ANNEX A

HEPATITIS C – PUBLIC ENQUIRY ISSUES ETC.

LINES TO TAKE FOR DOLAN MEETING

"explain how you have arrived at a package that is at variance from that recommended by your own Expert Group"

SIZE OF AWARDS cf EXPERT GROUP

Expert Group recommended £10k for everyone who contracted the virus, an additional £40k to those who developed 'chronic Hepatitis C', and awards based on common law damages for those progressing to cirrhosis, liver cancer or other similar conditions. Implementing these recommendations was costed at being between **£62m and £89m** (the £62m figure reflects 16% of those infected progressing to cirrhosis and the £89m figure reflects 60%). These figures are based on an estimated 4000 people being infected.

The figure of **£15m** quoted by the Executive is based on 580 people coming forward in the first 3 years of the scheme and 20% of those originally infected progressing to cirrhosis. On the basis of the same statistical report that was used to inform the Expert Group figures we would predict that 1165 eligible people are still alive and therefore another 585 persons might claim at some stage in addition to the 580 group. Using the same basis for calculations this would increase the £15m figure to £30m.

Not therefore valid to compare £15m with £89m – more appropriate to compare £30m with £62m.

The underlying principle behind the ex gratia payments announced is that they should go to people who are still alive and suffering. Have to weigh the issue of making a fair and reasonable payment to these people against all the other demands on the health budget. Lord Ross and the Expert Group were asked to ensure that any recommendations be consistent with efficient health service operation and represent a fair deal for all patients – but clearly they did not have access to information on other demands on the health budget to enable them to make that sort of judgement. [NB Dolan was a member of the Expert Group]

STATISTICAL BASIS UNDERPINNING AWARDS

Philip Dolan questions the validity of our estimate of 4000 people originally infected and 1165 still alive – he believes these to be over-estimates. He has previously quoted Professor David Goldberg of SCIEH as saying that the statistics (prepared by a DoH statistician) were suspect. I have checked this out with Goldberg – he says that some of the assumptions made in developing the statistics are questionable, but he was not prepared to say whether better assumptions would yield larger or smaller numbers.

SIZE OF AWARDS cf EIRE

[Dolan has consistently refused to acknowledge that the situation in Eire is not comparable with that in Scotland]

Payments made in the Republic followed on from a judicial inquiry (the Finlay Tribunal) which concluded that the contamination of the Irish blood supply should have been avoided, and was due to wrongful practices on the part of the Irish Blood Transfusion Service Board.

Those wrongful practices started when a blood from a patient with jaundice was used to manufacture blood products, and a catalogue of poor management following on from this meant that the entire Irish blood supply was jeopardised.

The size of the awards made in the Republic has to be viewed in that context – where the Transfusion Service has been shown to be negligent. And, much as you would expect in a scheme (called the Hepatitis C <u>Compensation</u> Tribunal) that is effectively making out of court settlements, there is no fixed tariff of awards. Each case is judged on its merits – there have been large awards (e.g. £3.1m) and modest awards too (e.g. £2000)

In contrast we do <u>not</u> acknowledge here in Scotland that there was any wrongful practice or negligence on the part of the Scottish National Blood Transfusion Service.

"concerned that relatives of those who have died were not included"

ELIGIBILITY

The eligibility date for the scheme is 29th August 2003. In the case of people whose situation on that date would have entitled them to payments, but who die before payment can be made, the payments will be made to their relatives.

[realise that might appear inconsistent with our policy of not paying the dependants of people who died <u>before</u> eligibility date for the scheme but the pragmatic thing to do is just live with that inconsistency.]

PAYMENTS TO 'DECEASED'

Have great sympathy for relatives and dependants of those who died before the eligibility date for the scheme, but have to consider the effects of the financial outlay on this scheme on ability to provide treatment for other patients. For that reason our scheme focuses on those who are <u>currently</u> suffering.

If 580 people come forward in the first three years then the cost to that the Health budget is likely to be over £15m – as much as can afford to divert away from other patient care. Those payments in the first three years would almost certainly cover all the haemophiliacs still alive and also some people infected via blood transfusions.

We know that isn't the end of the story. Our estimates indicate that <u>another</u> 580 people infected via transfusion might come forward in due course [SCIEH figures still rising]. And if we were to pay out in respect of people who have died then we are potentially looking at 4000 claimants and a bill of over £100m if everyone eligible claimed [NB Expert Group costs estimated on the basis that only <u>31%</u> would claim].

"several hurdles such as liver biopsy that would be required to determine whether individual had 'chronic Hepatitis C' .... We have now demonstrated that such tests are not required"

MEDICAL TRIGGER

Although Expert Group's recommendations included awards linked to a diagnosis of 'chronic Hepatitis C' this is not a feature of our announced scheme. Making the second payment of £25k to this additional group would increase the cost of the scheme beyond what can be afforded.

However, recognise that using cirrhosis as the medical trigger is not ideal as excludes some people who are experiencing significant suffering whilst including others who are not suffering. And there could be problems with patients asking for biopsies where it would not be in their medical interests to provide them.

Will take a fresh look at that to see whether we can use a better medical trigger. This is a complex medical area and will be guided by the experts in this field. No guarantee that can agree a better trigger – and adoption of any new trigger would have to take into account any cost implications for the scheme. [Happy to involve patient groups in these discussions at an appropriate stage]

DETAILS OF SCHEME

Don't envisage any major departure from the basic awards have previously announced. The basic requirement for people to be eligible will just be that they have contracted Hepatitis C as a result of having received blood or blood products from the NHS in Scotland before they were made 'Hepatitis C safe' – and that they have not cleared it spontaneously. [No requirement for eligibility that applicants have been registered with SCIEH – it is just that our prediction of £15m outgoings in the first 3 years was linked to the published SCIEH figures at the time of January announcement]

People who satisfy the basic eligibility criteria will receive £20,000. People who have progressed to a more serious stage of the illness (still considering the best way to define that) will receive a further £25,000. There will be no payments in respect of people who die before 29 August 2003 or to those who have cleared the virus.

All other scheme details yet to be decided. Have fairly advanced initial thoughts on all of these issues, but need to develop these to a stage where can be robustly incorporated into a scheme constitution. Will do that quickly – but until have done so would be counterproductive to make them public.

[Examples of scheme details to be finalised: UK Trust; use of Macfarlane; levels of evidence required; payments to people who have had liver transplants; co-infected with HIV; infected by virus being transmitted from someone themselves infected by NHS blood; adjustments for monies received form other litigation]

Officials are exploring possible benefits of a common administration scheme across all UK administrations but will not allow this to unduly delay the making of payments.

INVOLVEMENT OF PATIENT GROUPS

Will involve patient groups in discussions on scheme administration (and medical trigger at appropriate stage). [But <u>not</u> regarding basic scheme parameters]

WHEN PAYMENTS WILL START

People who satisfy the eligibility requirements for scheme as of 29 August will qualify for payments. When they receive those payments will depend on a number of factors.

Need to finalise details of scheme and how it will be administered. Anticipate making these payments through a charitable Trust. That will need to be established, detailed rules for its operation worked out and agreed and charitable status obtained. Payments to people who currently stand to lose social security benefits may best be delayed until social security legislation can be amended.

Once all details are finalised will make a high profile announcement advertising the scheme and making it quite clear what people need to do to apply. In meantime officials are taking details of people who contact the Department and will proactively contact them at the time of the announcement.

SOCIAL SECURITY

Now the devolved power issue had been resolved hopeful that social security payments won't be a problem for our scheme. However the social security issue can't be finally agreed until the key details of the schemes here and in the rest of the UK have been finalised.

Understand that the relevant social security legislation is routinely reviewed and amended twice yearly. Our working assumption is that any amendments to cover our scheme could come into effect next April. Will confirm the need for legislation and the timetable once the scheme has been finalised.

This won't, of course, prevent the scheme paying out to claimants who would be unaffected by social security benefit loss. It also won't prevent the scheme from processing applications in advance of the date when social security legislation is amended – so the actual payments can be made without delay after that date.

PUBLIC ENQUIRY

Lessons to be learned

Not convinced that there are any lessons to be learnt that have not already been learnt. Nowadays risk management and the precautionary principle are key issues for the Health service. And we are committed to better communication between clinicians and patients – especially on risk.

No consensus on seriousness of HCV infection

Acknowledge that some clinicians had serious worries about the seriousness of Hepatitis C infection as early as the mid 1970s (and in consequence about the use of commercial products). But many experts also took the view that it was a mild, non-progressive condition and the benefits outweighed any adverse consequences.

There was much debate in the medical press and between individuals as to whether non-A non-B hepatitis was a serious issue or not. Some 20 years later, and with the knowledge that hepatitis C may take 15 – 30 years to manifest itself in causing liver disease, it is not surprising that these discrepancies of opinion were present. This divergence of opinion continued until at least 1985 after which an increasing number of experts came to regard it as a serious disease with significant long term consequences. That view did not come to be universally held in the relevant medical and scientific communities until after 1989.

Link between HCV and clotting factor – public knowledge

Numerous published articles in eminent medical journals, such as the Lancet, in the 1970s and 1980s that record information, interest and controversy on this issue.

The link between treatment with blood clotting factor concentrates and HCV infection was regularly discussed at annual meetings of the Congress of the World Federation of Hemophilia (certainly as early as 1975). These meetings were organised by the World Federation of Hemophilia (WFH). The UK Haemophilia Society was a founder member of the WFH and will have seen the conference abstracts even if they did not attend.

Product information leaflets contained statements that the risk of transmitting hepatitis could not be excluded. This information was directly available to all clinicians involved in the treatment of haemophiliacs with these products and also to the substantial proportion of patients who were practising home therapy (40% in 1978).

Copies of published articles in medical journals (e.g. the Lancet) – demonstrating that the risk of HCV infection was widely and publicly acknowledged and that there was a wide range of opinion – were lodged in Parliament's Reference Centre in October 2000 as part of the documentation supporting the SE "Report on the Heat Treatment of Blood Products for Haemophiliacs in the 1980s".

Recent information provided to the Minister -'Haemophilia Directors' Hepatitis C Working Party Report for Year 1980-81

The point at issue is whether this document reveals new information about what that government officials knew, and whether in particular it confirms that they were aware from as early as 1974 that treatment with blood clotting factor concentrates carried a risk of infection with what we now know as Hepatitis C.

There is no doubt that this document does confirm that haemophilia directors and the Department of Health and Social Security were aware of such a link, but I am afraid that this does not constitute new evidence. Understand there are numerous published articles in eminent medical journals, such as the Lancet, in the 1970s and 1980s that record information, interest and controversy on this issue. It is important to consider the Haemophilia Directors' report in that context.

Professional judgement

In the circumstances prevailing in 1982 (the date of the report 'revealed' by the Sunday Times and the Scotland on Sunday) the fact that commercial products carried a greater risk of infection would have been viewed against:

- the background of conflicting expert opinion on the seriousness of Hepatitis C infection,
- variations in the efficacy of different products in treating haemophilia in individual patients,
- variation in the not inconsiderable side effects,
- the fact that both commercial and NHS products were licensed by the Medicines Division of the Department of Health and Social Security (the predecessor of the Medicines Control Agency – now the Medicines and Healthcare Products Regulatory Agency), and
- the inability of the NHS to meet UK demand.

Not convinced that any officials or NHS staff acted wrongly in the light of the facts that were available to them at the time

Infected products still in use in Scotland after 1986 and claims of infection of HCV from blood and blood products after the introduction of serological testing in September 1991

The Scottish Executive's report 'Hepatitis C and the Heat Treatment of Blood Products in the mid 1980s' published in 2000 was made available to organisations representing patient interests with other documents that show that the link between treatment with clotting factor concentrates and hepatitis C infection.

Factor VIII clotting agent used in the treatment of Haemophilia A – HCV-safe 1987
Factor IX clotting agent used in the treatment of Haemophilia B – HCV-safe 1985

The Hep C virus was first identified in 1989, and it was only after this that tests for screening of blood donors could be developed.

We are not currently aware of any claims in relation to infection contracted after 1991.

Serological testing for donors was introduced in 1991, but for a donor who was recently infected there is a possible 'window period' of several weeks during which infection might not be detected. This could theoretically allow the Hepatitis C virus to enter the blood supply and possibly be used for transfusion purposes.

A new method of testing for HCV - Polymerase Chain Reaction (PCR) was introduced in 1999/2000. This is a very sensitive DNA test which would identify any infection and greatly reduces the risk associated previously with newly infected donors.

Another possible explanation for the claims could be is that the patients in question have been informed of their infection at these times rather than this being the date of their infection. We are aware of several instances where people have written in to say they have only in the last few years found out that they were infected some years ago.

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