#### RESTRICTED - POLICY

#### NOTES FOR SUPPLEMENTARIES - HEPATITIS C

#### A HEPATITIS C

#### A1 WHAT IS HEPATITIS C?

\* Hepatitis C is a virus which circulates in the blood and causes inflammation of the liver. In many infected people the virus will persist without causing symptoms for many years. However their blood will remain infectious for other people. In some people, in the long term, the inflammation may progress to more serious liver damage including cirrhosis

#### A2 HOW SEVERE IS IT?

- \* Many people infected with HCV may enjoy a long period without any symptoms appearing.
- \* 50% of sufferers may progress to chronic hepatitis with varying degrees of ill health. It can cause liver damage and mortality.
- \* Perhaps 20% of infected patients will develop cirrhosis, a progressive destruction of the liver, that may take 20 to 30 years.
- \* In addition a small proportion will develop primary liver cancer after a further time.
- \* Certain patient groups may have a worse prognosis and a more rapid disease progression, eg. immuno suppressed patients, those co-infected with HIV and /or hepatitis B, and alcohol abusers.

#### A3 HOW IS IT TRANSMITTED?

\* Normal day to day social contacts do not transmit hepatitis C. The main source of transmission in the UK is by sharing of blood contaminated needles and equipment between intravenous drug misusers.

#### A4 HOW EASY IS IT TO TRANSMIT?

\* The disease is not easily transmitted except by contaminated needles.

#### B LOOK BACK PROGRAMME

#### B1 HOW IS THE LOOK BACK PROGRAMME UNDERTAKEN?

This is a process of identifying patients who were previously given blood from donors who have subsequently been shown to be Hepatitis C positive. Such patients would be counselled, tested and if found to be infected advised of the appropriate treatment.

#### B2 WHO ACTUALLY CARRIES IT OUT?

- \* The major task of identifying the donors who have turned out to be HCV positive after having given blood at a previous visit; tracing what happened to the blood and whether any patients may have been infected as a result will lie mainly with <u>the NBA</u>; the second stage with <u>the hospital</u> where the blood was used.
- \* <u>Consultants</u> will be involved at the hospitals which received the blood.
- \* If the patient can be traced then they will need to be counselled and tested. The <u>ad hoc working party</u> will be providing advice on who is best placed to do this and how it should be done.

[Note for information. This may be the GP, the hospital consultant or the local blood transfusion centre.]

#### B3 HOW LONG WILL IT TAKE?

- It is not possible to say how long this process will take.
- \* Some patients may be identified relatively quickly in a matter of a few weeks. Others may only emerge after a long and painstaking process of elimination and this may take many months.
- \* Not all patients at risk will be picked up.

[Note for information. Some will not be picked up because infected donors have not given blood since Sept. 1991. In others it may be because of difficulty in tracing hospital records.]

B4 WHEN WILL THOSE WHO ARE AT RISK KNOW AND WHEN WILL THOSE WHO HAVE NOTHING TO WORRY ABOUT BE TOLD?

\* Some patients may know within a few weeks; others may not be identified for many months.

[Note for information. It may be worth making some sort of announcement when the main part of the exercise has been completed. We should avoid making any commitment to write to all patients but this matter will undoubtedly require further thought]

#### B5 HOW MANY PEOPLE ARE BELIEVED TO BE AT RISK?

- \* We do not know.
- \* The transfusion directors estimate that in England there may be of the order of 3000 people alive who have received blood by transfusion from people who we now know to have been HCV positive.

#### B6 WHY WAS IT NOT DONE BEFORE?

- \* Until recently it was considered that look back to identify recipients of blood transfusion who are at risk would be technically difficult; and as there was no effective treatment, to inform people they were at risk, when there was nothing that could be done about it, would increase distress without any benefit.
- \* The long term effects of the disease were also unclear and it was not easily transmitted.
- \* The position is now clearer and a means of treatment has become available. There is now some confidence that many, but not all, recipients of blood infected with Hepatitis C can be identified and Interferon alpha has been licensed for the treatment of chronic hepatitis C. This may be of help to some people.
- \* For this reason the Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation (MSBT) at its meeting 15 December 1994 advised Ministers to undertake a look back exercise.

#### B7 WILL IT BE DONE ON A UK WIDE BASIS?

\* Yes

\* All four Health departments are committed to undertaking this exercise and they will do so on a common basis.

[Note for information. There is no argument about this as a principle. The exact extent will need to be agreed.]

#### B8 ARE THE SCOTS GOING AHEAD UNILATERALLY?

\* No

- \* The Scots, who of course have far fewer patients than there are in England, carried out a pilot research study last year and satisfied themselves that a look back exercise on Scottish patients would be feasible and practical.
- \* Their work will be made available to the ad hoc group which has been set up to draw up guidance on procedures and counselling.

# B9 WHAT WILL THE AD HOC WORKING PARTY DO?

- \* The ad hoc Working Party will draw up guidance for those undertaking the look back exercise so that everyone involved knows exactly how it is to be carried out. It will also ensure quality and a consistency of approach.
- In doing so they will take advantage of the research study already undertaken in Scotland.
- \* The working party will also produce guidance on counselling of those who are found to be at risk of having become infected.
- \* They will also draw up guidance on the various treatment options.
- \* They will consider any other actions (eg. additional research) which might be appropriate to ensure that those infected in this way receive appropriate treatment.
- B10 WILL THE RESULTS OF THEIR WORK BE PUBLISHED.
  - \* It is most likely that the outcome of their work will be an instruction to the NHS in the form of Health Service Guidelines.

C ACTION TO REASSURE MEMBERS OF THE PUBLIC AND ENSURE BEST ADVICE TO THOSE CONCERNED

- C1 WHAT WILL THE HELPLINE DO?
  - \* The helpline will provide a freephone facility so that members of the public, anywhere in the UK, may obtain information about the look back exercise
  - \* It will not be a counselling service nor will it seek to give medical advice. Callers who want more information will be advised to consult their GP.
  - \* If callers are very distressed and need to talk to someone immediately they will be referred to the Transfusion Centres which all have a 24 hour on-call consultant.

#### C2 HOW WILL IT OPERATE?

- \* The agency operating the helpline have been given a Q and A brief which will form the basis of the answers given.
- \* The helpline will initially operate around the clock and will be staffed to cope with the demand. This will be reduced when the level of demand decreases.
- The Health Information Service, operated by the NHS, will also be able to answer questions on the look back exercise. This is permanently available and will take over answering question when the helpline is eventually closed down.
- \* The helpline number is FREEPHONE 0800 716 197

### C3 WHAT ADVICE IS BEING GIVEN TO GPS?

- \* All GPs will be informed within the next 48 hours of the arrangements for the look back exercise and provided with basic information about hepatitis C and the Q and A brief being given to the Helpline. This will enable them to give advice to any patients consulting them with knowledge of how they may have been informed by the helpline.
- \* Similar arrangements will be made in the territorial Health Departments.

## C4 ARE HOSPITAL CONSULTANTS BEING GIVEN ADVICE?

\* Yes. The same information will be given to the consultants most likely to be affected.

[Note for information. The contents of the GP letter will also be sent to haematologists, consultants working in haemophilia centres, general physicians and general surgeons, immunologists, hepatologists, gastro enterologists and consultants in infectious diseases].

## D SAFETY OF THE BLOOD SUPPLY

D1 WHY WAS HEPATITIS C NOT ELIMINATED BEFORE IT GOT INTO THE BLOOD SUPPLY?

- \* In the absence of any reliable test for HCV the only way to safeguard blood was to limit those from whom blood was taken by a system of self deferral.
- This excluded those known to be suffering from hepatitis or any other liver disease; drug misusers; and men who had sex with other men.
- From 1985 Factor 8 and Factor 9 have been treated to destroy any viral infection.
- D2 WHY WERE HCV TESTS NOT INTRODUCED BEFORE 1991?
  - \* Screening was introduced in September 1991. The first anti-hepatitis C tests were reported in the literature in March 1989 but did not become available until later that year.
  - \* These first tests had too large a number of false positive and false negative results and no satisfactory confirmatory tests were available. Expert advice was that these tests should not be introduced because of these deficiencies.
    - The Department of Health funded several trials of the first and second generation anti-Hepatitis C test kits. Screening was introduced in late summer 1991, following advice from the Advisory Committee on the Virological Safety of Blood (AVSB). Satisfactory kits became available together with confirmatory tests. The screening kits now available are even more accurate than the second generation kits:

D3 WHICH OTHER COUNTRIES DID INTRODUCE HCV TESTING BEFORE BRITAIN?

\* We do not have precise details of the date at which each country introduced Hepatitis C testing. We do know that some did introduce testing before the UK. But it must be remembered that in some of these cases the incidence of Hepatitis C in donors is considerably greater than in the UK. Also in UK the general health of donors is the best in the world.

D4 HOW MANY OTHER COUNTRIES HAVE INTRODUCED LOOK BACK AND WITH WHAT RESULTS?

- We do not have this information.
- We understand that this is to be considered by a Committee of the Council of Europe in April 1 5.

#### D5 WHAT IS THE MSBT?

- The Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation.
- \* This committee advises the Secretaries of State of the four territorial Health Departments on all aspects of the safety of blood. It is the senior expert committee of its kind in UK.
- D6 WHO ARE THE MEMBERS OF THE MSBT?

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\* Dr Jeremy Metters is [I am] the Chairman. The members comprise leading experts in the relevant fields from each of the four Health departments and the NHS.

[Note for information. A handout showing the current membership will be available on request.]

D7 IS THERE ANY CONNECTION WITH HIV?

This is a totally different virus.

[Note for information. In fact both are blood borne infections and many people infected with HIV are also infected with HCV. Moreover the double infection makes treatment more difficult. Nevertheless it would not be helpful to respond in any other way than - No!]

#### E INFECTION OF BLOOD PRODUCTS

E1 IS THERE ANY LIKELIHOOD THAT HAEMOPHILIACS HAVE BEEN INFECTED THROUGH BLOOD PRODUCTS?

- Since 1985 all Factor 8 and Factor 9 has been treated to destroy viral infection including HCV.
- It is known that many people with haemophilia who received regular treatment with blood products (Factor 8 or Factor 9) prior to that date have become infected.
- \* This is because the plasma derived from individual donations is pooled for the fractionation process. Thus a single donation of blood may lead to infection of a whole pool of plasma and so place at risk the products coming from such a pool.
- \* The combined impact of this pooling effect and the large numbers of treatments that many people with haemophilia have had has led most consultants to assume that nearly all people, treated for haemophilia before 1985 by the use of blood product, will have contracted HCV.

#### E2 WHAT WILL BE DONE TO ASSIST THEM?

\* The Department are meeting with the Chairman and senior officers of the Haemophilia Centres later this month to discuss what more needs to be done to develop good practice guidance for the treatment of people with haemophilia who are also HCV positive and to ensure that such people have access to treatment centres.

[For information. The meeting was already set up for 24 January and this item has been added to the agenda. There is also a meeting of Regional Haemophilia Directors 30th January when this matter will be raised by Dr Rejman for the Department]

- E3 WILL YOU SUPPORT SELF HELP GROUPS?
  - \* The Department is already supporting an initiative by the Haemophilia Society to undertake research into the best way to support its members who are infected with HCV.

[Note for information. A first payment has been made to enable this project to go ahead. Ministers have recently agreed to fund the three year project and this will be made known to the Society 11 January.]

#### E4 WHAT ABOUT PEOPLE TAKING OTHER BLOOD PRODUCTS?

- \* Albumin and intra muscular immunoglobulins do not transmit any viruses. HCV is only known to have been transmitted through Factor 8 and 9 and through some preparations of intravenous immunoglobulin.
- \* Certain people have been infected with non-licensed Gammaguard and this is the subject of current legal discussions with Baxter. Infection through other  $\mathcal{HV}$ products is possible but not common.
- \* It will not be practical to undertake a look back exercise on all these patients but consultants who treat patients with these products have been made aware of the possibilities of infection prior to 1985. They will bear this in mind in the clinical treatment of their patients.

#### F ACTION TO BE TAKEN TO HELP THOSE AT RISK / TREATMENT

#### F1 WILL THEY BE TOLD?

It will be for their GP or consultant to decide if, and when to inform someone who is found to be at risk.

In most cases the medical practitioner will make known the situation to his patient but in some cases where it is judged that there is no benefit in so doing and the patient would be unnecessarily distressed, the information may be kept for medical purposes only.

- All patients who are to be informed will first receive 'Concud counselling.
- \* They will be informed of the possibility that they might have become infected; the implication of this if it proves to be the case; and the treatment options. They will then be sent for test.

#### F2 WHAT TREATMENT IS AVAILABLE?

- Many people go for many years without needing any treatment.
- \* Others need treatment for hepatitis and cirrhosis etc.
- \* One of the tasks of the ad hoc Working Party will be to advise on treatment options.
- \* Interferon Alpha has recently been licensed for the treatment of chronic hepatitis C. This is likely to be helpful to some, but by no means all, people.

[Note for information. Interferon Alpha is to date the only extensively studied agent shown to be effective but results are disappointing. In approximately 50% of patients with chronic hepatitis C treated with Interferon Alpha there is evidence of the virus being cleared from the blood. While the relapse rates are high some 20 to 25% of patients currently being treated have a sustained response. Advances in the treatment of viral disorders are expected in the next few years that may improve response rates.]

#### F3 WILL THEY HAVE PRIORITY ACCESS TO SUCH TREATMENT?

\* Every effort will be made to ensure that such people are given the treatment they need.

[Note for information. We need to avoid giving open ended guarantees of treatment. But any attempt to gualify such assurances by reference to "subject to priorities and resources available " are likely to be counter productive]

## G COMPENSATION FOR THOSE AFFECTED

# G1 WILL COMPENSATION BE PAID TO THOSE AFFECTED?

\* No

\* The Government does not accept that there was any question of negligence upon the part of the NHS.

G2 WILL THE GOVERNMENT INTRODUCE A NO FAULT COMPENSATION SCHEME?

- \* NO
- The Government are opposed to a no-fault compensations scheme.

[Note for information. The Government opposes no-fault compensation for five reasons;

i) the proof of causation is still needed, and it could be just as difficult to establish that medical treatment had caused injury - and that it was not a foreseeable and reasonable result of treatment - as it would be to prove that someone had been negligent;

ii) there would be <u>unfairness to others</u>, in that those disabled as a result of a medical accident would be compensated but those disabled as a result of disease would not:

iii) it is quite possible that the costs falling on the NHS could increase substantially and this would inevitably reduce the amount available for direct patient care;

iv) negligence in the health care field is not considered to be fundamentally any different from negligence in any other walk of life, where <u>claims for compensation are</u> resolved through the courts;

v) the present system arguably has a <u>deterrent effect on</u> <u>malpractice</u> and no-fault compensation could conceivably make doctors less careful.]

G3 WILL EX GRATIA PAYMENTS BE MADE AS WAS DONE FOR THOSE INFECTED WITH HIV?

- \* No
- \* The case does not have the exceptional circumstances as did the HIV infection where those affected were all expected to die very shortly and were subjected to significant social problems including ostracism.

[Note for information. Costs of the HIV Haemophilia payment scheme have reached £81 million. (This includes £15 million paid to the Macfarlane Trusts for the special needs of HIV haemophilia patients and their families.)

Costs of the scheme of payments for those infected with HIV through blood or tissue transfer has reached £3.5 million including £0.5 million paid to the Eileen Trust for the special needs of this group.]

#### H - NHS TREATMENT OF OTHERS INFECTED WITH HCV

- H1 WHO ELSE IS INFECTED WITH HCV?
  - \* The largest number will be in intravenous drug misusers some of whom may have only injected occasionally and many years ago.

#### H2 HOW MANY ARE INVOLVED?

- \* exact numbers are not known
- \* estimates have been made of up to 400,000
- \* best estimate is probably in the region of 100,000

#### H3 WILL THEY GET THE SAME ACCESS TO TREATMENT?

\* Those infected with HCV will be treated in the same way as any other patients under the NHS and will receive appropriate treatment subject to clinical priorities and resources available.

#### J COSTS

#### J1 WHAT IS THE COST OF THE LOOK BACK EXERCISE?

- \* It is not possible to estimate this precisely; the cost of actually undertaking the tracing process will not be great in cash terms. But it will divert people from other tasks.
- \* The cost of the helpline will depend very much on the number of people using it and the length of time it is required.

[Note for Information. Preliminary estimates have been made of about £100,000].

×

J2 WHAT IS THE ESTIMATED COST OF TREATING ALL THOSE INFECTED THROUGH NHS TREATMENT?

It is not possible to provide such an estimate.

[Note for Information. If all blood transfusion patients were suitable for treatment with Interferon then the cost of drugs might be in the order of £12 million. It is known that only a proportion will be able to benefit from such drugs and therefore the actual cost will be significantly less. There may also be a need to take on additional consultants or include additional sessions.]

#### NOTES FOR SUPPLEMENTARIES - BLOOD SERVICES

#### 1. PURPOSE OF THE REORGANISATION PROPOSALS

\* The purpose of the reorganisation proposed by the NBA is to improve the service for patients, hospitals and donors.

\* The proposals are designed to achieve greater coordination, standardise procedures wherever possible and simplify the management structure.

\* When the NBA took over management control of the Regional Transfusion Centres on 1 April 1994, the Regional Transfusion Directors became directly accountable to the Chief Executive of the Authority. The NBA decided that this change gave rise to the need for a new management structure based on three zones, notwithstanding the authority's proposals for reorganising the blood service.

# 2. CONCENTRATION OF PROCESSING AND TESTING

\* There is general agreement/that it is unnecessary for all the functions of collection, processing and testing, and storage and supply of blood to be conducted in the same place.

\* Present technology allows testing and processing to take place in fewer and larger centres leading to improved quality at a lower cost.

#### 3. INEFFICIENCIES IN THE EXISTING STRUCTURE

\* The NBA's review identified inefficiencies in the existing system such as significant mechanical over capacity. There are also eight different and incompatible computer systems operating in the 14 Transfusion Centres in England.

\* The blood service has the capacity to group around 7 million blood donations each year. We currently collect in England and Wales around 2.3 million donations per year.

4. DELIVERY TIMES WILL BE LONGER

\* The proposed network of stockholding units will provide hospitals with access to the same amount of, if not more, blood than they have now.

\* The NBA have said that those hospitals that presently receive emergency supplies in less than two hours will not have to wait any longer than now

## 5. A TWO HOUR WAIT FOR BLOOD UNDER THE NBA PROPOSALS

\* At present there are hospitals in England which have to wait more than two hours to receive blood in an emergency.

\* The NBA proposal would mean that in future no hospital would have to wait more than two hours for an emergency delivery and usually significantly less.

\* The NBA proposal is a significant improvement over the present situation.

#### 6. SERVICES FOR DONORS

\* As you may know, the majority of blood donation does not take place at the Transfusion Centres even though the centres are the administrative bases for the collection teams. The teams go out into the community to conduct pre-arranged donation sessions.

\* Under the NBA proposals, blood collection would continue as at present and would be easily accessible to donors. Mobile teams would go out to donors in all areas whether the centres are amalgamated or not.

\* Although the administration would be concentrated on just three Centres, the present number of collection team bases would be increased to ensure a better service for donors, more effective coverage of the country and enhance local links. It is important that donors, whose interests are a key feature in the proposals, are reassured on this crucial point.

#### 7. NBA CONSULTATION NOT GENUINE

\* The NBA has undertaken a thorough and widespread consultation and is currently evaluating the responses.

\* The NBA will invite an independent panel to ensure that the authority, in making its final decisions, has given due and objective consideration to the comments received during the consultation.

#### 8 PRIVATISATION

There is no question of turning the National Blood Authority into a commercial organisation still less of privatising it.

[If pressed about BPL commercial alliance - there are no plans for the Bio Products Laboratory to enter into an alliance with a commercial partner]

[ If pressed further the NBA have been exploring ways of utilising the surplus production capacity at BPL including the possible use of this capacity by commercial companies. We have no plans to pursue this option.]

#### 9 SELLING BLOOD

The NBA does not sell blood abroad, nor does it collect any more blood than is needed to meet the needs of patients in this country.

Occasionally collecting sufficient blood to meet domestic needs leads to a surplus of blood products (which are a <u>by</u> product of blood collection and made from plasma), <u>not</u> <u>blood</u>. This can be sold abroad, offsetting the NBA's costs. This means lower charges for the NHS hence benefit for patients. The only alternative would be to burn the surplus.

#### 10 ALT TESTING

The NBA did apply to the Secretary of State to extend the directions covering the screening tests that may be applied to blood donations to include ALT testing. The Authority's application was rejected. The Authority believed that the introduction of this test would increase the number of potential markets for any surplus products from BPL. Ministers are of the view that currently this is not sufficient reason to extend the directions. The Authority did not propose to increase the amount of blood collected in order to increase surpluses of blood products.

#### 11 SELLING SURPLUS BLOOD PRODUCTS

The NBA does not sell plasma abroad. (Irreducible) surpluses of blood products, that is after NHS demand has been satisfied, may be exported rather than destroyed. The only product where present availability significantly exceeds NHS demand is Albumin. Receipts from sales supplement NHS income.

### BACKGROUND - BLOOD SERVICES

1 The following notes may be of help in providing additional background material.

2. The main feature of the NBA restructuring proposals are an Survis amalgamation and rationalisation of functions, mainly on the survis administration and processing side of the blood service, which will result in the amalgamation (closure) of five of the present fifteen Transfusion Centres.

3. Duplication of effort and inconsistency resulting over the years from separate management of the 15 Centres were highlighted by the NBA's strategic review. For example there are currently eight different and incompatible computer systems operating in the 15 Centres.

4. The centres proposed for amalgamation and proposed dates are:

Lancaster - 1995/96 (work to go to Manchester);

Plymouth - 1995/96 (work to go to Bristol);

Mersey - 1996/97 ( work to go to Manchester);

Oxford - 1996/97 (work to go to Bristol, Birmingham, East Anglia and Colindale);

North East Thames (Brentwood) - [1997/98] (work to go to North London (Colindale))

5. Some of the centres due for amalgamation (closure) will retain residual functions for example as stock holding units or collection team bases. Grunder adving come.

6. The decisions on which centres are to be amalgamated (closed) was made on a full evaluation of several criteria including:

the ability to meet a long standing clinically driven convention that blood available for delivery will be within 2 hours reach of a hospital;

the proximity to key centres of customer demand;

the current size of the centre and the capacity to increase;

supply performance;

the future investment requirements of each centre.

7. Significant improvements in testing, grouping and processing should result from uniformity of procedures, economies of scale and more effective utilisation of staff and equipmen<sup>+</sup>

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#### Transfer of Administrative Functions to 3 New Zones

8. Routine administrative functions for the 10 transfusion centres will be conducted from 3 new zonal centres. Each zone will have an Executive Director accountable to the Chief Executive of the NBA. The Directors of the Transfusion Centres in each zone will be accountable to the new Zone Directors. This will provide a much tighter span of administrative control than the present unwieldy structure where each Transfusion Centre Director is individually accountable to the NBA Chief Executive. The three Directors (designate) of the new zones have been appointed.

#### Donor Management

9. Responsibility for the recruitment and management of donor panels would pass from the regional centres to the 3 new zonal centres.

#### Blood Collection

10. Blood collection will continue as at present with mobile teams going out to donors in all areas whether the centres are amalgamated or not. By 1997 the NBA will reduce the total number of collection teams from 85 to 65. The new teams will be larger, more strategically located, better organised with more effective working practices aimed at achieving an optimum collection rate of 120/140 donations per session compared with the present average of about 100. There are at present 35 collection team locations and the plan is to increase these to between 53 and 55.

#### Specialist Services

11. Specialist services, including platelets for leukaemia patients, will continue to be provided. The Director of each of the three new zones, who will be responsible for the transfusion centres in their area, will be arranging for consultation with the hospitals in their area and drawing up a detailed plan to cover all their requirements. They will also review plasma collection to ensure that patient demand for special plasma products is met and that plasma donors are kept fully informed of any organisation changes which affect them. The NBA has already indicated, for example, that the special plasma donor panel at Oxford which provides platelets and plasma for patients requiring specially matched products will be maintained.

#### Transfusion medicine

12. The NBA propose to raise the profile and strengthen the role of the consultants in Transfusion Medicine in the Transfusion Centres. The objective is, through a proactive approach to user hospitals and clinicians, to improve safety and patient care and to reduce the level of inappropriate demand for blood and blood products.

#### Impact of the Proposals

13. The impact of the complete package of proposals, not just centre amalgamations (closures), is an estimated reduction of around 450 posts - 10% of the workforce. This will achieved as far as possible by natural wastage but some redundancies are likely. Precise figures will not become known until the proposals begin to roll out. The NBA hope to keep redundancies to a minimum by offering relocation and retraining packages and access to new jobs that will be created. Significant savings, which will be passed on to the NHS in the form of a reduction in blood handling charges, are likely to result from the implementation of the proposals.

#### Consultation

14. The NBA has undertaken a thorough and widespread consultation, which ended on 11 November, and is currently evaluating the many and detailed comments which have been received.

15. The NBA has now decided to appoint a panel of independent "auditors" to examine the comments received during the recent consultation exercise on the reorganisation proposals. The purpose of the panel will be not so much to reconsider the original proposals but rather to ensure that the NBA, in coming to their final proposals, give objective consideration to the comments received during the consultation. The whole exercise is expected to last 3 months. In due course the NBA plan to publish their final proposals with a statement by the panel that they are satisfied that the NBA has given due and careful consideration to the comments. The NBA are finalising the appointment of the panel and DH will be informed when the individuals have been agreed. The NBA have issued a press release to this effect 22 December 1994.

#### ANNEX A

#### DRAFT

#### INSPIRED PQ TO BE TABLED 10 JANUARY 1995 FOR ANSWER 11 JANUARY

#### QUESTION

<u>Mr</u> To ask the Secretary of State for Health what action is being taken by the Government to trace those who may be at risk of having been infected with Hepatitis C as a result of blood transfusions.

#### ANSWER

<u>Tom Sackville</u>. The Government has accepted the recommendation of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation that a look back exercise should be undertaken to trace, counsel and treat those who may have inadvertently been infected with Hepatitis C through blood transfusions given in this country. My Rt Hon Friend has directed that this exercise should be undertaken as quickly as possible and the Secretaries of State for Scotland, Wales and Northern Ireland are making similar arrangements to ensure a co-ordinated UK approach.

The chairman of the Advisory Committee has been asked to bring together without delay an ad hoc Working Party of experts to draw up guidance on the procedures for undertaking the look back exercise and for counselling those identified as being at risk as well as guidance on the treatment options available.

The Blood Service in the UK continues to be one of the safest in the world and donors and patients should have the highest confidence that the standard of the service will be upheld.

#### (Revised 10 January 1995)

#### ANNEX B

#### DRAFT PRESS NOTICE

11 January 1995

#### HEPATITIS C AND BLOOD TRANSFUSIONS

Those who may have been inadvertently infected with Hepatitis C through blood transfusions are to be traced, counselled and - if necessary - treated. Tom Sackville, Parliamentary Secretary for Health, announced today.

Announcing the exercise, Mr Sackville said:

"I have accepted the recommendation of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation that a look-back exercise should be undertaken. I have asked Dr Metters, the Chairman of the Committee to bring together an ad hoc Working Party of experts to draw up guidance on the procedures for undertaking the look back exercise and for counselling those identified as being at risk, as well as guidance on the treatment options available.

"The blood services in the United Kingdom are some of the safest in the world. Since September 1991 all blood donations have been routinely tested for antibodies to the Hepatitis C virus. Prior to that date some recipients of blood transfusions may have been inadvertently infected, although the chances of this in any one case are extremely small.

"We shall do all we can to care for patients who have become infected in this way through counselling and, where appropriate, treatment. I recognise that people may be worried if they received a blood transfusion before 1991 and if they are they can call 0800 716197 for advice."

Dr Jeremy Metters, the Chairman of the Advisory Committee and the Government's Deputy Chief Medical Officer said:

"Until recently there was no treatment to offer those who might be identified and it was believed that this exercise would have been technically very difficult. However, following a pilot research study procedures have been established which make it possible to trace those at risk and, more importantly, certain drugs have recently been licensed which may be suitable for the treatment of some of those involved. This look-back programme will go ahead without delay."

[more]

-2-

#### Notes for Editors

1. Hepatitis C is a virus that circulates in the blood and causes inflammation of the liver. In many infected people the virus will persist without causing symptoms for many years. However their blood will remain infectious for other people. In some people in the long term the inflammation may progress to more serious liver damage including circhosis.

2. Normal day to day social contacts do not transmit Hepatitis C. The main source of transmission in UK is by sharing needles between intravenous drug misusers.

3. A licence has recently been granted for Interferon Alpha to be used in the treatment of chronic Hepatitis C. This drug has proved helpful in the treatment of some people.

4. The Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT) advises the four Secretaries of State (for Health) on all matters affecting the safety of the blood supply. It is chaired by Dr Jeremy Metters, the deputy Chief Medical Officer at the Department of Health and includes leading experts in the UK.

5. The ad hoc Working Party will include members of the MSBT and other experts and will meet for the first time next week.

6. Ministers in Scotland, Wales and Northern Ireland have asked their respective National Blood Transfusion Services to go ahead with the look back exercise in consultation with the other Blood Transfusion Services.

[ends]

#### ANNEX C

#### JOURNALISTS TO BE INVITED TO PRESS BRIEFING

Press Association Guardian Times Financial Times Independent Daily Telegraph Daily Mail Daily Express Daily Mirror Today Sun Daily Star Mandy Brown Chris Mihill Jeremy Laurence Alan Pike Ceilia Hall David Fletcher/Peter Pallot Jenny Hope Peter Anderson Jill Palmer

BBC Television BBC Radio ITN IRN Sky TV Niall Dickson Richard Hannaford Anya Sitaran

Health Services Journal British Medical Journal The Lancet BMA News Review General Practitioner Pulse Medeconomics Doctor Hospital Doctor Fundholder Nicola Hill

#### 3390

#### ANNEX D

# ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF BLOOD AND TISSUE FOR TRANSPLANTATION

#### MEMBERS (Jan 1995)

#### CHAIRMAN: DR Jeremy Metters, Deputy Chief Medical Officer, Department of Health, London

Dr E Angela Robinson Medical Director National Blood Authority

Prof A Zuckerman The Royal Free Hospital School of Medicine (UCL)

Dr R J Perry Director Protein Fractionation Centre

Dr P McMaster Consultant Transplant Surgeon Liver Transplant Unit Queen Elizabeth Hospital

Dr R E Warren Director of PHLS Lab Royal Shrewsbury Hospital

Dr A J Cant Director Northern Supra Regional Bone Marrow Transplant Unit Newcastle General Hospital

Miss R H H Lord Consultant Transplant Surgeon Cardiff Royal Infirmary

Dr R Mitchell Glasgow and West of Scotland Blood Transfusion Service Law Hospital, Carluke

Dr P Mortimer Public Health Laboratory Service

Prof J D Williams Consultant Microbiologist London Hospital Medical College Dr D W Gorst Consultant Haematologist Pathology Department Royal Lancaster Infirmary

Dr T J Snape Technical Director