally available and indeed that there was “an obligation” to provide it. It was therefore dealing with a decision rather "downstream" of the sort of decision under attack here. It is not clear that within the UK health service, which is funded from general taxation and not individual subscription, there can be said to be an equivalent "obligation" to provide treatment at all.)
14. In *Pentiacova* the court assumed Art 8 covered medical treatments for the purposes of an admissibility hearing, but it seems from that case Art 8 is only likely to be breached where the allegation is denial of access to a standard of treatment made generally available. It is not likely that Art 8 is engaged where the issue is a general judgement on acceptable cost effectiveness (In ruling the complaint manifestly ill founded and inadmissible, the Court commented that "the applicants had access to the standard of healthcare offered to the general public...") It is also notable that in *Pentiacova* the court referred to complaints about “insufficient funding of [the applicants] treatment” which suggests that the issue was affordability, rather than cost effectiveness. Affordability is outside the Institute’s remit. It also commented that it was necessary to strike a balance between the needs of individual patients and the community at large, and that, due to lack of resources, there would be many individuals who could not have access to "a full range of medical treatment, including life saving medical procedures and drugs". Even so (or perhaps, as a result,) the complaint failed.
15. *Tysiac* is a case concerning the denial of access to abortion. Clearly the facts of that case are rather different to this appraisal, but consistently with the advice being given in this paper the court affirmed that “the convention does not guarantee as such a right to any specific level of medical care.”
16. Finally there is *Sentges*, a case in which it was held that Art 8 was only engaged where there was a "direct and immediate" link between the measure sought (in that case the provision of a robotic arm to assist a severely disabled person) and the applicant's private life. In that case the court held there was no such link. On its face, the provision of the robotic arm would seem to have a very direct impact on the applicant's enjoyment of private life, in that it would certainly have enabled him to carry out a wider range of day to day tasks for himself, and so enjoy more autonomy and self determination, which are concepts that sit within Art 8. And yet

the court held Art 8 was not engaged. Once again the court observed that the facilities offered to the applicant met the standard of health care generally made available, which appears to be the essential issue protected by the ECHR as the cases stand today.

17. It isn't straightforward to rationalise all these cases into one coherent position. Notwithstanding the generally negative thrust of the cases above, the arguments under Art 8 for this particular treatment are more balanced here than under Art 2 and 3. The same general objection does apply as applied under Arts 2 and 3 (that the state is not interfering with private and family life, rather it is failing to provide a treatment to reduce the effect of an illness of private and family life). However the ECJ has left open the possibility of a complaint under Art 8 (although it seems not to have found any such complaint well founded) despite the apparent difficulty of drawing a logical distinction between Arts 2, 3 and 8 in this regard<sup>2</sup>. Possibly the rationalisation is that under all of Arts 2,3 and 8 there is indeed an obligation to provide some basic standard of care, (which goes beyond the cases on Art 2 and 3 but is consistent with the cases on Art 8) and also an obligation to provide equal and effective access to whatever standard of care is in fact settled upon, but that this is the limit of the convention rights in this sphere.
18. This treatment does extend life, and a patient would therefore enjoy longer family life if treated. Although on its facts *Sentges* sets the test of engagement of Art 8 very high, an additional 9.5 months of life is a very considerable benefit. The legal question of whether Art 8 is engaged is a difficult one, and the panel is not intended to address such finely balanced legal issues definitively. The author's advice would be that, having regard to the substantial duration of additional life gained, for the purpose of the appeal only and without binding the Institute for the future the better approach is for the panel to assume Art 8 should be taken to apply, and therefore that a failure to provide this treatment could amount to an infringement of Art 8(1).
19. It is therefore necessary for the panel to consider whether the infringement is lawful under Art 8(2), in other words is it (irrelevant material deleted) "*in accordance with the law and ... necessary in a democratic society in the interests of ... the economic well-being of the country, ... for the protection of health ..., or for the protection of the rights and freedoms of others* "
20. The interference will be in accordance with law in as much as NICE is lawfully set up and operating within a properly defined legal framework. The purpose of the interference would

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<sup>2</sup> There is the very practical distinction that Art 8 is a qualified right, whereas Arts 2 and 3 are absolute, which may well be the true reason a slightly more expansive approach is taken under Art 8, even if it does not really stand up to scrutiny

seem to be arguably for the economic well being of the country (in as much as general cost effectiveness in public spending achieves that goal), and arguably for the protection of health and the protection of the rights of others, again, in as much as maximising health gain from the NHS budget protects the health of the population generally, and tends to protect the population's rights in that regard. (The point is essentially the same as the point made above under Art 3: that inefficient use of NHS resources could be argued to infringe the rights of those who would have benefited had more efficient use been made.) Furthermore the ECJ has repeatedly referred to the need to strike a "fair balance" between the needs of an individual and the needs of the community at large (see eg *Pentiacova*), indicating that one or more of these permitted objectives was in play. Therefore the advice is that one or more of these permitted purposes applies.

21. That leaves the remaining question of whether this particular measure is "necessary", bearing in mind both that this is a higher test than "desirable" and that equally, there is a "margin of appreciation" allowed under the ECHR, particularly on questions of resource allocation by public bodies. The general reluctance of the ECJ to scrutinise the issue of the resourcing of healthcare provision too critically should be borne in mind.
22. The issue of necessity in this specific case is a question of fact, and so for the panel to decide. There may be a spectrum, from a highly cost ineffective use of resources likely to divert material sums of money from other treatments, where the panel may feel it is more likely to be necessary for use to be constrained, down to a marginally cost ineffective use unlikely to have any significant effect on budgets, where the panel may feel it is harder to establish necessity. You should be guided but not bound by NICE's usual thresholds for cost effectiveness, in as much as it would be difficult to argue that it is necessary to manage the availability of a drug below the usual thresholds, but it does not necessarily follow without more that it is necessary to manage its availability simply because it is above the threshold. You need instead to look at necessity in the round, with the fact that the drug is above the usual threshold (and the degree by which it exceeds the threshold) being one factor to weigh in the balance.
23. It is also legitimate for the panel to bear in mind the danger of the cumulative impact of many such arguments (ie, that this spending is surely too little to matter, and that this other spending is also de minimis, and so on, with no account being taken that when added together all of the "small" sums may come to a material sum.)
24. Finally the panel should itself decide on necessity de novo, rather than reviewing the committee's implied finding of necessity only on perversity grounds.
25. Therefore the advice is that the panel must decide if the restrictions contained in this guidance are "necessary", and should allow the appeal if it feels it is not.

26. Even if none of the substantive rights discussed above are breached by this guidance, Art 14 may nevertheless be in play so long as the guidance is within the "ambit" of any of the substantive rights. In light of the effects of the treatment the guidance does seem to be within the ambit of Art 8, at the least, and so the prohibition on discrimination comes into play.
27. However the advice is that the discrimination argument should fail on its facts. The argument is that "the vast majority of patients with higher risk MDS are over 70 years of age", that they are being denied treatment, and that this amounts to discrimination on the grounds of age. But unfortunately the argument compares two groups who are not properly comparable, ie, those with and those without higher risk MDS. It will often be the case that a disease has a distinctive age profile (or gender profile, or is otherwise more common in one part of the population than another), but something more is required to establish a discrimination argument. The protected right must be the right to access treatment for a specific condition, and so any comparison must be between two groups both of whom have the condition. It is not possible to compare a group with the condition with a group without, because then the reason for any difference in treatment must be the fundamental difference in the circumstances of the two groups, rather than any unlawful discrimination.
28. Alternatively, if it was argued that the right is a right to a "fair share" of healthcare provision, so that one could, perhaps, introduce comparators with different conditions, then the argument would seem to fail in that NICE's process is designed to achieve just such a fair distribution, by, all other things being equal, achieving broadly equal access to all treatments at or below a common level of cost effectiveness. Arguably the breach of Art 14 then comes not in denying access to a less cost effective drug, but in granting such access with the knock on effect that in some other part of the NHS more cost effective treatment for some other patient cannot be funded.
29. On either view the advice is that Art 14 is engaged, but is not breached.

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