Skipton Fund

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Professor Mark Mildred
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Dear Professor Mildred

Let me begin this letter by thanking you and your colleagues on the Appeal Panel, on behalf of my fellow Directors, for the huge amount of work that you have all undertaken for the Fund. I regret that the Panel was not established until a considerable pile of appeals had accumulated, which meant not only that you were faced with a daunting backlog but also that the scope for us, as lay assessors of the applications, to learn from your decisions was limited by virtue of the diminution in the flow of applications by the time you had processed the pile. I hope that we have not overly tried your patience.

The main reason for this letter is to ask whether the Panel might consider what we have always regarded as a defect in the *ex gratia* payments scheme and, if you agree with that view, make representations to the Department of Health. Bound as we are by the Agency Agreement between the Fund and the Department, we are no longer able to seek to have this aspect corrected.

The point concerns the exclusion from the scheme of "natural clearers", that is, those who appear to have cleared the hepatitis C virus from their bodies spontaneously during the acute phase of infection, deemed to be roughly the first 6 months. The point applies particularly to people with haemophilia, many of whom were infected in the early 1980s or even earlier, when the virus had not been correctly identified or understood. However, some of those without haemophilia are similarly affected.

Such early infection means that there can, in fact, be no unassailable evidence of infection or clearance during the acute phase because adequate testing processes were not available at that time. The wording in part 4 of clause 2a of the application form indicates what the form of evidence might be, but this could not have been used at the time in the case of these early infections.

The result has been inequity in two respects. Firstly, a number of leading hospitals with major and experienced haemophilia treatment centres have made no applications on behalf of any of their patients with haemophilia who

have cleared the virus naturally, believing that they are unable to distinguish, with any scientific accuracy, between those who cleared the virus during the acute phase and those who clearance occurred later. On the other hand, other similar institutions appear to have taken the view that any of their natural clearers were likely to have had chronic stage infection.

The issue has come into focus again now because of an imminent appeal from a young man with haemophilia who, on the criteria we have available, appears to have been a natural clearer. He had been infected very early, and had no detectable PCR levels during the 1980s. However, during the 1990s significant PCR levels were detected, but by then he was outside the time limit of the scheme.

He had a number of brothers or half-brothers, all also with haemophilia, who were similarly natural clearers. One, however, was admitted to the scheme on the basis of the results of PCR testing in the 1980s; but I think we probably gave this applicant the benefit of the doubt, because on review now the evidence cited by the doctor is weak and ambiguous. Another brother was accepted by the scheme when he needed a liver transplant, which is obviously unambiguous; this, however, shows up what we believe is the flaw in the scheme quite starkly, in that we could have excluded this man for a Stage 1 payment had he not clearly qualified for Stage 2.

We know that we have excluded about 180 applicants on the grounds of being natural clearers. What we do not know is the number who have been excluded through their clinicians' policy of not even submitting applications, but we suspect that this number is even higher.

We do, however, know that all multiple donor concentrates available before the introduction of virus inactivation were infectious for hepatitis C. Therefore, everyone who received them suffered a severe challenge to their liver function. Those lucky enough to have had the immunological defences to clear the virus "naturally" nevertheless suffered a longer or shorter period of ill health, whether or not it was monitored and documented at the time. Hence there is a strong feeling among a number of clinicians, with which we have considerable sympathy, that all those who were at some stage infected should be eligible on grounds of equity and natural justice.

Furthermore, as the appellant's case, and that of his brother, illustrate, "clearance" is not necessarily a permanent condition; so that somebody who appeared to clear the virus naturally, before there were any reliable tests for it, can subsequently be shown still to be infected but by then be outside the scheme's time limit.

If the Panel were to consider this and then to agree with us that the exclusion introduces a considerable inequity into the scheme, I am sure that a request from the Panel to the Department to amend the scheme rules would carry considerable weight. It might not be sufficient to change the officials' minds, but I believe that every attempt should be made to achieve that.

I am sorry to add this to your burdens, but it is an issue with which we have been concerned ever since the scheme opened for business; indeed, having been involved in the negotiations with the Department that started soon after the Secretary of State announced the scheme in August 2003, I can recall that our concerns began some months before we started operations. I think that at least two of those who serve on the Panel with you might have some strong feelings on this subject.

Thank you, again, for all the help you have given us, and, in advance, for your consideration of this aspect of the scheme.

Yours sincerely

Peter Stevens
Chairman