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AIDS summit

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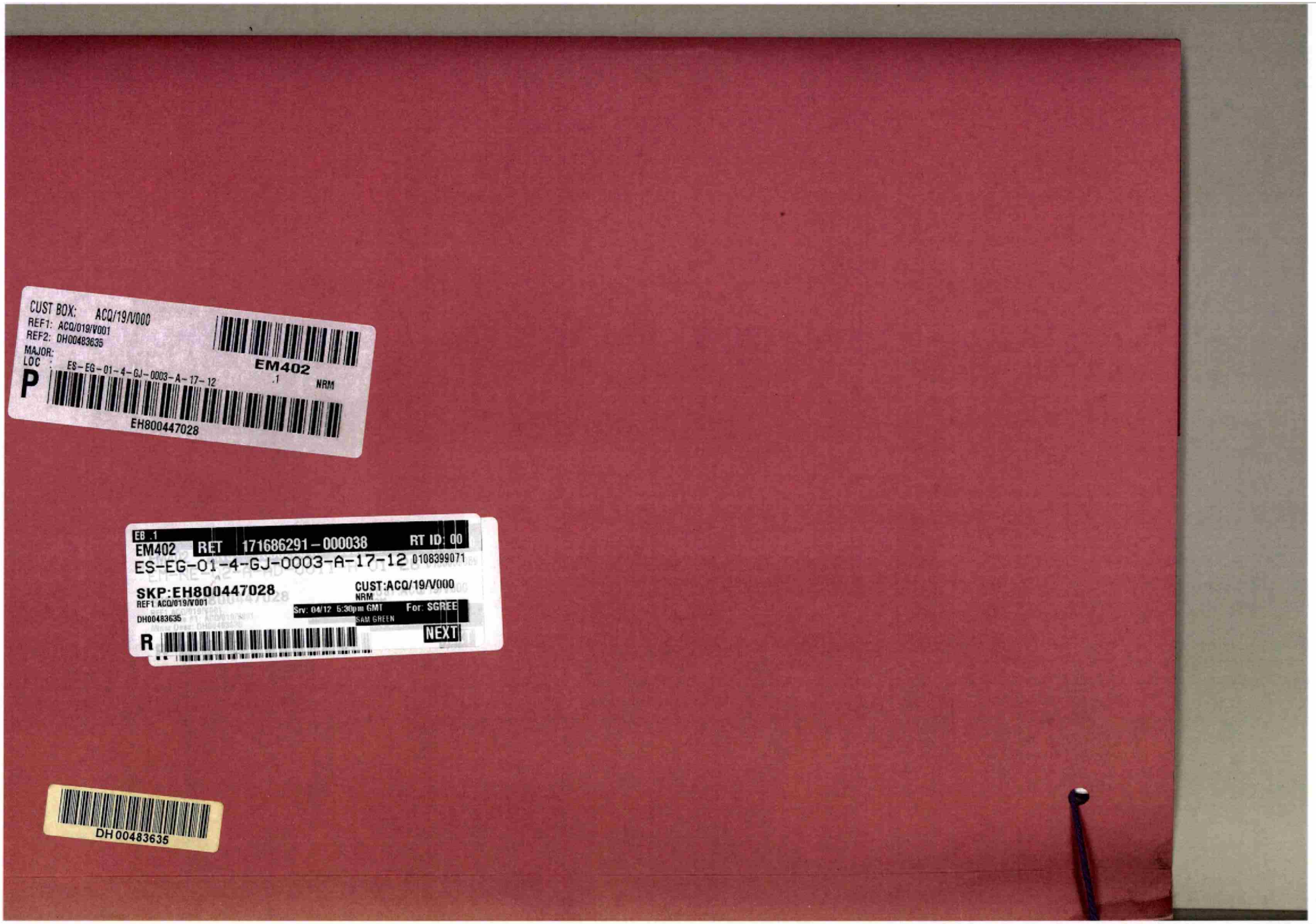

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Laurent ZYLBERBERG
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London, 29th september 1994

**URGENT**
fax : 071 972 4319

From : Laurent ZYLBERBERG
To : Dr RUBINSTEIN and M. PODGER

about : World AID summit in Paris 1st December

Please find enclose the report of the working group about blood transfusion and the names of the personns attending this meeting.

L. ZYLBERBERG

15 Pages

cc Mr Podger
Dr Nabarro
Dr Regman
Dr Reese
Dr Williams
Dr Turnbull
Ms Rutland
Dr Seigeaud
Ms Wellstead.

Could Ms Wellstead please coordinate comments on this by 5 October please

C Rubenstein
30/9/94

BIF c response.

# PARIS AIDS SUMMIT

**Government of France** — **World Health Organization**

**Report of the**

**Strategic Meeting on Blood Safety**

**Paris, 13 - 14 September 1994**

## Introduction

Blood transfusion saves countless lives every year. In developing countries, the main beneficiaries are women who haemorrhage during pregnancy or childbirth, severely anaemic children under five years old, and trauma victims.

It has always been important to ensure that transfused blood does not transmit any infectious agents to the recipient, such as those causing syphilis, hepatitis and malaria. Today, blood safety is more crucial than ever because an even more lethal virus - HIV - has joined the list of transmissible agents. For a person transfused with HIV-infected blood, the probability of becoming infected is close to 100%.

The overall risk of HIV transmission through blood in developed countries is now estimated to be less than 1 in 100 000. In developing countries, however, blood is considerably less safe. For example, an estimated 4 million blood donations a year are still being transfused without prior testing.

## Situation analysis

*In developing countries*, the major concern is the safety and adequacy of whole blood, red cell concentrates and fresh plasma, although the safety of other blood products both imported and domestically produced is growing in importance. At the same time, countries should attempt to diminish the need for blood transfusion in the first place, for example by reducing the incidence of anaemia through better nutrition and the prevention of malaria and other parasitic infestations.

In the developing world, the prime need is to ensure blood safety through a blood transfusion service (BTS) that coordinates and manages:

- the recruitment and retention of blood donors with no identifiable risk;

- the testing of all donated blood for HIV and other transfusion-transmissible agents as appropriate, so as to exclude infected units; and
- the rational use of blood products, with recourse to simple alternatives (such as saline and colloids or autologous transfusion) wherever possible.

In many developing countries, blood safety is still compromised by organizational and financial difficulties at one or more of these three stages. Staff trained in recruiting and retaining donors, or in carrying out testing assays, are often in short supply. There may not be a continuous supply of test kits. Only a few developing countries promote and monitor the implementation of guidelines to minimize unnecessary transfusions, and blood substitutes are often unavailable.

Perhaps the prime issue is that of national political commitment. Many developing countries have yet to organize a BTS that is financed by sufficient resources from the national health budget and supported by appropriate legislation, regulations or guidelines covering all aspects of blood safety from donor confidentiality and care to the testing, processing and use of blood and blood substitutes. Blood safety cannot be assured without a clear acknowledgement that it is the responsibility of government.

Even with national commitment, many developing countries will be unable to achieve blood safety without external support. Currently, international bodies and bilateral donor agencies provide some resources and technical assistance. However, there are both gaps and duplication of effort, in part because there is no single inventory of needs and responses.

*In developed countries*, where the security of red cell transfusions has been safeguarded, the major concern is the safety of other blood products used domestically or moving internationally.

Recent events have highlighted deficiencies in blood product processing and the application of Good Manufacturing Practice[1] in some developed countries. Public confidence in blood transfusion services has suffered as a result. Key issues include the need to select donors from population groups with the lowest risk of transfusion-transmissible diseases, and to be able to trace all blood products from donor to recipient.

## Priorities for action

In sum, blood safety is an ethical imperative for governments. It is cost-effective: ensuring blood safety through a coordinated BTS usually costs far less than caring for and treating recipients who become infected through contaminated blood. And it is feasible. The virtual elimination of the transmission of HIV and many other transfusion-

[1] Good Manufacturing Practice (GMP) can be defined as all the elements in established practice that will collectively lead to final products or services that consistently meet expected specifications.

transmissible infections through blood is a goal that is within reach of every country.

The Paris AIDS Summit could therefore endorse the following principles and national priorities, and launch the global initiative outlined below.

**Basic principles**

1. Governments have the responsibility to ensure blood safety and quality, as well as an adequate and sustainable supply of blood from voluntary, non-remunerated donors. Blood should be collected, tested and transfused in such a way that the confidentiality and health of both donors and recipients are protected. Information obtained during donor recruitment and selection must be kept confidential and safeguarded so that it cannot be used to stigmatize or discriminate.

2. All governments have a strong interest in global blood safety, given the scale of movement across national boundaries both by individuals and by blood products. It is thus in their common interest to cooperate in ensuring blood safety worldwide, recognizing that many developing countries will not be able to make their full contribution toward this goal without increased external resources.

3. All donors whose blood is to be tested for HIV or other transfusion-transmitted infections should receive appropriate pre-test counselling. No HIV testing should be carried out without their informed consent.

4. All donors should have the opportunity to learn the results of the tests performed. Donors informed that they are infected with HIV or other infectious agents should receive appropriate counselling and referral.

5. Where possible, recipients of blood products should be informed in advance of the risks and benefits of transfusion.

**Priorities for national action**

1. All governments should maximize the safety of their blood supply by, where appropriate, evaluating national needs, elaborating a national plan, and establishing or strengthening their national BTS.

2. Governments should cooperate towards global blood safety by increasing bilateral and multilateral cooperation so as to promote the sharing of knowledge and technology among countries and facilitate the flow of external resources to those countries in need.

3. All governments should endeavour to:

- protect from stigmatization and discrimination anyone, including blood donors and recipients, who is found to be infected with HIV;
- encourage the selection and retention of donors with no identifiable risk;

- promote and support voluntary, non-remunerated blood donation;

- promote the appropriate use of blood products and blood substitutes.

4. All governments should ensure that legislation, regulations or guidelines exist providing for the protection of the confidentiality and health of both donors and recipients, the systematic screening of all donations for HIV and other transfusion-transmissible infections as appropriate, and quality assurance at all stages.

5. While safeguarding confidentiality to the extent possible, all governments should ensure as soon as feasible the bidirectional traceability of blood products between donor and recipient, whether in country or across national boundaries.

6. All governments should ensure that legislation or regulations concerning plasma derivatives exist governing production, certification and licencing, as well as the procurement of source material.

## Global Initiative

The Paris AIDS Summit launches the World Alliance for Blood Safety to maximize blood safety and the quality of care of both patients and donors worldwide.

The activities of the Alliance will be managed by a Secretariat located in an existing global institution. The Secretariat will serve as the hub of an international information and coordination network. It will:

- implement the priorities of the Alliance;

- serve as the international point of contact for those seeking information and assistance, facilitating person-to-person contacts for both purposes;

- serve as a repository of information on technical and clinical subjects, ethical standards and initiatives against stigmatization and discrimination; regulatory standards and policies; and technical assistance needs and responses;

- provide technical guidance on organizing and strengthening blood transfusion services and maximizing blood safety, adequacy, quality, and rational use;

- ensure that developing countries' requirements for financial and other support are coordinated with the inputs of individuals or institutions potentially able to provide such assistance, and otherwise promote the flow of external resources to countries in need;

- explore mechanisms to improve access to essential supplies (including blood bags and test kits) for countries in need; and

- initiate and facilitate cooperative partnerships to achieve programs in

The Alliance will convene a Council comprising experts in blood safety and representatives of governments, regional groupings, and international governmental and nongovernmental institutions involved in the promotion and assurance of blood safety. The Council will:

- develop and support international regulatory standards concerning quality and traceability for all blood products; and

- meet at least annually to assess needs and set goals, objectives and priorities, to provide guidance to the Secretariat, and to review its performance.

# Paris AIDS Summit

## Government of France/World Health Organization

## STRATEGIC MEETING ON BLOOD SAFETY

## PARIS, 13 - 14 September 1994

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Fax cover sheet

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BL03

To DR WEIR HP(M)/

At 728 WELLINGTON

Fax number GRO-C

From DAVID BURRAGE

Telephone GRO-C

Date 15.6.94

Number of pages 14 including this one

Message JEAN PIERRE ALLAIN

If any part of this fax is illegible, immediately contact DAVID BURRAGE

LJP/3397/eh+

Dr Weir HP(M)1

From: D E Burrage
CA OPU2
313 Eileen House
Ext GRO-C

Date: 15 June 1994

**HEADS OF GOVERNMENT SUMMIT ON AIDS**

As promised I attach copies of papers from our file which set out the position Jean Pierre Allain:-

1. Letters (2) of 20 August 1993 from the British Embassy in Paris reporting the Appeal Court Trial;

2. Statement of the Royal College of Pathologists dated 19 November 1993;

3. HAP 6 note of 19 July 1993.

I hope these are helpful.

GRO-C

D E BURRAGE

20 August 1993

PA/92/278

Ms Debbie Ratcliffe
DICD
FCO



British Embassy
Paris

35 rue du Faubourg St Honoré
75383 Paris cedex 08

Telephone: (1) 42 66 91 42
Facsimile: (1) 42 66 95 90

Dear Debbie

**CONTAMINATED BLOOD - APPEAL: JEAN PIERRE ALLAIN'S DEFENCE AND SENTENCE**

1. We have been asked by the East Anglia Health Authority (Dr MGM Rowland, East Anglia Regional Health Authority, Union Lane, Chesterton, Cambridge, CB41RF) for photocopies of press cuttings relating to Jean-Pierre Allain's appeal case. I enclose such copies and, unless you see any objection, would be grateful if you could pass these on.

2. You may also like some comment from the Embassy. May I leave it to you how much, if any, of this to pass on? As you will recall, Allain, as ex-director of R&D at the CNTS (national transfusion service), was the only one of the four defendants to appeal against last October's judgement. In his case, the sentence was 4 years' imprisonment on charges of "fraud", of which 2 years were suspended. He was also allowed to remain at liberty pending the outcome of his appeal. In the event, however, the Appeal Court decided to review the verdicts on all 4 defendants. I have reported more generally on the trial separately (my letter of 20 August).

SUMMARY

3. The main thrust of Allain's appeal was twofold, that:

1) he had fulfilled his obligations as far as possible within his power by communicating available information to interested parties;

2) there had been uncertainties in scientific knowledge of Aids and as to the effectiveness of heating techniques until May 1985.

The Appeal Court in its judgement (30 July) in effect rejected Allain's arguments, concluding that he was well-informed of the risks in 1985, as was Garretta, and that he was guilty of "concealing vital information" from, above all, the AFH (French Haemophiliacs' Association) and his own patients. The magistrates court's sentence was confirmed and a warrant for Allain's arrest was issued for the 2 year prison sentence to take immediate effect at the close of proceedings.

.../

DETAIL

Preliminary procedures

4. As reported in my letter of 20 August on the appeal trial, the first week of this was largely devoted to procedural issues. These included Allain's claim that he had not received the Public Prosecutor's summons within the prescribed time-scale (ie at least 2 months before start of proceedings) and should therefore be tried separately. As you may recall, this was turned down by the Appeal Court on the grounds that he had wittingly avoided its receipt. Other correspondence from the Court is said to have reached him by the normal channels. His subsequent appeal to a higher jurisdiction also failed.

Allain's defence

5. In contrast to the original trial, instead of mutual attacks by Garretta (ex-director of the CNTS) and Allain, on the whole, both presented a united front. In last year's trial Allain's line of defence was that he clashed with Garretta on policy matters, particularly his own recommendation urgently to introduce heating treatment (thence, imports), estimating contamination of stocks at 47%. This time, however, he claimed that his letter of January 1985 to this effect was not based on any solid scientific fact. Indeed, Maître Schnerb, Allain's lawyer, presented his client as a "visionary" cautioning that were he condemned no scientist would ever again in future dare express their intuition on important subjects.

6. In his evidence Allain was also particularly critical of the haemophiliacs' doctors prescribing the blood products, whose role, in his view, should have been to ensure patients were informed of any known risks of contamination and, if needs be, demand "safe products" (heated imports) by putting pressure on the CNTS.

7. He also denied complaints by the AFH and contaminated haemophiliacs that he had undertaken experiments on the blood heating method as late as in 1985. This, they claim, involved 405 haemophiliac patients of which half, as a control group, were administered non-heated blood products.

The Court of Appeal's judgement

8. Criticism was particularly severe with regard to Allain's behaviour in his capacity as a medical practitioner and recognised haemophilia specialist. The Court concluded his

.../

attitude had been "ambiguous": on the one hand, expressing his disagreement within the transfusion establishment whilst at the same time supporting its policies outside the organisation by "concealing" his fears from the AFH and patients. It concluded he had seriously failed in his duty as a practising doctor and expert. The Court rejected the suggestion that the haemophiliacs' doctors shared responsibility for contamination on the grounds that they had no access to specialist knowledge on the subject, nor the means to obtaining inactivated blood products.

GRO-C

Joanna Macaulay
Technology Section

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Telephone: (1) 42 66 91 42
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20 August 1993

Miss Debbie Ratcliffe
DICD
FCO

Dear Miss Ratcliffe,

**CONTAMINATED BLOOD - APPEAL COURT TRIAL**

Summary

1. The appeal hearing opened on 3 May and ended on 11 June, six weeks later. Only Jean Pierre Allain (ex-director of R & D at the National Transfusion Service (CNTS)) and some of the victims had appealed against the October judgement. But, as reported earlier, for "coherence's sake", the court chose also to reexamine the charges against the three other defendants - Michel Garretta (former director of the CNTS), Jacques Roux (ex-director of the Direction Générale de la Santé, DGS, ie the General Health Division of the Ministry of Health) and Robert Netter (ex-director of the LNS (the National Health Laboratory)).

2. The verdict was delivered on 13 July confirming Garretta's 4 year imprisonment for fraud and Allain's 4 year prison sentence, with 2 years suspended, on the same charges, but requiring Allain's immediate arrest. However it reduced Roux's 4 year suspended prison sentence to 3 years, for "failure to render assistance to a person at risk", and attributed some responsibility to Netter, who was given a 1 year suspended prison sentence on the same charges. The damages awarded to the victims were increased from FF9 million to about FF15 million.

3. Given Allain's links with the UK, I am reporting separately on his particular case.

Detail

Background

4. As you will recall, the magistrates court last year rejected charging the defendants with poisoning on the grounds that the law required evidence of intent to kill. Garretta and Allain, were then found guilty of fraud on the grounds of 'deceit with regard to the quality of their products' under the 1905 Law usually applied to commercial products.

5. Intervening events and new evidence were introduced into

the appeal by both prosecution and defence. The most important of these are:

i) the Conseil d'Etat's ruling of April 1993 attributing to the State responsibility for contamination as early as November 1984. (My letter of 30 April refers).

ii) a letter of 18 February 1993 by 13 administrators of the national transfusion service, used by Garretta to support his claim of the uncertainties of scientific and technical understanding of Aids in 1985.

iii) a decision (apparently taken on 28 April 1993 but not announced until mid-trial) by the Conseil National d'Ordre des Médecins (French equivalent of BMA) which condemned Garretta for not immediately recalling blood supplies once he suspected their contamination by HIV (confirming the decision by the regional Ordre des Médecins d'Ile de France last October after complaints by the victims). However the new decision reduced Garretta's life ban to one of 2 years on the grounds there were mitigating circumstances - mainly the fact other members of the profession had acted similarly.

iv) Finally, documentary evidence and explanations by Roux to the effect that the Department of Social Security was itself responsible for choosing the late, October deadline for discontinuing reimbursement of patients' costs for unheated blood and its products.

6. To date an estimated 1,200 haemophiliacs and 4-6000 transfusion patients have been contaminated. Since the original trial, 2 of the prosecuting victims have died.

Conduct of the Trial

7. By nature somewhat limited in scope, the Appeal Court's concern was to reexamine the evidence whilst remaining within the terms of reference of the original case. Its main task was to clarify the context in which events took place, in particular the degree to which scientific knowledge on Aids and heating methods was available to the accused in 1985. A change in tactics by Garretta and Allain (now presenting a united front) helped to broaden the perspective. There were, however, no outstanding revelations.

Preliminary Procedures

8. The first week centred almost entirely on procedural issues. The three principal points examined were:

i) Allain's claim that the Public Prosecutor's summons had not been delivered to him at his home address in Cambridge and that he should thus be tried separately, later. This was turned down on the grounds that he had willingly avoided its receipt. (Other

correspondence from the Appeal Court is said to have reached him by the normal channels). His subsequent appeal to a higher jurisdiction also failed.

ii) Attempts by some of the lawyers for the victims to amend the charge to poisoning - a 'crime' rather than simply an 'offence' - and thus have the case referred to the highest criminal court. This was opposed by the Public Prosecutor, and rejected by the Court.

iii) Finally, whether the appeal should be postponed to allow the 3 ex-Ministers, whose case has not yet come before any court, to be tried first. This was opposed by a majority of the victims' lawyers for fear that the Haute Cour case may never get off the ground. This proposal was also turned down by the Court.

9. At the close of the first week the Court selected 21 witnesses. Roux's request for the three ministers to appear was turned down on the grounds that sufficient evidence had been recorded at the original trial.

The Body of the Trial

10. The defence's central argument was that the uncertainties of scientific knowledge of Aids at the time meant that the defendants were guilty of no more than 'errors of judgement' rather than 'fault' (the October verdict), particularly given their professed efforts to communicate information to interested parties as soon as it was known. Each of the accused thus endeavoured to widen the share of responsibility to include other health officials, the Ministers' advisers, medical practitioners and even scientists. It is worth noting an additional point made by Roux. It appears he acted promptly to warnings in Dec 1984, sending a circular round the appropriate ministries urging donor selection by preliminary questionnaires until availability of an effective HIV test. However, this was not systematically practised as it was considered discriminatory against 'gays' and people of African origin. Other witnesses, including respected authorities such as Professor Luc Montaigner, broadly contradicted this claim.

The Verdict

11. The verdict was pronounced on 13 July, confirming Garretta's and Allain's sentences, but giving immediate effect to Allain's 2 year prison sentence (he had been at liberty pending appeal); reducing Roux's sentence and giving one year's suspended sentence to Netter. Damages awarded to the victims were increased from FF9 million to about FF15 million.

12. The Court attributed total responsibility to Garretta on the grounds that he knew the extent of contamination and yet

had failed in his obligation to take immediate action. It was concluded he had given priority to commercial benefits by postponing discontinuation of distribution of non-heated blood for some months, from March to July 1985.

13. Allain was judged equally well-informed and also guilty of concealing vital information from, above all, the AFH (Haemophiliacs' Association) and his patients. His behaviour is viewed as 'ambiguous' and, as a doctor and recognised haemophilia specialist, a serious failing.

14. Finally, the Court found that Roux and Netter had not communicated the situation to the appropriate authorities with sufficient urgency.

Conclusion and Comment

15. It is not clear how the case of the three Ministers will develop, but nothing is likely to happen before the Autumn. The creation of a new 'Cour de justice de la République', specifically for citizens' petitions against ministers, was adopted on 20 July after complex constitutional changes. The Court will be operational in the Autumn.

Related events

A complaint for poisoning filed against the General Health Division and the Ministers' advisers

16. Before the appeal hearing one of the civil plaintiffs, Jean Péron-Garvanoff, filed a new complaint against Mme Pierre (a colleague of Roux's at the DGS) and the Ministers' advisers for poisoning and intentionally concealing vital evidence from the magistrates court last year. It remains to be seen when this complaint, based on new information from DGS archives will be followed up. But Péron-Garvanoff is one of the first haemophiliac victims, whose efforts were largely responsible for the trial of Garetta et al.

Two regional transfusion services (CRTS) pay damages

17. While the appeal was being heard the CRTS at Rouen and Montpellier were both sentenced in two separate cases to pay damages to HIV-contaminated transfusion patients.

- in the case of Rouen, damages of FF500,000 were awarded to a woman contaminated by transfusion in November 84 (signalling application of the Conseil d'Etat's April ruling).

- in Montpellier, two brothers suffering from haemophilia were compensated for failure by the CRTS to 'fulfil its obligation to provide safe blood products'. The verdict also covers contamination by Hepatitus C in the case of one of the boys.

18. I have a great deal more information on the appeal hearing and related issues and would be happy to provide

details on any aspect should you require it. Given his UK connections, I am reporting Allain's defence in more detail separately.

GRO-C

Joanna Macaulay
Science & Technology

cc M J Upton Esq, WED, FCO
R Tyrell Esq, Hd/AIDS Unit, DoH
ESED, FCO

10.8blood

## Statement of the Royal College of Pathologists on the matter of Professor Jean-Pierre Allain: 19 November 1993

Professor Jean-Pierre Allain is Professor of Transfusion Medicine in Cambridge and Director of the East Anglian Blood Transfusion Service. In October 1992 he was found guilty by a French court of charges relating to the distribution of HIV-contaminated Factor VIII in France during the period from January to October 1985. Since Professor Allain is a member of the College, the Royal College of Pathologists is clearly an interested party in this matter and the College set up a Working Party to review the relevant matters and to prepare a College statement.

In 1982 there appeared the first reports of AIDS among haemophiliacs in the United States. This was based on clinical and immunological parameters and preceded the discovery of HIV. Late in 1983 Jean-Pierre Allain, who was at that time the Head of the Department of Research and Development for Plasma Derivatives in the Central Blood Transfusion Service in Paris (CNTS) and as such in the third tier of its management structure, organised a trial of immunodeficiency in French haemophiliacs receiving Factor VIII from various sources to see whether they showed any difference in the incidence of parameters of immunodeficiency. In particular they were investigating whether the French Factor VIII gave rise to immunodeficiency to the same extent as imported American material. The study took place in 7 centres with 29 participants and is judged by the College to be an entirely well conceived and skilfully completed cross-sectional study addressing questions that were at that time clearly both relevant and important.

In the middle of 1984 the first HIV test became available in Paris and the sera taken in this study were then tested for HIV sero-positivity. The results of these HIV antibody tests were not communicated to the patients because of uncertainty about false positives and negatives in these early tests and also because the clinical significance of HIV sero-positivity was not well established in 1984. The consensus decision not to communicate the results of the HIV tests to patients was criticised by the Court but the same decision would very probably have been taken in the UK for similar reasons at that time. The paper based on this study was submitted to the Lancet in January 1985 but rejected, resubmitted to Blood in February 1985, accepted in April 1985 and did not appear in Blood until October 1985[1]. However, the draft paper had been widely circulated among the French haemophilia directors before that time. The lines of communication clearly gave Professor Allain direct responsibility for the management of his own haemophiliac patients (and the Court found no justified criticism of this). However, other haemophiliacs in France were similarly under the direct responsibility of the individual Haemophilia Centres to which each patient was attached. There is ample evidence in Professor Allain's collaborative studies that his colleagues (*ie* other Directors of Haemophilia Centres) were fully informed of his views, both through publications and several joint committees. Professor Allain was a relatively junior member of these committees which included some of France's most senior and distinguished haematologists and virologists.

The results of anti-HIV blind testing of samples from a comparative trial of heat-treated products for the occurrence of non A, non B hepatitis suggested, when the results were analysed in December 1984, that one brand of heated Factor VIII from the United States did not give rise to HIV sero-conversion. Meanwhile in February 1985 these 'Travenol' trial results were published in a letter to the Lancet[2] which gave clear preliminary evidence that heat-treated Factor VIII did not give sero-conversion to HIV. However, on 16 January 1985 Professor Allain wrote to the President and Director General of CNTS pointing out that almost half of French haemophiliacs were already sero-converted, that this was independent of whether the Factor VIII derived from France or America and advocated the early signing of an agreement with Immuno AG in Vienna to transfer their techniques for heating plasma products to France so that the Factor VIII could be heated. He also pointed out that short of this transfer, massive importations of heat-treated products would be necessary.

This letter is the basis of the finding by the French Court that Professor Allain knew of the dangers of giving unheated Factor VIII in January 1985 and that he did not decisively prevent its use in the months between then and October 1985 when the Ministry of Health decided that only heated Factor VIII should be used. There is, however, clear evidence that Professor Allain did his utmost to see that his advice was taken. In February 1985, following the publication of the Travenol letter, Dr Allain urged the Director of CNTS to use only heated material and his request was refused on the grounds of the expense that importing the heated material would involve. The question was debated at a specially called meeting of the French Society for Blood Transfusion in March 1985 where Professor Allain's wife, Dr Helen Lee, stated publicly that, if heat-treated Factor VIII were not immediately introduced, between 20-50 people per month would be at risk of infection in France. This public statement led to Dr Lee being reprimanded by the Director of CNTS. Following the Atlanta AIDS Congress in April 1985 Dr Allain again made representations to CNTS on this subject, again without success. He gave an interview on the subject to the French newspaper, Le Matin, but it was not published.

In July 1985 general HIV testing of haemophiliacs was introduced using the Pasteur Institute test, as was the use of French heat-treated products for sero-negative or sero-undefined patients. In October 1985 the universal use of heated Factor VIII became mandatory in France. In March 1986 Professor Allain and Dr Lee left CNTS to work in the United States.

It should be noted that the universal use of heated Factor VIII was introduced in the United States in May 1985 and in the United Kingdom in August 1985 and in Switzerland and Germany not until 1986. Since the epidemic occurred much earlier in the United States there is really no cause for the French to feel that their blood transfusion service was particularly dilatory in making this decision.

Having considered the events and the background papers, the Working Party came to the following conclusions:

1. The College applauds the good judgement and insight of Professor Allain in writing the letter of 16 January 1985. In spite of the fact that at the time when the relationship between sero-positivity to HIV and the probability of developing clinical AIDS was not fully established and when the accuracy of the tests was still under some dispute, he nevertheless correctly concluded that the cautious and proper action to take was to use heat-treated Factor VIII only. The letter shows him in the highest light, both in regard to knowledge of his subject and in his concern for French haemophilia patients. In the months following the writing of his letter and until the universal introduction of heated Factor VIII was imminent he and his wife did all that could possibly be expected of them to persuade those in administrative charge of CNTS to follow their advice.
2. The College recognises that Professor Allain's early conversion to the view that heat treated Factor VIII was superior was, in large part, based on the results of the studies carried out in 1983-84 which they regard as being in the best traditions of clinical investigation and

presenting, neither then nor now, with hindsight, any ethical problems. The question of whether sero-positive results obtained by an unestablished antibody test at that time should have been communicated to the sero-positive patients is one that is endlessly debatable and on which neither then nor now is there any clear consensus. It is noted that the AIDS-French haemophilia study group sought advice from the National Ethical Committee on that matter and that all other French Haemophilia Centre Directors adopted the same policy.

3. Professor Allain appears to the College to have acted at all times with a high level of professional competence and ethical propriety. The College wish to point out strongly that it is wholly inimical to the pursuit of medical research or to the high standard of medical practice that doctors who give their professional opinions in good faith and on the basis of proper knowledge and skill can be held legally accountable for the failure of their advice to be taken.

The College believes that this raises a major issue of principle, whose importance goes beyond the interests of our own College.

**Members of the Working Party**

Professor P J Lachmann (President), Professor A J Bellingham (Vice-President), Professor J Banatvala, Professor R Carrell, Professor V Hoffbrand and Dr W Wagstaff.

**References**


1. AIDS-Haemophilia French Study Group. Immunologic and virologic studies of multi-transfused patients: role of type of origin of blood products. Blood 1985; 66:891-901.
2. Rouzioux C *et al*. Absence of antibodies to AIDS virus in haemophiliacs treated with heat-treated factor VIII concentrate. Lancet 1985; i:271.


## Treasurer's Report

### Annual Subscriptions

It will be recommended at the Annual General Meeting in November 1993 that UK members' subscriptions be raised by 2% in 1993/94 in line with inflation.

### Examiners' Fees and Honoraria

Following the recent Inland Revenue audit of the College, the Inland Revenue withdrew a concession given some years ago in which payments in respect of examiners' fees were allowed to be paid gross of tax; such payments being reported annually. From July 1993 the College is now obliged to tax all fees and honoraria at source under PAYE regulations, in line with other Medical Colleges.

Because of the sheer volume of such fees and honoraria relating to each specialty, the cost of administering the PAYE system would be extremely onerous and beyond the resources of the present staff of the College. (The average payment is less than £50.00).

At the meeting of Council on 22 July 1993 it was agreed that:

- Fees to examiners will cease from the date of the Council decision.
- Secretarial and technical assistants would be paid and taxed by their own employers and the employing authority would recover such costs by invoicing the College.
- Accommodation and travel expenses and the cost of consumables would as before be claimed from the College in the usual way.

### Fees for Examination by Published Works

As from 1 September 1993 the fees for applications for membership on the basis of published works will be amalgamated to £300.

NHS STAFF - IN CONFIDENCE

Mr Creighton PPS/SofS

From: Martin Staniforth HAP6

Date: 19 July 1993

cc Mrs Ing PS/M(H)
Ms Harper PS/PS(H)
Miss Burnett PS/PS(L)
Dr McGovern PS/CMO
Mr Naysmith PS/CE
Dr Metters DCMO
Dr Winyard HCD
Mr Venning PD
Mr Shaw DCA
Mr Heppell HSSG
Dr Bourdillon MME
Mr Thompson SOL +
Mr Podger IRU +
Miss Nisbet PMD1
Dr Rejman HC(M)2
Mr Pink CAIU
Mr Gibbs HAP6B
Mr Murphy ID

+ By Fax

**PROFESSOR ALLAIN**

1. This note is to bring Secretary of State up to-date with the latest developments in this saga.

2. Professor Allain, Director of the Blood Transfusion Service in East Anglia, was convicted last year by the French Courts in respect of the provision of contaminated blood to haemophiliacs. He appealed against his conviction and sentence and at the same time the RHA established an independent enquiry under Lady Warnock to establish whether or not he was fit to hold the post of Transfusion Director. Following discussions between Secretary of State and Sir Colin Walker the Region delayed publication of the Warnock report until the end of the appeal hearing last month and took no decision at the time on the reinstatement of Professor Allain.

Contd.....

3. The outcome of Professor Allain's appeal has now been announced, rather earlier than previously expected. The original conviction and sentence (4 years in jail 2 of which were suspended) have been upheld and Professor Allain has now started his jail sentence. In the circumstances it is clearly impractical for him to be reinstated into his post though we await a formal decision from the Region on what they intend to do next.

4. I will keep you informed of any further developments.

MARTIN STANIFORTH
HAP6
Room 2E58
Ext GRO-

AC Q8
BLO 3

Mr Podger HP(A)
Ms Mithani HP(A)1

From: D E Burrage
CA OPU2
313 Eileen House
Ext GRO-C

Date: 15 June 1994

cc: Dr Weir HP(M)1
Dr Rejman HC(M)1 o/r
Dr Purves MCA
Mr Kelly CA OPU2

File

**HEADS OF GOVERNMENT SUMMIT ON AIDS**

As requested additional briefing is submitted on:-

**1. Details of the categories of people who are asked not to give blood:**

The categories are most concisely set out in a Parliamentary Answer dated 21 May 1993, Hansard extract attached. Since then we have added to the list those people who have ever been treated with human pituitary gonadotrophins (used in treatment for infertility). I am also attaching for information a photocopy of the Blood Transfusion Service's current AIDS leaflet.

**2. Actions taken in the UK to safeguard blood and blood products**

A short note is attached.

GRO-C

D E BURRAGE

Mr Gibbons,

As PS - The copies have been sent out.

GRO-C

15/6

## SAFETY OF BLOOD AND BLOOD PRODUCTS: UK MEASURES

### Blood and cellular blood products (eg red cells and platelets)

1. The National Blood Transfusion Service is responsible for the testing of whole blood and the Blood Transfusion Centres are subject to G.M.P. (Good Manufacturing Practice) inspection. Since September 1983, the National Blood Transfusion Service has issued guidance asking people who consider themselves to be in certain categories not to give blood.

2. In this country all blood donations are screened for Hepatitis B surface antigen, and antibodies to Hepatitis C and HIV1 and 2.

### Manufactured blood products

3. The Medicines Control Agency is responsible for licensing of manufactured blood products. Under the Medicines Act, companies which supply blood products for use in the UK are inspected and licensed and individual products are licensed for safety, quality and efficacy.

4. All blood products released for use in this country are batch tested by the National Institute for Biological Standard and Control. This includes the testing of plasma pools for viral markers. (There are no specific requirements to regulate the size of pool for manufactured blood products.) The UK system of batch release is specifically designed to reduce the possibility of any infection which might occur due to error early in the screening process. Fractionated blood products have further safeguards in that the processes include virucidal steps.

they must fulfil the duty under section 5 of the National Health Service Act 1977 to provide for the inspection and treatment of children at maintained schools—duties which may be extended to independent schools by arrangement with the school's proprietors. How they do so is a matter for local decision. With the increasing involvement of general practitioners and their primary care teams in child health surveillance, many school children receive the bulk of the health care they require from GPs as part of a comprehensive family practitioner service. It is therefore no longer appropriate to insist on a separate school health service responsible for all school children. We foresee a continuing need for some specialised services, particularly for children with special educational needs and for those not adequately covered by primary care. We intend to publish guidance on such provision within a good practice guide to child community health services.

**Mr. Blunkett:** To ask the Secretary of State for Health what was the funding allocation for the schools health service for each year since 1985.

**Mr. Yeo:** Funding is provided through the general allocation for community health services. It is not possible to identify specific allocations to health services for school children.

**Mr. Blunkett:** To ask the Secretary of State for Health how many *(a)* school nurses and *(b)* school medical officers were employed by each district health authority in each year since 1985.

**Mr. Yeo:** The information requested can be provided only at disproportionate cost.

### Blood Donors

**Mr. Wareing:** To ask the Secretary of State for Health what categories of person are prevented from donating blood for the national blood transfusion service.

**Mr. Sackville:** People wishing to donate blood but who consider themselves to be in the following categories are asked not to give blood:

anyone who has AIDS, is HIV positive or thinks they may need an AIDS test
anyone who has ever injected themselves with drugs
any man who has ever had sex with another man
anyone who has ever worked as a prostitute
any man who has had sex with a woman he knows has AIDS or is HIV positive
any woman who has had sex with a man she knows has ever had sex with another man
anyone who has had sex with a man or woman who they know has ever injected themselves with drugs
any woman who has had sex with a man who she knows has haemophilia.

People who consider themselves to be in the following categories are asked not to give blood if the last two years they have had sex with:

a male or female prostitute
any man or woman of any race living in Africa—but not Morocco, Algeria, Tunisia, Libya or Egypt—or any man or woman who has had sex in the last two years with anyone living there.

Others may be deferred from giving blood, either permanently or for a period if

they have had an infectious disease in the last two years, or if they have been in contact with an infectious disease in the last six months
they have visited or lived abroad other than in Europe
they have received any innoculations or vaccinations in the last six months or ever been treated with human growth hormone
they have had any of the following: anaemia; asthma; brucellosis (undulant fever); cancer; diabetes; epilepsy (fits); glandular fever; hay fever; heart disease; high blood pressure; hospital admission; jaundice (including contact with a case during the past six months); kidney disease; malaria; stroke; tuberculosis.

## TRANSPORT

### Nuclear Fuel (Transport)

**Ms Walley:** To ask the Secretary of State for Transport what steps he takes to monitor the compliance with weight regulations of wagons used for the shipments of spent nuclear fuel sent to Sellafield from Germany; and which shipments he has checked for their compliance.

**Mr. Freeman:** I refer the hon. Member to the answers I gave to her rail freight questions on 12 May, *Official Report*, column *462*.

### Scirocco

**Sir Teddy Taylor:** To ask the Secretary of State for Transport what steps he has taken following the refusal of the Spanish authorities to permit, and the use of gunboats to prevent, the landing at Almeria of the British-registered vessel Scirocco.

**Mr. Norris:** We are continuing our efforts to resolve the matter. In our view, Cenargo is entitled to operate this service under European Community legislation on shipping liberalisation. We welcome the fact that the Spanish Government have conceded that there is no legal obstacle to Cenargo operating such a service.

### Marine Emergencies Organisation

**Mr. Dunn:** To ask the Secretary of State for Transport what consideration he has given to the future of the Marine Emergencies Organisation.

**Mr. MacGregor:** I have decided that the Marine Emergencies Organisation should be a candidate for executive agency status within my Department. I am confident that this will provide the MEO with the incentive and opportunity to enhance the well-regarded service it already provides. The necessary preparatory work is being put in hand for the organisation to become an agency on 1 April 1994.

### East London Rail Study

**Mr. Austin-Walker:** To ask the Secretary of State for Transport, pursuant to his answer of 16 July 1992, *Official Report*, columns *861-63*, what further work has been undertaken on the options identified in the east London rail study phase 2.

**Mr. Norris:** I understand that work has focused on a Thames crossing between the royal docks and Woolwich and that a joint London Transport—London Docklands development corporation study has been looking at the local and more strategic impact of such a link. Improved access to London City airport by the docklands light railway and improved local links between the royal docks and Barking remain possibilities and will be the subject of further studies.

170 CW82/9 Job 2-7

# MEN

# BEFORE YOU GIVE BLOOD READ THIS LEAFLET

## HELP US KEEP BLOOD TRANSFUSIONS SAFE

UNITED KINGDOM BLOOD TRANSFUSION SERVICES

# MEN

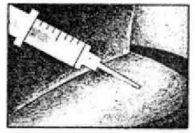
## HELP US KEEP BLOOD TRANSFUSIONS SAFE

- All blood donations are tested for HIV, the virus that causes AIDS.
- Someone who is HIV positive may feel healthy for many years.
- Infected blood is not used for transfusions **but our tests may not always detect early stages of HIV infection.**
- This is why you must not give blood if you think you have been exposed to the risk of infection by HIV/AIDS.
- The chance of infected blood getting past our screening tests is very small, but we rely on your help and cooperation.
- Please read this leaflet carefully and remember **you cannot get HIV/AIDS, or any other infection, by giving blood.**

## YOU MUST NOT GIVE BLOOD IF:


**YOU HAVE AIDS, ARE HIV POSITIVE, OR THINK YOU NEED AN AIDS TEST.**

**YOU HAVE EVER HAD SEX WITH ANOTHER MAN**

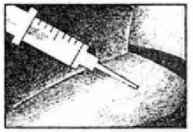


**YOU HAVE EVER INJECTED YOURSELF WITH DRUGS.**

**YOU HAVE EVER WORKED AS A PROSTITUTE.**

## YOU MUST NOT GIVE BLOOD IF, YOU HAVE EVER HAD SEX WITH:


**A WOMAN WHO YOU KNOW HAS AIDS OR IS HIV POSITIVE.**



**A WOMAN WHO YOU KNOW HAS EVER INJECTED HERSELF WITH DRUGS.**

## YOU MUST NOT GIVE BLOOD IF, IN THE LAST TWO YEARS YOU HAVE HAD SEX WITH:

**A FEMALE PROSTITUTE**

**A WOMAN, OF ANY RACE, LIVING IN AFRICA* OR A WOMAN WHO HAS HAD SEX, IN THE LAST TWO YEARS, WITH ANYONE LIVING THERE**

**(*BUT NOT MOROCCO, ALGERIA, TUNISIA, LIBYA OR EGYPT.)**

## CARING FOR YOU AND FOR PATIENTS

If you are worried that you have been exposed to the risk of HIV/AIDS you can — talk in confidence to a doctor or nurse at the session — leave the session without giving blood — phone your local Transfusion Centre.

Safer sex can reduce the risk of infection by HIV, but we cannot rely on safe sex to keep blood transfusions safe.

**Please do not give blood just to get an AIDS test.** You can get a confidential AIDS test from your GP, or a clinic for sexually transmitted or venereal diseases (which can be found in the phone book).

For more information about AIDS phone The National AIDS Helpline FREE on 0800 567123.

NBTS 1322

# WOMEN

## BEFORE YOU GIVE BLOOD READ THIS LEAFLET

## HELP US KEEP BLOOD TRANSFUSIONS SAFE

UNITED KINGDOM BLOOD TRANSFUSION SERVICES

# WOMEN

## HELP US KEEP BLOOD TRANSFUSIONS SAFE

- All blood donations are tested for HIV, the virus that causes AIDS.
- Someone who is HIV positive may feel healthy for many years.
- Infected blood is not used for transfusions **but our tests may not always detect early stages of HIV infection.**
- This is why you must not give blood if you think you have been exposed to the risk of infection by HIV/AIDS.
- The chance of infected blood getting past our screening tests is very small, but we rely on your help and cooperation.
- Please read this leaflet carefully and remember **you cannot get HIV/AIDS, or any other infection, by giving blood.**

## YOU MUST NOT GIVE BLOOD IF:


**YOU HAVE AIDS, ARE HIV POSITIVE, OR THINK YOU NEED AN AIDS TEST.**

**YOU HAVE EVER INJECTED YOURSELF WITH DRUGS.**

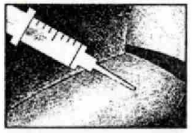
**YOU HAVE EVER WORKED AS A PROSTITUTE.**

## YOU MUST NOT GIVE BLOOD IF, YOU HAVE EVER HAD SEX WITH:


**A MAN WHO YOU KNOW HAS AIDS OR IS HIV POSITIVE.**

## YOU MUST NOT GIVE BLOOD IF, YOU HAVE EVER HAD SEX WITH:

**A MAN WHO YOU KNOW HAS EVER HAD SEX WITH ANOTHER MAN.**



**A MAN WHO YOU KNOW HAS EVER INJECTED HIMSELF WITH DRUGS.**

**A MAN WHO YOU KNOW HAS HAEMOPHILIA**

## YOU MUST NOT GIVE BLOOD IF, IN THE LAST TWO YEARS YOU HAVE HAD SEX WITH:

**A MALE PROSTITUTE**

**A MAN, OF ANY RACE, LIVING IN AFRICA* OR A MAN WHO HAS HAD SEX, IN THE LAST TWO YEARS, WITH ANYONE LIVING THERE**

**(*BUT NOT MOROCCO, ALGERIA, TUNISIA, LIBYA OR EGYPT.)**

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For more information about AIDS phone The National AIDS Helpline FREE on 0800 567123.

NBTS 1322

P:\DATA\Blood\Summ...HIV

BL03 & INB3 & AC08

14/6.

1. Mr Kelly CA OPU2

2. Miss A Mithani HP(A)1

From: D E Burrage
CA OPU2
313 Eileen House
Ext GRO-C

Date: 13 June 1994

cc: Dr Rejman HC(M)1 o/r

File

**HEADS OF GOVERNMENT SUMMIT ON AIDS**

Please see the attached request for briefing from Miss Mithani HP(A)1. We have been asked for a contribution to cover the item "SECURITE TRANSFUSIONELLE". Mary Sandillon has kindly provided a translation of the item.

I understand from Miss Mithani that PS(L) will attend the Summit. A draft briefing on HIV and blood transfusion, which also needs to cover the UK position on self sufficiency in blood and blood products, is attached.

GRO-C

D E BURRAGE

Sent by E McN 14/6.

## TRANSFUSION SECURITY

### Background on self sufficiency

The UK is self sufficient in whole blood. Long standing Government policy has been that the UK should be self-sufficient in blood products from voluntary blood donation. This position is consistent with a recent EC decision to promote a policy of community self-sufficiency on voluntary blood donation. The UK position is that we should pursue self-sufficiency, but not to the point where it jeopardises adequate amounts of treatment or cuts off products which may be clinically beneficial for patients.

The UK supports the concept of promoting self-sufficiency through individual states becoming self sufficient in their own right rather than "trading" across borders. Otherwise it may be difficult to motivate voluntary donors. However the UK supports sharing of experience across EC on technical issues concerning quality and safety of products and donor recruitment.

### German scandal

The scandal last year was provoked by revelations that the Federal Health Office (BGA) concealed evidence of list of cases of HIV infection through blood/ blood products, and widened with discovery by German authorities that HIV screening by Koblenz based UB Plasma was inadequate, in that individual donations were not tested. UB plasma was closed down and all outstanding supplies of its products withdrawn in Germany and abroad. Efforts were made to trace recipients of UB Plasma products supplied to 60-70 German hospitals or medical institutions, and blood transfusion recipients advised to take HIV tests.

The World Health Organisation concluded at the end of last year that existing guidelines and regulations for the correct handling of plasma and its derivatives were sufficient, if properly applied, to prevent HIV transmission.

### Implications of German problem for UK

We do not import blood or plasma and the majority of blood products we use are produced by UK fractionators. We import some blood products, manufactured primarily from paid plasma. Last year Immuno recalled from UK a small amount of 2 products implicated in the German problem as a precaution.

No HIV has been found in any products authorised for release in this country by our own authorities.

### UK safeguards

- All blood used in this country for transfusion comes from our own donations which are screened for HIV and other viruses.
- Fractionated blood products are additionally subject to viral inactivation steps in the manufacturing process and are licensed by the Medicines Control Agency.
- Blood products released onto our market are tested by our National Institute for Biological Standards and Control as are all plasma pools used in their manufacture.

These safeguards ensure the safety of the blood supply in this country.

TRANSLATION

**CHIEFS OF GOVERNMENT SUMMIT ON AIDS**

Ministerial meeting taking place in Paris on 17 and 18 June, to consider AIDS issues under the following headings, and formulate proposals for action, prior to above Summit which will take place in December 1994.

TRANSFUSION SECURITY

The prevention of the transmission of HIV by blood transfusion or by use of blood products, must be considered a primary objective, to be achieved without delay.

**Don't think this applies to you, but have put it down in case anything seems relevant.**

PROTECTION OF MEMBERS OF THE POPULATION PARTICULARLY AT RISK FROM HIV TRANSMISSION

Certain members of the public are particularly exposed to risk due to vulnerability stemming from biological, social or economic factors. The protection of these members of the public - children, women, itinerants, migrant workers, drug addicts(?)- requires the establishment or reinforcement of services for care and prevention, which are accessible to all, in the interests of respecting the rights of the individual.

DEPARTMENT OF HEALTH
WELLINGTON HOUSE
133 - 155 WATERLOO ROAD
LONDON SE1 8UG

FROM: MISS A MITHANI

MY FAX NUMBER IS: GRO-C

MESSAGE FOR: Mr. Burrage CA-OPU2

MESSAGE FROM: Miss Mithani HP(A)1

NUMBER OF PAGES TO FOLLOW: 9

SPECIAL INSTRUCTIONS: We spoke. I should be most grateful for briefing by 3.00 pm tomorrow to enable us to get it up to PS(L) tomorrow.

IN CASE OF ANY PROBLEMS WITH THIS FAX PLEASE RING
071-972- 24020/24103

**FRENCH EMBASSY**

**LABOUR COUNSELLOR'S OFFICE**

*Telephone n°*
*Fax n°* GRO-C

Dave Burrage

*To the attention* Fax GRO-C

*Number of page*
*(first page included)*

*Fax n° :* GRO-C

*From : Laurent*

* * * * * *

*Message : Dear Ms Mithani,*

*Please find hereafter the timetable and a new draft for the conference of 17th and 18th June 1994 about the fight against AIDS.*

*The conference will be held at : **Centre Kleber, 19 avenue Kleber, 75016 Paris.***

*It would be very helpful if you could tell me as soon as possible who is going to attend this conference.*

*Thank you once again for your cooperation.*

*Yours sincerely,*

*L. ZYLBERBERG*

UNCLASSIFIED

Foreign & Commonwealth Office
London SW1A 2AH
Telephone: 071-

From: Miss Debbie Ratcliffe

To: Miss Almas Mithani, Communicable Diseases Branch, DH

cc: Mr David Daniels, HPD, ODA

Date: 9 June 1994

Our reference: DDA 031/2

Number of pages, including this header: 5

GRO-C

## Drugs and International Crime Department FACSIMILE

**AIDS MEETING, PARIS, 17-18 JUNE: AGENDA**

1. I attach a copy of the agenda for the Paris AIDS meeting on 17-18 June, together with a "Note de Présentation", which Joanne Hodges at the Embassy in Paris has sent.

GRO-C

Debbie Ratcliffe

# SOMMET DES CHEFS DE GOUVERNEMENT SUR LE SIDA

## Paris, le 1er décembre 1994

## Note de Présentation

1. En l'an 2000, si le rythme actuel de la propagation de la pandémie du VIH SIDA se poursuit, 30 à 40 millions de personnes - parmi lesquelles 13 à 15 millions de femmes et 5 à 10 millions d'enfants - seront infectées par le VIH. A eux seuls, ces chiffres reflètent une tragédie humaine et un bouleversement social que nul ne peut se permettre d'ignorer. Par ses conséquences humaines d'abord, par son impact aussi sur l'économie et la stabilité sociale, la pandémie du SIDA risque d'accroître les inégalités de développement entre les pays. Elle aggrave par ailleurs les difficultés que traversent à l'heure actuelle les pays en développement qui sont les plus touchés.

2. Refusant de voir dans cette évolution une fatalité, la communauté internationale souhaite agir dans la solidarité. C'est au plus haut niveau que la volonté politique doit être réaffirmée afin que soient rapidement mises en oeuvre toutes les mesures nécessaires pour infléchir le cours de la pandémie. Tel sera l'engagement solennel que prendront les chefs de gouvernement qui se réuniront le 1er décembre 1994 au Sommet de Paris.

3. Cet engagement politique que consacrera le Sommet de Paris rappellera le respect des droits de la personne et de l'éthique. Il visera à bannir toute forme de discrimination et d'exclusion à l'encontre des personnes affectées par le VIH/SIDA et à promouvoir notamment le droit à l'accès aux services de santé, à la prévention, à l'éducation et à l'information. L'expression d'une volonté politique forte et déterminée est d'autant plus nécessaire au moment où la communauté internationale prépare la mise en oeuvre du programme commun coparrainé des Nations Unies sur le VIH/SIDA.

4. Le Sommet de Paris apportera un soutien résolu au programme commun coparrainé des Nations Unies sur le VIH/SIDA. Ce programme, fondé pour une meilleure coordination au sein du système des Nations Unies, permettra également aux institutions intergouvernementales, gouvernementales et non-gouvernementales d'apporter une réponse plus adaptée aux problèmes fondamentaux liés à la pandémie. Dans ce cadre, le Sommet de Paris mettra l'accent sur la coordination des actions d'aide bilatérales.

5. Les chefs de gouvernement réunis au Sommet de Paris concrétiseront leur engagement politique par des initiatives novatrices qui compléteront les efforts déjà entrepris et qui apporteront des solutions efficaces aux problèmes que pose la pandémie. En préparation des travaux du Sommet, la réunion ministérielle des 17 et 18 juin à Paris élaborera des propositions concernant ces initiatives qui pourraient se situer dans les domaines prioritaires suivants :

## ☛ PRÉVENTION

Une politique de prévention efficace doit s'appuyer sur une large diffusion des connaissances et de l'information sur la maladie. Elle doit promouvoir l'ensemble des comportements à moindre risque tels que l'abstinence, la fidélité mutuelle, la réduction du nombre de partenaires et l'utilisation de préservatifs qui doivent être accessibles à tous.

## ☛ SÉCURITÉ TRANSFUSIONNELLE

La prévention de la transmission du VIH par la transfusion sanguine ou par l'utilisation des produits sanguins doit être considérée comme un objectif primordial et réaliste qu'il faut atteindre sans délai.

## ☛ PROTECTION DES POPULATIONS PARTICULIÈREMENT EXPOSÉES AU RISQUE DE TRANSMISSION DU VIH

Certaines populations sont particulièrement exposées du fait de vulnérabilités biologiques, sociales ou économiques spécifiques. La protection de ces populations – enfants, femmes, personnes déplacées, travailleurs migrants, toxicomanes - exige d'abord la mise en place ou le renforcement de services de soins et de prévention qui soient assurés à tous, dans le plein respect des droits de la personne.

## ☛ PRISE EN CHARGE MÉDICALE ET SOCIALE DES PERSONNES AFFECTÉES PAR LE VIH/SIDA

L'augmentation du nombre des infections opportunistes, dont la tuberculose, combinée aux coûts de prise en charge et à la détérioration économique dans les pays les plus pauvres, aggrave les inégalités d'accès au soins. Le Sommet de Paris cherchera à garantir à tous l'accès aux médicaments essentiels et à favoriser la mise au point de produits anti-viraux curatifs. La prise en charge médicale doit s'accompagner d'une prise en charge sociale. Le nombre croissant d'orphelins du SIDA met en relief la nécessité urgente de prendre des mesures qui assurent un soutien social non seulement aux malades mais aussi à leurs proches.

## ☛ VACCIN

La recherche pour la mise au point d'un vaccin, qui viendra compléter les autres mesures de prévention, doit constituer une des priorités de la lutte contre le SIDA. Le Somme proposera une initiative internationale pour mettre en place des mécanismes favorisant la collaboration entre les secteurs privés et publics dans les domaines de la recherche fondamentale et clinique. Cette initiative veillera à faciliter l'accès à ce vaccin dès sa mise au point aux pays les plus pauvres.

6. Le Sommet de Paris réaffirmera le rôle essentiel des Associations de lutte contre le SIDA à travers le monde, notamment celles représentant les personnes vivant avec le virus et les associera à la réalisation de ses objectifs.

**Une déclaration finale exprimera l'engagement des chefs de gouvernement réunis à Paris. Un plan d'action précisera les modalités de mise en oeuvre des initiatives qu'ils auront lancées.**

II -===OBJECTIFS===-

1. EN L'AN 2000, SI LE RYTHME ACTUEL DE LA PROPAGATION DE LA PANDEMIE DU VIH-SIDA SE POURSUIT, 30 A 40 MILLIONS DE PERSONNES PARMI LESQUELLES 13 A 15 MILLIONS DE FEMMES ET 5 A 10 MILLIONS D'ENFANTS - SERONT INFECTEES PAR LE VIH. A EUX SEULS, CES CHIFFRES REFLETENT UNE TRAGEDIE HUMAINE ET UN BOULEVERSEMENT SOCIAL QUE NUL NE PEUT SE PERMETTRE D'IGNORER. PAR SES CONSEQUENCES HUMAINES D'ABORD, PAR SON IMPACT AUSSI SUR L'ECONOMIE ET LA STABILITE SOCIALE, LA PANDEMIE DU SIDA RISQUE D'ACCROITRE LES INEGALITES DE DEVELOPPEMENT ENTRE LES PAYS. ELLE AGGRAVE PAR AILLEURS LES DIFFICULTES QUE TRAVERSENT A L'HEURE ACTUELLE LES PAYS EN DEVELOPPEMENT QUI SONT LES PLUS TOUCHES.

2. REFUSANT DE VOIR DANS CETTE EVOLUTION UNE FATALITE, LA COMMUNAUTE INTERNATIONALE SOUHAITE AGIR DANS LA SOLIDARITE. C'EST AU PLUS HAUT NIVEAU QUE LA VOLONTE POLITIQUE DOIT ETRE REAFFIRMEE AFIN QUE SOIENT RAPIDEMENT MISES EN OEUVRE TOUTES LES MESURES NECESSAIRES POUR INFLECHIR LE COURS DE LA PANDEMIE. TEL SERA L'ENGAGEMENT SOLENNEL QUE PRENDRONT LES CHEFS DE GOUVERNEMENT QUI SE REUNIRONT LE 1ER DECEMBRE 1994 AU SOMMET DE PARIS.

3. CET ENGAGEMENT POLITIQUE QUE CONSACRERA LE SOMMET DE PARIS RAPPELLERA LE RESPECT DES DROITS DE LA PERSONNE ET DE L'ETHIQUE. IL VISERA A BANNIR TOUTE FORME DE DISCRIMINATION ET D'EXCLUSION A L'ENCONTRE DES PERSONNES AFFECTEES PAR LE VIH/SIDA ET A PROMOUVOIR NOTAMMENT LE DROIT A L'ACCES AUX SERVICES DE SANTE, A LA PREVENTION, A L'EDUCATION ET A L'INFORMATION. L'EXPRESSION D'UNE VOLONTE POLITIQUE FORTE ET DETERMINEE EST D'AUTANT PLUS NECESSAIRE AU MOMENT OU LA COMMUNAUTE INTERNATIONALE PREPARE LA MISE EN OEUVRE DU PROGRAMME COMMUN COPARRAINE DES NATIONS UNIES SUR LE VIH-SIDA.

4. LE SOMMET DE PARIS APPORTERA UN SOUTIEN RESOLU AU PROGRAMME COMMUN COPARRAINE DES NATIONS UNIES SUR LE VIH-SIDA. CE PROGRAMME, FONDE POUR UNE MEILLEURE COORDINATION AU SEIN DU SYSTEME DES NATIONS UNIES, PERMETTRA EGALEMENT AUX INSTITUTIONS INTERGOUVERNEMENTALES, GOUVERNEMENTALES ET NON-GOUVERNEMENTALES D'APPORTER UNE REPONSE PLUS ADAPTEE AUX PROBLEMES FONDAMENTAUX LIES A LA PANDEMIE. DANS CE CADRE, LE SOMMET DE PARIS METTRA L'ACCENT SUR LA COORDINATION DES ACTIONS D'AIDE BILATERALES.

5. LES CHEFS DE GOUVERNEMENT REUNIS AU SOMMET DE PARIS CONCRETISERONT LEUR ENGAGEMENT POLITIQUE PAR DES INITIATIVES NOVATRICES QUI COMPLETERONT LES EFFORTS DEJA ENTREPRIS ET QUI APPORTERONT DES SOLUTIONS EFFICACES AUX PROBLEMES QUE POSE LA PANDEMIE. EN PREPARATION DES TRAVAUX DU SOMMET, LA [illegible] ET
16 JUIN A PARIS ELABC [illegible] AIENT
SE SITUER DANS LES DC

Presentation Notes – Draft.

===PREVENTION=

UNE POLITIQUE [illegible]
CONNAISSANCES ET DE [illegible]
DES COMPORTEMENTS A [illegible]
REDUCTION DU NOMBRE [illegible]
ETRE ACCESSIBLES A [illegible]

***SECURITE TRANSFUSIONNELLE***

LA PREVENTION DE LA TRANSMISSION DU VIH PAR LA TRANSFUSION SANGUINE OU PAR L'UTILISATION DES PRODUITS SANGUINS DOIT ETRE CONSIDEREE COMME UN OBJECTIF PRIMORDIAL ET REALISTE QU'IL FAUT ATTEINDRE SANS DELAI.

***PROTECTION DES POPULATIONS PARTICULIEREMENT EXPOSEES AU RISQUE DE TRANSMISSION DU VIH.***

CERTAINES POPULATIONS SONT PARTICULIEREMENT EXPOSEES DU FAIT DE VULNERABILITES BIOLOGIQUES, SOCIALES OU ECONOMIQUES SPECIFIQUES. LA PROTECTION DE CES POPULATIONS - ENFANTS, FEMMES, PERSONNES DEPLACEES, TRAVAILLEURS MIGRANTS, TOXICOMANES - EXIGE D'ABORD LA MISE EN PLACE OU LE RENFORCEMENT DE SERVICES DE SOINS ET DE PREVENTION QUI SOIENT ASSURES A TOUS, DANS LE PLEIN RESPECT DES DROITS DE LA PERSONNE.

***PRISE EN CHARGE MEDICALE ET SOCIALE DES PERSONNES AFFECTEES PAR LE VIH-SIDA.***

L'AUGMENTATION DU NOMBRE DES INFECTIONS OPPORTUNISTES, DONT LA TUBERCULOSE, COMBINEE AUX COUTS DE PRISE EN CHARGE ET A LA DETERIORATION ECONOMIQUE DANS LES PAYS LES PLUS PAUVRES, AGGRAVE LES INEGALITES D'ACCES AUX SOINS. LE SOMMET DE PARIS CHERCHERA A GARANTIR A TOUS L'ACCES AUX MEDICAMENTS ESSENTIELS ET A FAVORISER LA MISE AU POINT DE PRODUITS ANTI-VIRAUX CURATIFS. LA PRISE EN CHARGE MEDICALE DOIT S'ACCOMPAGNER D'UNE PRISE EN CHARGE SOCIALE. LE NOMBRE CROISSANT D'ORPHELINS DU SIDA MET EN RELIEF LA NECESSITE URGENTE DE PRENDRE DES MESURES QUI ASSURENT UN SOUTIEN SOCIAL NON SEULEMENT AUX MALADES MAIS AUSSI A LEURS PROCHES.

***VACCIN***

LA RECHERCHE POUR LA MISE AU POINT D'UN VACCIN, QUI VIENDRA COMPLETER LES AUTRES MESURES DE PREVENTION, DOIT CONSTITUER UNE DES PRIORITES DE LA LUTTE CONTRE LE SIDA. LE SOMMET PROPOSERA UNE INITIATIVE INTERNATIONALE POUR METTRE EN PLACE DES MECANISMES FAVORISANT LA COLLABORATION ENTRE LES SECTEURS PRIVES ET PUBLICS DANS LES DOMAINES DE LA RECHERCHE FONDAMENTALE ET CLINIQUE. CETTE INITIATIVE VEILLERA A FACILITER L'ACCES A CE VACCIN DES SA MISE AU POINT AUX PAYS LES PLUS PAUVRES.

6. LE SOMMET DE PARIS REAFFIRMERA LE ROLE ESSENTIEL DES ASSOCIATIONS DE LUTTE CONTRE LE SIDA A TRAVERS LE MONDE, NOTAMMENT CELLES REPRESENTANT LES PERSONNES VIVANT AVEC LE VIRUS, ET LES ASSOCIERA A LA REALISATION DE SES OBJECTIFS.

UNE DECLARATION FINALE EXPRIMERA L'ENGAGEMENT DES CHEFS DE GOUVERNEMENT REUNIS A PARIS. UN PLAN D'ACTION PRECISERA LES MODALITES DE MISE EN OEUVRE DES INITIATIVES QU'ILS AURONT LANCEES''.

# SOMMET DES CHEFS DE GOUVERNEMENT SUR LE SIDA

**Paris, 1er décembre 1994**

**Réunion préparatoire des Ministres de la Santé**

**Paris, 17 et 18 juin 1994**

**Ordre du jour provisoire**

## Vendredi 17 juin

**Présidence : Madame Simone VEIL**

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|---|---|
| **8 h 30** | **Accueil des participants** |
| 9 h 00 | Ouverture par Madame Simone VEIL, Ministre d'Etat |
| 9 h 15 | Message du Docteur NAKAJIMA |
| 9 h 20 | Discussion générale :<br>1. Objectifs<br>2. Actions proposées<br>3. Calendrier de travail |
| 10 h 45 | Pause |
| 11 h 15 | Discussion générale (suite) |
| **13 h 00** | **Déjeuner** |
| 14 h 30 | Discussion générale |
| 15 h 45 | Résumé |
| 16 h 00 | Pause |
| 16 h 30 / 17 h 30 | Discussion de deux thèmes (répartition par groupes de travail thématiques) |
| 17 h 30 / 18 h 30 | Discussion de trois thèmes (répartition par groupes de travail thématiques) |
| 18 h 30 | Fin des travaux |
| 19 h 00 | Réception au Quai d'Orsay |

## Samedi 18 juin

**Présidence : Madame Simone VEIL**

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| **9 h 00** | **Ouverture** |
| **9 h 30 / 10 h 30** | Rapports des présidents de groupes et discussion générale |
| **10 h 30** | Pause |
| **11 h 00** | Conclusions |
| **11 h 30** | **Clôture - Conférence de presse** |

1. ===ORDRE DU JOUR PROVISOIRE===
===VENDREDI 17 JUIN 1994===
===PRESIDENCE MME S. VEIL===
08 H 30 : ACCUEIL DES PARTICIPANTS
09 H 00 : OUVERTURE PAR MADAME LE MINISTRE D'ETAT SIMONE VEIL
09 H 15 : MESSAGE DU DR. NAKAJIMA
09 H 20 : DISCUSSION GENERALE
1. OBJECTIFS
2. ACTIONS PROPOSEES
3. CALENDRIER DE TRAVAIL
10 H 45 : PAUSE
11 H 15 : DISCUSSION GENERALE - SUITE
13 H 00 : DEJEUNER

14 H 30 : DISCUSSION GENERALE
15 H 45 : RESUME.
16 H 00 : PAUSE
16 H 30 / 17 H 30 : DISCUSSIONS DE DEUX THEMES (REPARTITION PAR GROUPES DU TRAVAIL THEMATIQUES)
17 H 30 / 18 H 30 : DISCUSSIONS DE TROIS THEMES (REPARTITION PAR GROUPES DE TRAVAIL THEMATIQUES)
18 H 30 : FIN DES TRAVAUX.
19 H 00 : RECEPTION AU QUAI D'ORSAY
===SAMEDI 18 JUIN 1994===
===PRESIDENCE MME S. VEIL===
09 H 00 : OUVERTURE
09 H 30/10 H 30 : RAPPORT DES PRESIDENTS DE GROUPES ET DISCUSSION GENERALE
10 H 30 : PAUSE
11 H 00 : CONCLUSIONS
11 H 30 : CLOTURE - CONFERENCE DE PRESSE.